SECOND MASTER CLINICAL STUDY AGREEMENT

This Second Master Clinical Study Agreement ("Agreement"), effective as of January 10, 2018 ("Effective Date"), sets forth the terms and conditions by and between Pharmacyclics LLC, an AbbVie Company and a Delaware Limited Liability Company ("Pharmacyclics") and The University of Texas System for the benefit of Clinical Trials Xpress (as defined in Section 1 (c) below), The University of Texas Health Science Center at Houston; The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Tyler; The University of Texas Medical Branch at Galveston; The University of Texas Southwestern Medical Center; The University of Texas Rio Grande Valley, and The University of Texas at Austin ("Institution" or collectively, "Institutions"), each a member institution of The University of Texas System ("UT System").

WHEREAS, a certain previous Master Clinical Study Agreement was entered into by and between Pharmacyclics and the Institutions dated March 9, 2001 (the "First Master Clinical Study Agreement");

WHEREAS, Pharmacyclics was recently acquired by AbbVie, Inc., and in light of such acquisition, the parties desire to enter into this Second Master Clinical Study Agreement with respect to all new clinical studies in which Pharmacyclics is the Sponsor (defined below), on a going-forward basis; and

WHEREAS, the First Master Clinical Study Agreement shall remain in effect with respect to those clinical studies currently being conducted thereunder.

NOW THEREFORE, In consideration of the mutual promises set forth herein, the parties hereto agree as follows:

1. Scope of Agreement.

(a) For purposes of the Agreement, "Affiliate" means an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the party being referenced. For purposes of this definition, "control" means the possession, direct or indirect, of the power to cause the direction of the management and policies of the applicable entity, whether through ownership of fifty percent (50%) or more of the voting securities of such entity, by contract or otherwise.

(b) This Agreement allows the parties to specify distinct clinical studies to be performed by Institution through the issuance of multiple individual written statements of work between Pharmacyclics and Institution related to the specific clinical study, forms of which are attached hereto and incorporated herein as Exhibit A (Statement of Work or Work Order Template – Employee Principal Investigator) (a "Statement of Work"). This Agreement covers the provision of certain Pharmacyclics-sponsored clinical studies (each, the "Study") in relation to certain products of Pharmacyclics, and its Affiliates, and/or collaborators identified in the Statement of Work (the "Study Product"). Pharmacyclics shall be considered the "Sponsor," as that term is defined in 21 C.F.R. § 312.3(b), for the Study relating to such Statement of Work. Pharmacyclics shall, in its sole discretion, determine when and whether to offer a Study under this Agreement to Institution including, without limitation, the decision whether or not to enter into a specific Statement of Work.

2. UT System represents and certifies as follows: (i) Clinical Trials Xpress ("CTX") [www.clinicaltrialsxpess.org], a wholly-owned initiative of UT System, is the central coordinating office and team established to promote efficient and streamlined study start-up processes of multi-institutional clinical trials; (ii) the CTX network operating model accelerates study implementation by negotiating a single, common clinical trial study budget; using pre-approved master clinical trial agreements and by adopting the UT System IRB Reciprocity model or central IRBs for regulatory oversight; and (iii) that Pharmacyclics may engage the services of the CTX central coordinating office when the applicable Study contemplated by this Agreement will be considered for participation by more than one Institution. As such, Clinical Trials Xpress may be added as a party to the relevant Statement of Work for the services Clinical Trials Xpress provides.
3. **Statement of Work.** The specific details and tasks of each Study shall be specified in writing in the Statement of Work. The Statement of Work shall be executed by an authorized representative of Institution and Pharmacyclics and shall be acknowledged by the relevant qualified lead Institution employee responsible for the conduct of the Study at Institution (each a “Principal Investigator”). Each Statement of Work shall include, without limitation, identification of the Study Product, identification of the Principal Investigator, the title of the Study protocol, which may be amended from time to time (the “Protocol”), the detailed Study budget and payment schedule (the “Budget”); and term of Statement of Work (the “Study Term”). The Protocol shall be provided separately for each individual Study and shall be referred to and incorporated by reference into the Statement of Work. The Statement of Work shall be subject to all of the terms and conditions of this Agreement, in addition to the specific details set forth in the Statement of Work.

4. **Conduct of Study.**

(a) Institution shall conduct and shall require Principal Investigator, subinvestigator(s), and Institution’s other employees, subcontractors and agents performing work in connection with the Study (collectively, “Institution Personnel”) to conduct the Study in accordance with: (i) this Agreement and the relevant Statement of Work; (ii) the IRB-approved Protocol; (iii) all reasonable written instruction provided by or on behalf of Pharmacyclics; (iv) Institution’s ethical standards and/or policies; and (v) all applicable federal, state and local laws and regulations and guidelines (collectively, “Law(s)”), including without limitation (and each to the extent applicable to a Study), anti-bribery and anti-corruption laws, International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use E6 Good Clinical Practice as adopted by the FDA (“ICH-GCP”), regulations of the United States Food and Drug Administration (the “FDA”), the Patient Protection and Affordable Care Act of 2010, the Medicare/Medicaid Anti-kickback statute, the Social Security Act of 1935, the Controlled Substances Act, data protection and privacy laws, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and the Federal Food, Drug and Cosmetic Act of 1938, as each may be amended, from time to time. In furtherance of the foregoing obligations, Institution shall ensure that an Institution Review Board (“IRB”) established and constituted in accordance with applicable Laws approves and oversees the conduct of the Study prior to the commencement of the Study. Institution will comply with the instructions of the IRB respecting the conduct of the Study, and will notify Pharmacyclics to the extent any such instructions vary from the Protocol.

(b) Prior to each Study subject’s participation in the Study, Institution shall obtain a signed informed consent and/or authorization document (collectively, “ICF”), as reviewed by Pharmacyclics and approved by the IRB. If Institution or Principal Investigator proposes to publish any Study subject recruitment advertisements, such advertisements require Pharmacyclics’ prior review in advance of submission to the applicable IRB. Institution and Principal Investigator shall report all serious adverse events or other safety concerns arising from the conduct of the Study that Principal Investigator becomes aware of as further specified in the Protocol and in accordance with applicable Laws.

(c) Institution represents and certifies that Principal Investigator identified in a Statement of Work is an employee of Institution. Institution agrees that no other investigator may be substituted for the Principal Investigator without the prior written consent of Pharmacyclics. If the Principal Investigator is no longer employed by Institution or becomes unwilling or unable to perform the duties required by this Agreement and relevant Statement of Work, Institution shall promptly notify Pharmacyclics and reasonably cooperate with Pharmacyclics to promptly find a mutually acceptable replacement Principal Investigator. If the parties cannot agree to a replacement Principal Investigator, either party may immediately terminate the relevant Statement of Work upon written notice to the other party.

(d) Institution shall ensure that Principal Investigator and subinvestigator(s): (i) complete and return to Pharmacyclics the FDA Form 1572 provided by Pharmacyclics to ensure compliance with 21 C.F.R. Part 312.53 prior to the initiation of the Study and promptly notify Pharmacyclics of any change in its accuracy during the Study Term of the applicable Statement of Work; and (ii)
complete and return to Pharmacyclics the Financial Disclosure Certification provided by Pharmacyclics to ensure compliance with 21C.F.R. Part 54 prior to the initiation of the Study and promptly notify Pharmacyclics of any change in the accuracy of the Financial Disclosure Certification during the Study Term of the applicable Statement of Work and for one (1) year following completion of the Study. Institution understands and agrees that Principal Investigator and subinvestigator(s), and their immediate families, may not, in violation of any applicable Law, have a direct ownership interest (including, without limitation, intellectual property rights or royalty rights) in the Study Product and may not be compensated with Pharmacyclics’ and/or its Affiliates’ securities in exchange for being a Principal Investigator or subinvestigator(s) in the Study.

(e) Institution shall require Principal Investigator to comply with all applicable disclosure Laws relating to his/her relationship with Pharmacyclics, and its Affiliates and/or collaborators, including, without limitation, full disclosure of the existence and nature of this relationship that (i) may be externally imposed on Principal Investigator based on his/her affiliation with any formulary, pharmacy and therapeutics (P&T) committee, or committee associated with the development of treatment protocols or standards (including clinical guidelines); or (ii) are required by any health care institution, medical committee or other medical or scientific organization with which Principal Investigator is affiliated. Institution shall require Principal Investigator to abide by such committee’s or medical or scientific organization’s procedures, which may include recusing himself/herself from decisions relating to any Study Product for which Principal Investigator is conducting the Study under the relevant Statement of Work. This disclosure requirement shall extend for one (1) year beyond the termination or expiration of the relevant Statement of Work.

(f) Institution and Institution Personnel shall not bill or seek reimbursement from any third party for any Study Materials (as defined below in Section 5(a)) or other items or services that are paid for or provided without charge by or on behalf of Pharmacyclics under this Agreement. Institution shall follow all applicable Laws requiring disclosure that such Study Materials and/or other items, or services were paid for or provided without charge by or on behalf of Pharmacyclics under this Agreement.

(g) All completed CRFs (defined below in Section 6(a)) must be entered in the electronic data capture system within ten (10) business days of each visit and within ten (10) business days of each follow-up visit; and within ten (10) business days of the completion of the Study subject's participation in a Study and receipt of Study subject's test results, if any, but in no event later than the Study completion date. Any requests by or on behalf of Pharmacyclics to Institution for verification, clarification or correction of data on CRFs must be responded to within ten (10) business days of Institution’s receipt of such request.

5. Pharmacyclics Obligations.

(a) Pharmacyclics shall comply with applicable Laws in the performance of its activities relating to the Study and shall obtain all approvals required in connection with such activities.

(b) Pharmacyclics shall be responsible for data and safety monitoring as specified in the Protocol. During the performance of the Study at Institution and for two (2) years thereafter, Pharmacyclics agrees to report promptly to the Institution any information (including without limitation any aspect of the Protocol, information discovered during site monitoring visits, or the Study Records/results) that Pharmacyclics reasonably expects to affect, as applicable, (i) the well-being, medical care, health or safety of past or current Study subjects, (ii) Study subjects’ willingness to continue participation in the Study, (iii) the conduct of the Study, or (iv) the IRB’s approval to continue the Study. Notwithstanding anything to the contrary in this Agreement, Institution and Principal Investigator are free to communicate such information to each Study subject and the IRB.

(c) Pharmacyclics shall promptly register the Study on www.clinicaltrials.gov in accordance with the requirements described in Section 801 of the Food and Drug Administration Amendment Act.

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6. **Study Materials: Equipment.**

(a) Pharmcyclics will provide sufficient quantities of Study Product, investigator brochures, and if applicable, access to an electronic data capture system for completing Case Report Forms ("CRFs"), any other compounds, materials, and access to or copies of certain patient reported outcomes (electronic or paper) surveys, questionnaires, and/or scales (collectively, "PROs") that the Protocol specifies or that Pharmcyclics deems necessary to conduct the Study at no cost to Institution (together, the "Study Materials"). All Study Materials and other information provided by Pharmcyclics in connection with this Agreement and Statement of Work are and shall remain the sole property of Pharmcyclics. Pharmcyclics represents that the Study Product will have been manufactured in accordance with current Good Manufacturing Practices.

(b) Institution shall maintain adequate records to account for the Study Materials including, without limitation and if applicable, dates, quantity, and use by Study subjects. Institution or Principal Investigator shall, if applicable, inspect the Study Materials upon receipt and notify Pharmcyclics upon becoming aware that any Study Materials are damaged or that the supply of Study Materials is inadequate.

(c) Study Materials shall (i) be stored and handled in accordance with the labeling, investigator brochure, or material data safety sheet, as applicable, of the applicable Study Materials, and in accordance with applicable Laws, and Pharmcyclics’ reasonable written instructions, (ii) not be used past their respective labeled expiration dates, if any.

(d) Neither Institution, Principal Investigator, nor any other Institution Personnel shall (i) publish any part of the PROs in any manuscript, poster, oral presentations, or otherwise, except to the extent information contained in the PROs constitutes Study data and/or results, in which case such information may be published in accordance with Section 13 (Publications and Presentations) below; (ii) remove or alter any notice contained in the PROs; or (iii) modify, transfer, distribute, or release the PROs to any third party, except in connection with performing the Study, in accordance with the Protocol or except as set forth in this Agreement.

(e) Upon conclusion of the Study, termination of this Agreement or a Statement of Work, or at Pharmcyclics’ request, any remaining or expired Study Materials, as applicable, shall be returned to Pharmcyclics at Pharmcyclics’ reasonable expense in accordance with the Protocol and Pharmcyclics’ reasonable written instructions and in compliance with applicable Laws governing the shipment of such Study Materials. If the parties agree that the return of such Study Materials is not practicable or is prohibited under applicable Laws, any remaining or expired Study Materials, as applicable, will be destroyed in full compliance with applicable Laws. Upon any such destruction, Institution will provide Pharmcyclics with a certificate of destruction or similar document verifying the final disposition of the Study Materials.

(f) If necessary for purposes of conducting the Study, Pharmcyclics may provide Institution with certain equipment. Any equipment provided by Pharmcyclics hereunder is described in Attachment 2 to the Statement of Work (Equipment To Be Provided By Pharmcyclics) ("Equipment"). For any Equipment provided by Pharmcyclics, Institution shall (i) promptly inspect the Equipment following receipt and notify Pharmcyclics upon becoming aware that any Equipment is damaged or malfunctioning; (ii) use the Equipment in accordance with the user manual and/or other reasonable instructions provided with the Equipment; (iii) maintain the Equipment in a secure manner designed to protect such Equipment from unauthorized use, theft, or damage and exercise the same degree of care with respect to the Equipment that Institution exercises with respect to its own equipment of similar type and value. If, due to the gross negligence of Institution or any Institution Personnel, any of the Equipment is lost, stolen, or damaged, then Institution shall pay the reasonable cost of replacement or repair, as applicable, which shall not exceed the estimated value of such Equipment set forth in Attachment 2 to the Statement of Work. At Pharmcyclics’ direction and expense, the Equipment shall be returned to a location specified by Pharmcyclics at the end of the Study or earlier termination of the Statement of Work.
(g) In the event the Protocol requires Institution to provide Equipment to Study subjects for their use during the Study, Institution shall instruct the Study subjects as to the proper use of the Equipment. If any of the Equipment is lost, stolen, or damaged by a Study subject or while under the control of a Study subject, then Pharmacyclics shall pay the reasonable cost of replacement or repair, as applicable.

(h) Institution shall use the Study Materials and the Equipment solely for the conduct of the Study and not for any other study nor for any other use.

7. Monitoring of Study; Records; Reporting.

(a) Upon the reasonable request of Pharmacyclics, Institution shall submit oral or written reports on the progress of the Study at reasonable intervals during the Study Term. Within ninety (90) days following completion or termination of a Study at Institution, Institution shall furnish Pharmacyclics with (i) a final IRB report on the Study, which may be the final IRB Study report prepared by the Principal Investigator for the IRB; and (ii) all data, records, CRFs (not already provided pursuant to the CRF timelines set forth in Section 4 (g) above), reports, and other information generated (excluding source documents, medical records, and Institution Records) in the conduct of the Study (collectively, “Records”), which shall be the exclusive property of Pharmacyclics. Notwithstanding the foregoing, source documents, medical records, laboratory notebooks, Protected Health Information (as such term is defined by HIPAA), Institution’s business records, regulatory and compliance documents, research notebooks, or any other information that is required by Law or regulation to be retained by Institution, (collectively referred to as “Institution Records”) shall be considered the exclusive property of Institution. Institution agrees that, subject to Section 10 (Subject Confidentiality; Data Protection) of this Agreement, Pharmacyclics shall have the right to use the information described in such source documents and medical records (i) to the extent permitted by the IRB approved ICF signed by the Study subject (“Subject ICF”); and (ii) only in accordance with applicable Law. Notwithstanding the foregoing and subject to Section 9 (Confidentiality), Section 10 (Subject Confidentiality; Data Protection), and Section 13 (Publications and Presentations), Institution retains the right to use any Records for its internal and non-commercial research, teaching, and Study subject patient care purposes. To the extent authorized by the Constitution and the laws of the State of Texas, Institution shall indemnify, defend, and hold harmless Pharmacyclics from and against any and all liability, losses and expenses (including reasonable attorneys’ fees), arising out of third party claims resulting directly from or directly arising out of the use of Records by or on behalf of Institution in accordance with this Section 7 of this Agreement.

(b) During normal business hours, Institution shall permit Pharmacyclics and Pharmacyclics’ designees access to any facilities at which the Study is conducted to monitor the conduct of the Study and to audit the Records, source documents generated in the conduct of the Study, and other Study data and results (collectively, “Study Documents”) to verify compliance with this Agreement, provided that Institution may redact such Study Documents as legally required to protect subject confidentiality. Except in cases where Pharmacyclics requires immediate access to Study site in connection with audits and responses to requests made by regulatory authorities (in which case Institution shall permit access upon reasonable advance notice), monitoring visits shall be scheduled at mutually agreeable times.

(c) If, as a result of Study monitoring, Pharmacyclics identifies a significant audit finding that is not timely cured or is incapable of timely cure, Pharmacyclics may immediately terminate any Statement of Work. Pharmacyclics’ rights in this Section shall be subject to Institution’s reasonable measures for purposes of confidentiality, safety, and security, and will be further subject to Pharmacyclics’ compliance with Institution’s premises rules that are generally applicable to all persons at Institution’s facilities; provided, however, that all such policies and procedures are reasonable, and consistent with applicable Laws and regulations. Should Pharmacyclics utilize one or more third party(s) in exercising its rights in this paragraph, Pharmacyclics certifies that such party(s) shall be subject to an obligation of confidentiality consistent with the obligations of confidentiality required of Pharmacyclics hereunder and such
third party(s) shall be subject to any and all conditions upon Pharmacyclis’ rights that are set forth in this Section 7.

(d) Institution shall, to the extent permitted by applicable Laws, promptly (i) notify Pharmacyclis upon receiving any requests to inspect and have access to Study Documents by any regulatory authority having jurisdiction over the Study, and (ii) provide Pharmacyclis with a copy of any documents received from such regulatory authority that relate to the Study. In the event a regulatory citation or notice (including, without limitation, a FDA Form 483 or FDA warning letter) is issued relating to the Study, Institution agrees, to the extent permitted by applicable Laws, to furnish to Pharmacyclis within fifteen (15) days of receipt of such regulatory citation or notice (A) notification of such citation or notice, and (B) a summary of such citation or notice; and (C) Institution’s response to such citation or notice. Pharmacyclis shall hold all such documents, citations, notice, and correspondence in confidence except as may be required by applicable Laws (including but not limited to the Texas Open Records Act) and for responding to the FDA.

(e) Institution shall retain the Study Documents in accordance with applicable Laws (the “Retention Period”). If Pharmacyclis requests that Institution retain the Study Documents beyond the Retention Period, the parties shall cooperate in good faith in an effort to mutually agree upon the costs to be paid by Pharmacyclis and the duration for such extended Retention Period.


(a) Pharmacyclis may delegate certain payment obligations under a Statement of Work to a contract research organization (“CRO”). In such event, Institution agrees that as to any payments delegated by Pharmacyclis to such CRO, Institution shall first seek redress from the CRO for compensation. If after seeking redress from the CRO for such payments Institution is not paid the amounts due under this Section 8, then Pharmacyclis shall pay undisputed amounts. Additionally, Pharmacyclis will ensure that each Statement of Work under this Agreement will be entered into directly between Pharmacyclis and the individual Institution and that Pharmacyclis’ CRO would not be a party to these SOWs and therefore its CRO would not need a separate clinical study agreement directly with a UT System Institution.

(b) In support of the conduct of each Study, Pharmacyclis, or CRO acting on behalf of Pharmacyclis, shall pay Institution and, if applicable, UT System (for study services performed by CTX) in accordance with the Budget. Institution understands and agrees that none of Principal Investigator or subinvestigator(s) will receive any funds from Pharmacyclis in connection with the performance of the Study other than the funds paid to Institution in accordance with the Budget. The parties agree that the amount for payments set forth in the Budget represents the fair market value for the services to be rendered and has not been determined in any manner that takes into account the volume or value of any referrals or business otherwise generated between Institution and Pharmacyclis. Institution agrees that the overhead charged to Pharmacyclis under a Statement of Work shall be as stated in the Statement of Work.

(c) In the event that the Agreement or Statement of Work is terminated, Pharmacyclis shall pay Institution for work performed, expenses incurred and non-cancelable obligations made up to the effective date of termination. Additionally, Pharmacyclis, or CRO on behalf of Pharmacyclis, shall also pay Institution for budgeted costs and expenses for unscheduled visits associated with removing subjects from the Study up to the effective date of termination, in accordance with the Budget. In the event that the Agreement or Statement of Work is terminated, Pharmacyclis shall not be obligated to reimburse Institution for expenses that are invoiced to Pharmacyclis more than one hundred eighty (180) days after the termination date of the relevant Statement of Work.

(d) Pharmacyclis shall not be responsible for paying for: (i) data contained in a CRF which is misleading, incomplete or inaccurate; or (ii) work performed in violation of the Protocol (provided, however, that actions (including Protocol Deviations (defined below in Section 16(c)) taken by Institution or Institution Personnel that are based on generally accepted standards of clinical research and medical practice, necessary to treat a condition that poses an immediate risk to the safety, life or well-being of a Study subject shall not, in and of themselves, constitute a violation of

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the Protocol or this Agreement). If Pharmacyclics has previously paid for such work, the payment shall be deducted from the final payment due under the Statement of Work (the "Final Payment").

(e) In the event of any payment dispute under a Statement of Work, (i) Pharmacyclics, or CRO, on behalf of Pharmacyclics, shall pay undisputed amounts upon receipt of an invoice therefor, and (ii) the parties shall cooperate in good faith to resolve such dispute in a timely manner. Following resolution of such dispute, Institution shall re-invoice Pharmacyclics, or CRO on behalf of Pharmacyclics, and Pharmacyclics, or CRO on behalf of Pharmacyclics, shall pay the amounts the parties mutually agree are due. In no event may Institution or Institution Personnel withhold Records that are otherwise required to be submitted to Pharmacyclics hereunder, pending resolution of a payment dispute.

(f) Pharmacyclics, or CRO on behalf of Pharmacyclics, will make the Final Payment due under a Statement of Work after performing a financial reconciliation and after Institution's completion of the performance of all work contemplated thereunder and the delivery to Pharmacyclics of all CRFs and all other items described in Section 7(a). If Pharmacyclics, or CRO on behalf of Pharmacyclics, has paid Institution less than Institution is entitled at the time of financial reconciliation, Pharmacyclics, or CRO on behalf of Pharmacyclics, shall pay the remaining amount due within ninety (90) days of discovery of such underpayment along with an explanation of such underpayment as part of the Final Payment. Any overpayment due Pharmacyclics, or CRO on behalf of Pharmacyclics, at the time of final reconciliation, shall be deducted from the Final Payment and will include an explanation of such overpayment and include any supporting documentation.


(a) During the Term of this Agreement, including any extensions thereof, and for a period of seven (7) years after expiration or termination of this Agreement, (i) Institution and Institution Personnel (collectively "Receiving Party") shall not disclose to any third party or use Pharmacyclics Confidential Information (as defined below) for any purpose other than that indicated in this Agreement without Pharmacyclics' prior written consent and (ii) Pharmacyclics shall not disclose Institution's Confidential Information (as defined below) without Institution's prior written consent unless permitted hereunder. Notwithstanding the foregoing, Confidential Information identified as a trade secret will not be disclosed by Pharmacyclics to Institution unless Pharmacyclics first notifies Institution in writing that Pharmacyclics wishes to disclose a trade secret and the nature of the trade secret, and Institution has then specifically agreed in writing in advance to receive such trade secret. In such event, Institution’s obligations of confidentiality and non-use with respect to such disclosed trade secret shall survive for the period required by law.

(b) "Pharmacyclics Confidential Information" shall include any information provided to Receiving Party by or on behalf of Pharmacyclics and its Affiliates, and/or collaborators, including but not limited to the Protocol, Investigator Brochures, Study Materials, and Records. "Institution Confidential Information" shall include the information and materials provided to Pharmacyclics by or on behalf of Institution, including proprietary information concerning Institution and its business related to the Study. Pharmacyclics Confidential Information and Institution Confidential Information shall be referred to herein collectively as "Confidential Information".

(c) Pharmacyclics Confidential Information shall not include information or any portion thereof which:

(i) is known to the Receiving Party prior to receipt thereof under this Agreement, as evidenced by its written records;

(ii) is disclosed to the Receiving Party after acceptance of this Agreement by a third party who, to the knowledge of Receiving Party, has a right to make such disclosure in a nonconfidential manner;

(iii) is or becomes part of the public domain through no fault of the Receiving Party; or
(iv) is independently developed by the Receiving Party without use of, or reference to Pharmacyclics Confidential Information.

(d) Institution Confidential Information shall not include information or any portion thereof which:

(i) is known to Pharmacyclics prior to receipt thereof under this Agreement, as evidenced by its written records;

(ii) is disclosed to Pharmacyclics after acceptance of this Agreement by a third party who, to the knowledge of Pharmacyclics, has a right to make such disclosure in a non-confidential manner;

(iii) is or becomes part of the public domain through no fault of Pharmacyclics; or

(iv) is independently developed by or for Pharmacyclics without use of or reference to the Institution Confidential Information, as evidenced by its written records.

(e) Notwithstanding the foregoing, Institution may disclose Pharmacyclics Confidential Information: (i) to the extent it is required by an applicable Law to be disclosed; (ii) to the extent required in order to obtain informed consent from subjects who may wish to enroll in the Study, provided, however, that the Pharmacyclics Confidential Information will be disclosed only to the extent necessary and will not be provided in answer to unsolicited inquiries by telephone or to individuals who are not eligible Study candidates; (iii) to a Study subject for the protection of the safety or well-being of the Study subject; or (iv) to the extent that is required to be communicated to Institution’s scientific and/or institutional review committees provided, however, that such persons are obligated to maintain the confidentiality of such information consistent with the terms of this Agreement.

(f) Nothing in this Agreement will be construed to restrict either party from disclosing Confidential Information as required by Law or court order or other governmental order or request, provided in each case such party shall, to the extent practicable, give the other party written notice as soon as reasonably possible in order to allow the affected party to take whatever action it deems necessary to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or either party waives compliance with the terms of this Section 9, a disclosing party shall furnish only that portion of the Confidential Information which it is legally required to disclose. In addition, each party will permit the affected party to attempt to limit such disclosure by appropriate legal means.

(g) Neither party will disclose to the other party any information which is confidential or proprietary to a third party unless such party has first obtained the prior written approval of both such third party and the other party.

(h) Within forty-five (45) days following completion or termination of the applicable Statement of Work, each party will return or destroy all tangible materials that contain the other party’s Confidential Information, provided, however, that each party will be permitted to retain one (1) archival copy of the other’s party’s Confidential Information on a confidential basis solely as required for regulatory, legal, or insurance purposes or as permitted by this Agreement.

10. Subject Confidentiality; Data Protection. Institution shall comply with all applicable Laws regarding Study subject confidentiality and data protection, including without limitation, HIPAA, HITECH, and applicable state privacy laws, in the collection, use, storage and disclosure of protected health information, as defined in HIPAA (“PHI”). Institution does not intend to provide any PHI to Pharmacyclics, provided, however, that to the extent any Records, Study Documents, results or data of the Study or information provided to Pharmacyclics or accessed by Pharmacyclics may include any PHI, Pharmacyclics shall and shall ensure that Pharmacyclics’ representatives shall hold such information in confidence, and collect, use, store, access and disclose such PHI only in accordance with applicable Law and to the extent permitted by the applicable Subject ICF and in accordance with any reasonable instructions from Institution’s IRB that are consistent with the Protocol and such Subject ICF.
11. Publicity.

(a) Except as required by Law or regulation or as permitted hereunder, including, but not limited to requirements set forth in Section 13 (Publications and Presentations), neither party shall disclose the terms of this Agreement or make any public announcements regarding the terms of this Agreement without the other party's written consent.

(b) Neither party shall use the trademark, servicemark, or logo of the other party or the other party's Affiliates in any publicity, advertising, or other information intended to be used for commercial or promotional purposes without the other party's prior written consent. Neither party shall use the name of the other party or the other party's Affiliates in any publicity, advertising, or other information intended to be used for commercial purposes without the other party's prior written consent. Notwithstanding the foregoing, Institution and Principal Investigator may without prior written approval, disclose their participation in the Study (including the names of Pharmacyclics or Pharmacyclics’ Affiliates, name of the Study, funding source, and total funding amount) as required by applicable Laws, court order or state regulation, as required by Section 13 (Publications and Presentations), or in (i) curriculum vitae, (ii) internal reports, (iii) grant applications to government funding sources, (iv) required government reports and filings, (v) Institution's clinical trials website exactly as such information appears on clinicaltrials.gov, and (vi) conflict of interest disclosures. Institution understands and agrees that the terms and conditions of this Agreement and any Statement of Work and the amount of any payment made thereunder may be disclosed and made public by Pharmacyclics to the extent required by Pharmacyclics to comply with applicable Laws. As Pharmacyclics reasonably requests, Institution shall cooperate in good faith with Pharmacyclics to promptly provide accurate and complete information that is not already in Pharmacyclics’ possession in connection with such disclosures related to the Study. The parties understand that the terms and conditions of this Agreement may be disclosed and made public by Pharmacyclics and/or Institution to the extent required by Law.


(a) Each party (and with respect to Pharmacyclics, including all Affiliates and collaborators) hereto retains all right, title and interest in any patent, patent application, trade secret, know-how and other intellectual property that was owned by such party (and with respect to Pharmacyclics, including all Affiliates and collaborators) prior to the Effective Date. No license grant or assignment, express or implied, by estoppel or otherwise, is intended by, or shall be inferred from this Agreement, except as specifically set forth herein.

(b) Any invention, or discovery (whether patentable or not), conceived, reduced to practice, made, generated or developed by Institution or Institution Personnel that is made from use of the Study Materials provided hereunder or made in the conduct of the Study (collectively, “Intellectual Property”) shall be promptly disclosed to Pharmacyclics, and Institution hereby assigns to Pharmacyclics all of Institution’s rights, title, and interest in and to such Intellectual Property. Upon Pharmacyclics’ request and at Pharmacyclics’ expense, Institution shall require Institution Personnel to execute, or cause to have executed such documents and to take such other reasonable actions to obtain, record or enforce patents, assignments or other proprietary protection in Pharmacyclics’ name covering any such Intellectual Property. Subject to Section 9 (Confidentiality) and Section 13 (Publications and Presentations), Pharmacyclics grants to Institution a free, non-transferable, non-sublicensable, non-exclusive license to use any Intellectual Property solely for its internal and non-commercial research, teaching patient care purposes and for publication purposes.

13. Publications and Presentations. For purposes of this Agreement, as it relates to Institution, “Scientific Publication” means any scientific publication or medical communication regarding Study data and results in any form that is intended for disclosure to third parties, including, without limitation, manuscripts, abstracts, posters, slides or other materials used for presentations. For sake of clarity and for the purposes of this Agreement, a Scientific Publication may or may not be peer-reviewed.

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(a) Pharmacyclics is committed to fostering the highest standard of conduct related to Scientific Publications and transparency, while at the same time, protecting its Confidential Information provided hereunder. Authorship related to Scientific Publications shall be determined in accordance with and governed by the criteria defined by the International Committee of Medical Journal Editors (ICMJE) “Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals”, and Institution shall require that Pharmacyclics’ role in support of the Study be appropriately disclosed in any Institution Publications (as defined below).

(b) For the purposes of this Agreement, for a Pharmacyclics Multi-Site Publication, Institution acknowledges that, as the Study sponsor, Pharmacyclics retains the right to disclose the Study data and results first in a peer-reviewed manuscript published in a scientific journal based on the final Study data and results from all appropriate sites (“Multi-Site Publication”).

(c) Following the earliest of: (i) Pharmacyclics’ Multi-Site Publication; or (ii) twelve (12) months after completion, abandonment or termination of the Study at all Study sites, Institution and Principal Investigator shall have the right to prepare and submit for public disclosure Institution’s Study data and results through a Scientific Publication or other public disclosure (an “Institution Publication”). Institution and/or Principal Investigator shall provide Pharmacyclics with a draft of any proposed Institution Publication at least thirty (30) days prior to submission of such publication for Pharmacyclics to ascertain whether any patentable Intellectual Property or Pharmacyclics Confidential Information (other than the data and/or results of the Study generated hereunder) are disclosed therein. Institution or Principal Investigator shall send its/his/her draft proposed Institution Publication via e-mail to Publications@pcyc.com. Pharmacyclics shall return comments to Institution and/or Principal Investigator within thirty (30) days after receipt of the draft Institution Publication (“Review Period”). Institution and/or Principal Investigator shall delay any proposed Institution Publication an additional ninety (90) days after the Review Period in the event Pharmacyclics requests the delay to enable Pharmacyclics, and its Affiliates, and/or collaborators, to secure patent or other proprietary protection for any Intellectual Property contained within such Institution Publication (“Delay Period”). Institution agrees and shall ensure that Principal Investigator agrees to (A) keep the proposed Institution Publication confidential until expiration of the Review Period and, if elected by Pharmacyclics, any Delay Period, and (B) delete Pharmacyclics Confidential Information (other than data and/or results of the Study generated hereunder) from any Institution Publication. In the event that Institution, and/or Principal Investigator, and Pharmacyclics differ in their conclusions or interpretation of Study data and results in the Institution Publication, the parties shall, during the Review Period, use good faith efforts to attempt to resolve such differences through appropriate scientific debate. Subject to Institution’s and/or Principal Investigator’s removal of Pharmacyclics Confidential Information (other than data and/or results of the Study generated hereunder), Institution or Principal Investigator, as applicable, shall retain control over the final version of the Institution Publication.


(a) Institution represents and certifies that during the Term of this Agreement:

(i) the terms of this Agreement and Statement of Work are valid and binding obligations of Institution, and are not inconsistent with (A) any other contractual or legal obligation it may have; or (B) policies and procedures of Institution;

(ii) Institution’s and Institution Personnel’s performance of the activities hereunder is in compliance with all policies and procedures of Institution, and Principal Investigator’s performance of such activities does not present a conflict of interest with Principal Investigator’s official duties;

(iii) Institution and Principal Investigator have, as applicable, adequate facilities, resources, training and expertise to conduct the Study in accordance with the Protocol and applicable Laws; and

(iv) Principal Investigator has a current and valid medical license in the jurisdiction in which the Study is being performed.
Institution shall notify Pharmacyclics promptly if at any time during the Term, Institution learns that Institution would no longer be able to truthfully make any of the representations and certifications in this Section 14(a) and Pharmacyclics shall have the right to immediately terminate this Agreement.

(b) Institution represents and certifies that neither Institution nor Institution Personnel are Debarred or, to the best of Institution’s knowledge, have been Debarred or are the subject of a proceeding that could lead to Institution or any Institution Personnel becoming Debarred. For purposes of this Agreement, “Debarred” means (A) debarred by the FDA under 21 U.S.C. § 335a; (B) excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; (C) listed on the FDA’s Disqualified and Restricted Lists for clinical investigators; or (D) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. In the event Institution receives notice of, or otherwise becomes aware of, the Debarment, proposed Debarment of itself or any Institution Personnel, Institution shall notify Pharmacyclics immediately and Pharmacyclics shall have the right to immediately terminate this Agreement. The obligations of this Section 14(b) shall survive termination or expiration of the Agreement for a period of two (2) years.

(c) Pharmacyclics represents and certifies that the Study Product that is delivered to Institution will be manufactured in accordance with current Good Manufacturing Practices and will meet the product specification identified in the product label at the time of delivery to Institution.

15. Term and Termination.

(a) Unless terminated earlier as provided in Section 15(b) below, this Agreement shall be effective on the Effective Date and shall continue for five (5) years following the Effective Date (“Term”).

(b) This Agreement may be terminated:

(i) by either Pharmacyclics or Institution upon written notice to the other party if the other party has breached a material term of this Agreement and the breaching party fails to cure such breach within thirty (30) days of receiving written notice of such breach; or

(ii) by Pharmacyclics (A) without cause upon thirty (30) days prior written notice to Institution to the extent such termination will not harm a Study subject or is medically permissible; or (B) as otherwise permitted in this Agreement.

(c) A Statement of Work may be terminated:

(i) by either Pharmacyclics or Institution upon written notice to the other party if: (A) the other party has breached a material term of this Agreement or Statement of Work and the breaching party fails to cure such breach within thirty (30) days of receiving written notice of such breach; (B) the Study is terminated or suspended by the IRB, FDA or any other governmental or regulatory authority; (C) if the Principal Investigator leaves Institution or is otherwise unable to continue to participate in the Study, and the parties are unable to find a mutually acceptable replacement principal investigator within thirty (30) days; or (D) if either Pharmacyclics or an Institution, in its sole judgment, believes an adverse safety concern with respect to Study Product makes continued testing unadvisable, provided that if Institution terminates for this reason, it shall be after the Suspension Period as defined, and in accordance with Section 15(d).

(ii) by Pharmacyclics (A) without cause upon thirty (30) days prior written notice to Institution to the extent such termination will not harm a Study subject or is medically permissible; or (B) as otherwise permitted in the Statement of Work.

(d) In the event Institution or Principal Investigator have concerns about the health, safety and welfare of the Study subject(s), Institution shall give prompt notice to Pharmacyclics of such concerns, and may suspend enrollment of Study subjects for a period not to exceed thirty (30)
calendar days ("Suspension Period"). During such Suspension Period, the parties shall evaluate the concerns raised by Institution or Principal Investigator to determine whether the Statement of Work should be terminated. In any event, Institution and Principal Investigator shall continue monitoring and follow-up in strict adherence to the Protocol for currently enrolled Study subjects during the Suspension Period. After the Suspension Period and following written notice including a detailed written explanation to Pharmcyclics, Institution may terminate a Statement of Work if Study subject health, safety, and welfare remain a concern to Institution of such magnitude to support such termination.

(e) Termination or expiration of this Agreement or Statement of Work shall not affect any rights or obligations which have accrued prior thereto or any other rights or remedies provided at law or equity which either party may otherwise have. If the Study Term of a Statement of Work extends beyond the termination or expiration date of this Agreement, the applicable terms and conditions of this Agreement shall extend automatically for such Statement of Work until such Statement of Work’s termination or expiration date. In the event of premature termination of a Statement of Work, Institution shall (i) appropriately withdraw and discontinue all then-enrolled subjects if medically permissible, (ii) complete the Study for then-enrolled Study subjects where required by accepted medical practice, or (iii) reasonably cooperate with Pharmcyclics to arrange for then-enrolled Study subjects to enroll at an alternative Study site.

16. Subject Injury; Indemnification.

(a) If the Study under a Statement of Work is a Phase I, Phase II or Phase III Study and any injury or illness occurs to a Study subject as a result of: (i) the administration of the Study Materials, or (ii) the performance of Protocol-mandated procedures on Study subjects that such Study subjects would not have received but for their participation in the Study ("Procedures") in each case in accordance with the Protocol ("Study Injury"), Pharmcyclics agrees to pay all reasonable medical expenses necessary to treat such Study Injury, provided that such Study Injury is not due to the natural progression of any pre-existing disease or any underlying illness. Institution shall not submit claims for such medical expenses for a Study Injury paid by Pharmcyclics to a third party payor.

(b) If the Study under a Statement of Work is a Phase IV Study, the parties acknowledge and agree that because Pharmcyclics is not providing any Study Product in connection with such Phase IV Study, Pharmcyclics’ foregoing obligation to pay for Subject Injury will not apply to any such Phase IV Study.

(c) Pharmcyclics’ Indemnification Obligations for Phase I, Phase II or Phase III Studies: Pharmcyclics shall indemnify, defend and hold harmless Institution, System, their Regents, officers, agents, employees, Institution Personnel and Institution’s officers, trustees, and IRB members ("Indemnities") in the conduct of a Phase I, Phase II or Phase III Study, for (i) the costs of defense (until such time as Pharmcyclics assumes the defense thereof) and (ii) any liability or loss resulting from judgments or claims against Indemnities (collectively, "Losses") as a result of any claim or lawsuit made by a third party as a result of (i) a Study Injury; (ii) Pharmcyclics’ or its representatives’ negligent acts or omissions, recklessness, or intentional misconduct during and/or in connection with the Study; (iii) Pharmcyclics’ use of the Study data and results; or (iv) Pharmcyclics’ material breach of this Agreement. Pharmcyclics’ indemnification obligation applies only if (A) Study Materials are administered by Institution Personnel and Procedures are performed during the Study in accordance with the Protocol (provided however, that a deviation from the Protocol taken by Institution or Institution Personnel that is based on generally accepted standards of clinical research and medical practice and is necessary to treat a condition that poses an immediate risk to the safety, life or well-being of a Study subject (a "Protocol Deviation") shall not, in and of itself, constitute a violation of the Protocol), with accepted medical practice, and with any other reasonable written instructions furnished by Pharmcyclics, and (B) Study data and results communicated to Pharmcyclics by Institution Personnel are not misleading, inaccurate, or incomplete.
(d) **If the Study under a Statement of Work is a Phase IV Study**, the parties acknowledge and agree as follows:

(i) if Pharmacyclics is **not** providing any Study Product, then Pharmacyclics shall indemnify, defend and hold harmless Indemnitees only for any Losses caused as a result of Pharmacyclics’ use of the Study data and/or results.

(ii) If Pharmacyclics **is** Providing Study Product that has not yet been approved by the FDA for the applicable indication under Study, then Pharmacyclics shall indemnify, defend, and hold harmless Indemnitees for any Losses caused as a result of (i) a Study Injury; (ii) Pharmacyclics’ or its representatives’ negligent acts or omissions, recklessness or intentional misconduct during the Study; or (iii) Pharmacyclics’ use of the Study data and/or results.

(e) The foregoing agreement to indemnify, defend, and hold harmless Indemnitees is conditioned upon the following obligations of Indemnitees to:

(i) advise Pharmacyclics of any claim or lawsuit, in writing addressed to Pharmacyclics LLC, Attention: Head of Legal, Legal Department, Pharmacyclics LLC, 995 E. Arques Avenue, Sunnyvale CA 94085-4521 within fifteen (15) days after any Indemnitee has received notice of said claim or lawsuit or within such other time frame so that Pharmacyclics’ ability and rights to defend or settle such claim or lawsuit are not materially prejudiced, provided, however, the failure to notify Pharmacyclics within the above-referenced fifteen (15) days shall not relieve Pharmacyclics of its indemnification obligations unless Pharmacyclics is materially or adversely affected by such failure.

(ii) reasonably assist Pharmacyclics and its representatives in the investigation and defense of any lawsuit or claim for which indemnification is provided; and

(iii) not compromise or otherwise settle any such claim or lawsuit without Pharmacyclics’ prior written consent.

(f) Pharmacyclics’ obligations to pay reasonable medical expenses in connection with a Study Injury or to indemnify, defend, or hold harmless shall not apply in the event any Losses or Study Injury, respectively, are attributable to (i) the negligence, recklessness or willful misconduct of, or failure to follow the Protocol (except for Protocol Deviations) by, any of the Indemnitees or (ii) Institution’s or Institution Personnel’s breach of any obligations under this Agreement or Statement of Work.

(g) Institution represents and certifies that this **Section 16** is subject to the statutory duties of the Texas Attorney General.

17. **Insurance.** Each party shall maintain a policy or program of insurance or self-insurance with policy limits sufficient to support its obligations under this Agreement. Upon request by a party, the other party shall furnish evidence of such party’s applicable insurance. Each party’s insurance coverage shall comply with applicable Laws and insurance guidelines. Each member of The University of Texas System is self-insured pursuant to The University of Texas Professional Medical Liability Benefit Plan under the authority of Chapter 59, Texas Education Code.

18. **Independent Contractor.** Each party’s relationship to the other party is that of an independent contractor, and neither party has authority to bind or act on behalf of the other party.

19. **Assignment.** Neither party may assign this Agreement to any other party without the other party’s prior written consent; provided, however, that upon prior written notice to the other party, either party may assign this Agreement without consent to any successor by merger, de-merger or sale of substantially all of the assets to which this Agreement relates; provided further that any successor of Institution is a hospital or other health care facility or patient treatment center. Any attempted assignment except in accordance with this **Section 19** shall be null and void and shall constitute a material breach of this Agreement.

CONFIDENTIAL
20. **Subcontracting.** In the event Institution subcontracts any aspect of Study performance to a subcontractor, Institution shall (a) ensure each subcontractor’s compliance with the requirements of this Agreement and Statement of Work, and (b) be responsible for any subcontractor’s non-compliance with the terms and conditions of this Agreement and Statement of Work to the same extent that Institution would be responsible if Institution were performing the subcontracted services directly. If a subcontractor does not strictly adhere to the provisions of this Agreement and Statement of Work, Institution shall promptly notify Pharmacyclics, and Pharmacyclics may immediately terminate this Agreement or relevant Statement of Work.

21. **Notices.**

   (a) Routine communications regarding the conduct of the Study shall be sent to the Pharmacyclics individual identified to Institution by Pharmacyclics as the primary contact for the Study ("Pharmacyclics Study Contact") set forth in the Statement of Work.

   (b) Communications related to the assignment of this Agreement shall be made by email, mail or recognized national or international courier and shall be sent to the Pharmacyclics notice address set forth below with a copy to the Pharmacyclics Legal Notices address set forth below.

   (c) All notices under this Agreement shall be in writing, refer to this Agreement, and be sent by recognized national or international overnight courier or registered or certified mail, postage prepaid, return receipt requested, or delivered by hand to the notice address(es) set forth below.

   **If to Institution:**
   See Appendix A for the name and address of an administrative contact for each Institution.

   **With a copy to:**
   The University of Texas System
   Office of General Counsel
   210 West 7th Street
   Austin, TX 78701
   ATTN: Intellectual Property Section in the Office of General Counsel

   **If to Pharmacyclics:**
   Clinical Development
   Pharmacyclics LLC
   995 E. Arques Avenue
   Sunnyvale, CA 94085-4521

   **If to Pharmacyclics (legal notices):**
   Head of Legal
   Legal Department
   Pharmacyclics LLC
   995 E. Arques Avenue
   Sunnyvale, CA 94085-4521

   Notices under this Agreement shall be deemed to be duly given: (i) when delivered by hand; (ii) two (2) days after deposit with a recognized national or international courier; or (iii) on the delivery date indicated in the return receipt for registered or certified mail. A party may change its notice address immediately by sending written notice to the other party’s legal notice address as set forth in this Section 21.

22. **Survival.** Any other terms which by their intent or meaning are intended to survive termination or expiration of this Agreement shall so survive, including, without limitation, the parties’ obligations with respect to financial disclosure reporting and conflict of interest disclosure and management, record retention and audit rights, confidentiality, publicity, intellectual property, publications and presentations, notification requirements with respect to such party’s representations and certifications as set forth in **Section 14(b)**, subject injury and indemnification.

23. **Severability.** If any provision, right or remedy provided for herein or any Statement of Work is held to be unenforceable or inoperative by a court of competent jurisdiction, the validity and enforceability of the remaining provisions shall not be affected thereby.
24. **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature, either handwritten or digital, or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Agreement. The parties may use DocuSign, or other comparable web-based signature programs, to circulate and execute this Agreement and applicable Statements of Work.

25. **Entire Agreement.** This Agreement including, without limitation, all Exhibits, Appendices and Attachments hereto, contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. In the event a purchase order is issued to provide for payment of the services under a Statement of Work, the terms and conditions of this Agreement and relevant Statement of Work shall control over any conflict between terms and conditions of the purchase order and this Agreement or Statement of Work. In the event of a conflict between provisions of the Protocol and this Agreement or any Exhibits, Appendices or Attachments hereto, the Protocol shall control with respect to matters of science, medical practice, and Study subject safety. In all other matters, the provisions of this Agreement shall control. In the event of any conflict between the terms and provisions of this Agreement and those in the Exhibits, Appendices and Attachments hereto or any Statement of Work, the provisions of this Agreement shall control, unless a particular Statement of Work specifically acknowledges the conflict and expressly states that the conflicting term or provision found in the Statement of Work controls for that Statement of Work only (but then only with respect to that particular Statement of Work and with respect only to such matter). Neither this Agreement nor any of its terms, including any Exhibit, Appendix or Attachment hereto, may be amended, restated or otherwise altered except by written agreement signed by the parties.

26. **State Agency.** Institution hereby represents and certifies as follows: (i) Institution is an agency of the State of Texas and under the Constitution and the laws of the State of Texas, possesses certain rights and privileges; (ii) is subject to certain limitations and restrictions; (iii) only has such authority as is granted to it under the Constitution and laws of the State of Texas; (iv) nothing in this Agreement is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas; (v) notwithstanding the generality or specificity of any provision hereof, the provisions of this Agreement as they pertain to Institution are enforceable only to the extent authorized by the Constitution and laws of the State of Texas; and (vi) accordingly, to the extent any provision hereof conflicts with the Constitution or laws of the State of Texas or exceeds the right, power or authority of Institution to agree to such provision, then that provision will not be enforceable against Institution or the State of Texas.

[Remainder of page intentionally left blank; signature page follows.]
IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives on the dates set forth below and this Agreement shall be effective as of the Effective Date set forth above.

PHARMACYCLICS LLC
By: [Signature]
Name: Susan Wong
Title: Director, Clinical Operations
Date: Jan-10-2018

THE UNIVERSITY OF TEXAS SYSTEM FOR THE BENEFIT OF CLINICAL TRIALS XPRESS
By: [Signature]
Name: Raymond S. Greenberg, MD, PhD
Title: Executive Vice Chancellor for Health Affairs
Date: January 31, 2018

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON
By: [Signature]
Name: 
Title: 
Date: 

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO
By: [Signature]
Name: 
Title: 
Date: 

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER
By: [Signature]
Name: 
Title: 
Date: 

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY
By: [Signature]
Name: 
Title: 
Date: 

THE UNIVERSITY OF TEXAS AT AUSTIN
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By: ________________________________
Name: ______________________________
Title: ______________________________
Date: ______________________________

PHARMACYCLICS LLC
By: ________________________________
Name: Aaron Taylor
Title: Associate Director, Procurement
Date: Jan-10-2018

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON
By: ________________________________
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Name: [Name]
Title: [Title]
Date: [Date]

PHARMACYCLICS LLC
By: [Signature]
Name: Aaron Taylor
Title: Associate Director, Procurement
Date: Jan-10-2018

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON
By: [Signature]
Name: [Name]
Title: [Title]
Date: [Date]

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO
By: [Signature]
Name: Chris G. Green, CP
Title: Director, Office of Sponsored Programs
Date: 23 January 2018

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
By: [Signature]
Name: [Name]
Title: [Title]
Date: [Date]

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY
By: [Signature]
Name: [Name]
Title: [Title]
Date: [Date]

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
By: [Signature]
Name: [Name]
Title: [Title]
Date: [Date]

THE UNIVERSITY OF TEXAS AT AUSTIN
By: [Signature]
Name: [Name]
Title: [Title]
Date: [Date]
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By: [Signature]
Name: 
Title: 
Date: 

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
By: [Signature]
Name: Kathleen M. Kreidler
Title: Assoc. VP, Sponsored Projects
Date: 01/30/2018

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
By: [Signature]
Name: 
Title: 
Date: 

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<td>Name:</td>
<td>Aaron Taylor</td>
</tr>
<tr>
<td>Title:</td>
<td>Associate Director, Procurement</td>
</tr>
<tr>
<td>Date:</td>
<td>Jan-10-2018</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO</th>
<th>THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER</th>
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</thead>
<tbody>
<tr>
<td>By:</td>
<td>By:</td>
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<tr>
<td>By:</td>
<td>By:</td>
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<tr>
<td>Name:</td>
<td>Name: Juan M. Sanchez, Ph.D.</td>
</tr>
<tr>
<td>Title:</td>
<td>Title: Interim Sr. VP for Research &amp; Innovation</td>
</tr>
<tr>
<td>Date:</td>
<td>Date: January 24, 2018</td>
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<tr>
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<td>Date:</td>
<td>Date:</td>
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CONFIDENTIAL
IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives on the dates set forth below and this Agreement shall be effective as of the Effective Date set forth above.

**PHARMACYCLICS LLC**

By: ❇️

Name: Susan Wong

Title: Director, Clinical Operations

Date: Jan-10-2018

**THE UNIVERSITY OF TEXAS SYSTEM FOR THE BENEFIT OF CLINICAL TRIALS XPRESS**

By: ❇️

Name: ❇️

Title: ❇️

Date: ❇️

**THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON**

By: ❇️

Name: ❇️

Title: ❇️

Date: ❇️

**THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO**

By: ❇️

Name: ❇️

Title: ❇️

Date: ❇️

**THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON**

By: ❇️

Name: ❇️

Title: ❇️

Date: ❇️

**THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY**

By: ❇️

Name: ❇️

Title: ❇️

Date: ❇️

**THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER**

By: ❇️

Name: Megan Marks, Ph.D

Title: Asst. VP, Sponsored Programs Administration

Date: 1/30/2018 | 8:54 AM CST

**THE UNIVERSITY OF TEXAS AT AUSTIN**

By: ❇️

Name: ❇️

Title: ❇️

Date: ❇️

CONFIDENTIAL
IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives on the dates set forth below and this Agreement shall be effective as of the Effective Date set forth above.

PHARMACYCLICS LLC

By: [Signature]

Name: Susan Wong

Title: Director, Clinical Operations

Date: Jan-10-2018

THE UNIVERSITY OF TEXAS SYSTEM FOR THE BENEFIT OF CLINICAL TRIALS XPRESS

By: [Signature]

Name: 

Title: 

Date: 

PHARMACYCLICS LLC

By: [Signature]

Name: Aaron Taylor

Title: Associate Director, Procurement

Date: Jan-10-2018

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: [Signature]

Name: 

Title: 

Date: 

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: [Signature]

Name: 

Title: 

Date: 

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT TYLER

By: [Signature]

Name: 

Title: 

Date: 

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: [Signature]

Name: 

Title: 

Date: 

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

By: [Signature]

Name: 

Title: 

Date: 

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By: [Signature]

Name: 

Title: 

Date: 

THE UNIVERSITY OF TEXAS AT AUSTIN

By: [Signature]

Name: Bill Catlett

Title: Director

Date: 24 Jan 18

CONFIDENTIAL
APPENDIX A

Administrative contact person and address for each Institution named in Agreement between Pharmacyclics LLC and the UT System.

<table>
<thead>
<tr>
<th>Institution Name</th>
<th>Contact Person</th>
<th>Title/Position</th>
<th>Current Address</th>
<th>Phone</th>
<th>Fax</th>
<th>Email</th>
<th>Tax ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>The University of Texas at Austin</td>
<td>David Hawkins</td>
<td>Associate Director</td>
<td>Office of Sponsored Projects</td>
<td>P.O. Box 7726 Austin, Texas 78713-7726</td>
<td>512-471-6424</td>
<td>512-471-6564</td>
<td><a href="mailto:dhawkins@austin.utexas.edu">dhawkins@austin.utexas.edu</a></td>
</tr>
<tr>
<td>The University of Texas Southwestern Medical Center</td>
<td>Arriel Stevens</td>
<td>Sponsored Programs Administrator</td>
<td></td>
<td>5323 Harry Hines Blvd. Dallas, TX 75390-9105</td>
<td>214-648-4139</td>
<td>214-648-4474</td>
<td><a href="mailto:arriel.stevens@UTSouthwestern.edu">arriel.stevens@UTSouthwestern.edu</a></td>
</tr>
<tr>
<td>The University of Texas Health Science Center at San Antonio</td>
<td>Mr. Chris G. Green, CPA</td>
<td>Director, Office of Sponsored Programs</td>
<td></td>
<td>7703 Floyd Curl Dr, Mail Code 7828 San Antonio, TX 78229-3900</td>
<td>210-567-2340</td>
<td>210-567-8107</td>
<td><a href="mailto:contracts@uthscsa.edu">contracts@uthscsa.edu</a></td>
</tr>
<tr>
<td>The University of Texas Health Science Center at Houston</td>
<td>Kathleen Kreidler</td>
<td>Director, Contracts</td>
<td></td>
<td>P.O. Box 20036 Houston, TX 77225</td>
<td>713-500-3999</td>
<td>713-500-4939</td>
<td><a href="mailto:Kathleen.kreidler@uth.tmc.edu">Kathleen.kreidler@uth.tmc.edu</a></td>
</tr>
<tr>
<td>The University of Texas Health Science Center at Tyler</td>
<td>David Anderson</td>
<td>Director, Office of Sponsored Programs</td>
<td></td>
<td>11937 U.S. Hwy. 271 Tyler, TX 75708-3154</td>
<td>903-877-7486</td>
<td>903-877-7558</td>
<td><a href="mailto:david.anderson@uthct.edu">david.anderson@uthct.edu</a></td>
</tr>
<tr>
<td>The University of Texas Medical Branch at Galveston</td>
<td>Toni D'Agostino</td>
<td>Associate VP for Research</td>
<td></td>
<td>301 University Boulevard 5.106 W Admin. Building Galveston, TX 77555-0133</td>
<td>409-772-2138</td>
<td>409-266-9469</td>
<td><a href="mailto:todagost@utmb.edu">todagost@utmb.edu</a></td>
</tr>
<tr>
<td>The University of Texas Rio Grande Valley</td>
<td>BethLynn Maxwell, Ph.D., J.D.</td>
<td>Chief Health Research Officer, Office of Health Affairs</td>
<td></td>
<td>210 West 7th Street Austin, TX 78701</td>
<td>512-499-4518</td>
<td>512-499-4523</td>
<td><a href="mailto:bmaxwell@utsystem.edu">bmaxwell@utsystem.edu</a></td>
</tr>
<tr>
<td>The University of Texas System</td>
<td>Glorimar Colon</td>
<td>Research Liaison Officer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><a href="mailto:Glorimar.colon@utrgv.edu">Glorimar.colon@utrgv.edu</a></td>
</tr>
</tbody>
</table>

CONFIDENTIAL

29553_The University of Texas System & Pharmacyclics_2MCSA
OGC # 165622; Five Year Term
EXHIBIT A

STATEMENT OF WORK OR WORK ORDER NO. TEMPLATE

[USE WHEN PRINCIPAL INVESTIGATOR IS AN EMPLOYEE OF INSTITUTION]

This Statement of Work or Work Order No. [###] ("Statement of Work"), effective as of [______] (the "Statement of Work Effective Date") is entered into by and between [Insert Name of UT Campus(es)] ("Institution") and Pharmacyclics LLC ("Pharmacyclics"), and is issued under that certain Second Master Clinical Study Agreement (Pharmacyclics Contract Number 29533) effective as of January 10, 2018 (the "Agreement") by and between Pharmacyclics LLC ("Pharmacyclics") and The University of Texas Health Science Center at Houston; The University of Texas Health Science Center at San Antonio; The University of Texas Health Science Center at Tyler; The University of Texas Medical Branch at Galveston; The University of Texas Southwestern Medical Center; The University of Texas Rio Grande Valley; and The University of Texas at Austin. This Statement of Work includes the terms and conditions of the Agreement, which are hereby incorporated herein by reference.

1. **Protocol**. The Study is to be conducted in relation to the product or products of Pharmacyclics, and/or its Affiliates, and/or collaborators (individually and/or collectively, the “Study Product”) pursuant to Protocol No. [Insert Protocol No.] entitled “[Insert Protocol Title]”, which may be amended from time to time (the “Protocol”), the terms of the Agreement, and this Statement of Work.

2. **Principal Investigator and Medical Monitor**. Pharmacyclics is entering into this Statement of Work with the understanding that [Insert Investigator’s Name] ("Principal Investigator"), an employee of the [Insert Campus], shall be responsible on Institution’s behalf for the conduct of the Study. The Pharmacyclics Medical Monitor is: [Insert Medical Monitor Name], whose address is: Pharmacyclics LLC, 995 E. Arques Avenue, Sunnyvale, CA 94085-4521.

3. **Equipment**. Pharmacyclics will provide Institution with the equipment described in Attachment 2 (Equipment To Be Provided By Pharmacyclics) ("Equipment") in accordance with the terms of the Agreement.

4. **Compensation**. In consideration for Institution’s services hereunder, Pharmacyclics, or CRO, on behalf of Pharmacyclics, shall pay Institution in accordance with the budget attached hereto and incorporated herein as Attachment 1 (Budget Summary and Payment Schedule) (the “Budget”) and with the terms of the Agreement.

   a. **Site Maximum Enrollment**. Institution may enroll up to [______] patients into the Study (the “Site Maximum”). Patient enrollment is expected to be completed on or before [______]. In the event that Pharmacyclics and the Institution wish to enroll more than the Site Maximum, an amendment to the Statement of Work will be made accordingly. No payments shall be made for patients enrolled over the Site Maximum without the written agreement of Pharmacyclics.

   b. **Maximum Compensation**. Institution herein acknowledges and agrees that the total compensation due Institution for full, complete, and satisfactory performance of the Study in accordance with the Protocol and the terms of the Agreement shall in no event exceed the amount set forth in the Budget, inclusive of all associated costs, fees, and charges, including any relevant or applicable overheads due any party, entity, or investigator ("Maximum Compensation").

   c. **Start-Up Fees**. Pharmacyclics or CRO, on behalf of Pharmacyclics, will pay Institution start-up fee payments as set forth in the Budget ("Start-Up Fees"). The Start-Up Fees will be paid by or on behalf of Pharmacyclics to Institution as follows: (i) after full execution of this Statement of Work; (ii) after IRB approval; and (iii) within thirty (30) days of Pharmacyclics’, or CRO’s, on behalf of Pharmacyclics, receipt of the applicable invoice. The foregoing Start-Up Fees will be non-refundable, except in the event of Institution’s uncured breach of the Agreement or this Statement of Work. In such event, if there are any Start-Up Fees which have been made by or

CONFIDENTIAL

29553_The University of Texas System & Pharmacyclics_2MCSA
OGC # 165622; Five Year Term
on behalf of Pharmacyclics, but not yet earned or used by Institution, then Institution will refund such Start-Up Fees within thirty (30) days of receipt of Pharmacyclics’ notice to Institution of Institution’s breach. Subsequent payments will be made within thirty (30) days of the end of each calendar quarter as applicable, upon Pharmacyclics’ receipt of the completed CRFs for such quarter.

(d) **Invoiceables.** Neither Pharmacyclics nor CRO shall be obligated to reimburse Institution for services or expenses that are invoiced more than sixty (60) days after the completion of the applicable services, or incurrence of the applicable expenses, hereunder.

(e) **Patient Fees.** Pharmacyclics or CRO, on behalf of Pharmacyclics, may withhold **ten percent (10%)** of the patient fees portion of the Maximum Compensation pending resolution of all data queries and completion of the Study closeout procedures. Final payment of any outstanding amounts due under this Statement of Work will be made following the completion of Study closeout procedures.

(f) **Invoices.** Institution shall send invoices to ______ as follows: Invoices may be sent by email to: ____________________.

(g) **Key Payment Terms.** As set forth in **Section 8** of the Agreement:

(i) overhead charged to Pharmacyclics for the Study shall not exceed the percentage amount stated in the Budget;

(ii) neither Pharmacyclics nor CRO, on behalf of Pharmacyclics, shall be responsible for paying for services performed in violation of the Protocol or for data contained in a CRF which is incomplete or inaccurate. If Pharmacyclics, or CRO, on behalf of Pharmacyclics, has previously paid for such services, the overpayment shall be deducted from the Final Payment, as described in **Section 8(e)** of the Agreement; and

(iii) in the event of a termination of a Statement of Work, Pharmacyclics shall not be obligated to reimburse Institution for expenses that are invoiced to Pharmacyclics more than one hundred eighty (180) days after the termination date of the Statement of Work.

(h) **Payee.** The name and address of the payee for all payments due to Institution hereunder is:

Payable to: ______________________

Tax ID Number of the payee: ______________________

**Check Payment Information:**

-----------------------------------------------------------

**Wire Transfer Information:**

-----------------------------------------------------------

Contact Name: ______________________

Email Address: ______________________

Phone Number: ______________________

CONFIDENTIAL
(i) **Timelines for Completed CRFs.** As set forth in **Section 4(g) of the Agreement,** all completed CRFs must be entered in the electronic data capture system within **ten (10) business days** of each visit and within **ten (10) business days** of each follow-up visit; and **within ten (10) business days** of the completion of the Study subject's participation in a Study and receipt of Study subject's test results, if any, but in no event later than the Study completion date. Any requests by or on behalf of Pharmacyclics for verification, clarification or correction of data on CRFs must be responded to within **ten (10) business days** of Institution’s receipt of such request.

5. **Study Term.** This Statement of Work shall be effective upon the Statement of Work Effective Date and shall terminate on the earliest of: (i) **one (1) year from the Statement of Work Effective Date,** if there is no Study subject enrollment at Institution under this Statement of Work; (ii) upon completion of the Study at Institution, if there is Study subject enrollment at Institution under this Statement of Work; or (iii) **[Insert number of years of Study + 1 buffer year]** years from the Statement of Work Effective Date (the "**Study Term**"), unless terminated earlier pursuant to the terms of the Agreement. All contractual and regulatory documentation must be completed, executed and received by Pharmacyclics prior to Study initiation.

6. **Notices.**

(a) Routine communications regarding the conduct of the Study shall be sent to the Pharmacyclics individual identified by Pharmacyclics to Institution as the primary contact for the Study ("**Pharmacyclics Study Contact**").

(b) Communications related to the replacement of the individuals identified on FDA Form 1572 shall be made by email, mail, or recognized national or international courier and shall be sent to the appropriate Pharmacyclics Study Contact at Pharmacyclics LLC, 995 E. Arques Avenue, Sunnyvale CA 94085-4521.

(c) All notices under this Statement of Work shall be in writing, refer to this Statement of Work, and be sent by recognized national or international overnight courier or registered or certified mail, postage prepaid, return receipt requested, or delivered by hand to the notice address(es) set forth below.

<table>
<thead>
<tr>
<th>If to Institution:</th>
<th>If to Principal Investigator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>See Appendix A to the Agreement for the name and address of an administrative contact for each Institution and insert in applicable Statement of Work.</td>
<td>Insert Name</td>
</tr>
<tr>
<td></td>
<td>Insert Title</td>
</tr>
<tr>
<td></td>
<td>Insert Address</td>
</tr>
<tr>
<td></td>
<td>Insert City, State Zip</td>
</tr>
</tbody>
</table>

**With a copy to:**
The University of Texas System
Office of General Counsel
210 West 7th Street
Austin, TX 78701
ATTN: OGC Intellectual Property General Counsel and IP Legal Expert

<table>
<thead>
<tr>
<th>If to Pharmacyclics Study Contact:</th>
<th>If to Pharmacyclics (legal notices)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Development Pharmacyclics LLC 995 E. Arques Avenue Sunnyvale, CA 94085-4521</td>
<td>Head of Legal Pharmacyclics LLC 995 E. Arques Avenue Sunnyvale, CA 94085-4521</td>
</tr>
</tbody>
</table>

Notices under this Statement of Work shall be deemed to be duly given: (i) when delivered by hand; (ii) two (2) days after deposit with a recognized national or international courier; or (ii) on the delivery date indicated in the return receipt for registered or certified mail. A party may change
its notice address immediately by sending written notice to the other party’s legal notice address as set forth in this Section 6 of this Statement of Work.

7. **Counterparts.** This Statement of Work may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature, either handwritten or digital, or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Statement of Work. The parties may use DocuSign, or other comparable web-based signature programs, to circulate and execute this Statement of Work.

8. **Entire Agreement.** This Statement of Work including, without limitation, all Exhibits, Appendices, and Attachments hereto and the Agreement contain the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. In the event of a conflict between the provisions of the Protocol and the terms and provisions of this Statement of Work or any Exhibits, Appendices, or Attachments hereto, the Protocol shall control with respect to matters of science, medical practice and Study subject safety. In all other matters, the terms and provisions of this Statement of Work shall control. In the event of any conflict between the terms and provision of this Statement of Work and those of the Agreement, the terms and provisions of the Agreement shall control, unless this Statement of Work specifically acknowledges the conflict and expressly states that the conflicting term or provision found in this Statement of Work controls for this Statement of Work only. This Statement of Work may be modified only by written agreement signed by the parties to this Statement of Work.

[Remainder of page intentionally left blank; signature page follows.]
IN WITNESS WHEREOF, the parties have caused this Statement of Work to be executed by their duly authorized representatives on the dates set forth below and this Statement of Work shall be effective as of the Statement of Work Effective Date set forth above.

PHARMACYCLICS LLC

By: DRAFT – NOT FOR SIGNATURE
Name: ___________________________
Title: ___________________________
Date: ___________________________

PHARMACYCLICS LLC

I have read the Agreement and this Statement of Work and acknowledge the obligations under the provisions of the Agreement and this Statement of Work.

By: DRAFT – NOT FOR SIGNATURE
Name: ___________________________
Title: ___________________________
Date: ___________________________

By: DRAFT – NOT FOR SIGNATURE
Name: ___________________________
Title: Principal Investigator
Date: ___________________________
ATTACHMENT 1 TO STATEMENT OF WORK
BUDGET SUMMARY AND PAYMENT SCHEDULE

(See accompanying attachment)
# ATTACHMENT 2 TO STATEMENT OF WORK

## EQUIPMENT TO BE PROVIDED BY PHARMACYCLICS

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<thead>
<tr>
<th>Manufacturer</th>
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<th>Basic Description</th>
<th>Replacement Value</th>
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