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Investigator Initiated Research Study Agreement

This Investigator Initiated Research Study Agreement ("**Agreement**"), effective as of the last date of signature ("**Effective Date**"), is by and between Veloxis Pharmaceuticals, Inc., a Delaware corporation, with offices located at 1001 Winstead Drive Suite 310, Cary, NC 27513 ("**Veloxis**") and Temple University – Of The Commonwealth System Of Higher Education with a place of business located at 3401 N Broad St, Philadelphia, PA 19140 ("**Institution**"), on behalf of its employees Adam Diamond, PharmD and Antonio Di Carlo, MD (collectively referred to as "**Principal Investigator**")

WHEREAS, Veloxis is a commercial pharmaceutical company with an interest in the research development, manufacture and sale of pharmaceutical products;

WHEREAS, Institution is engaged in research in the area(s);

WHEREAS, Institution and Principal Investigator intend to initiate a study entitled "Dosing strategies for de novo once-daily extended release tacrolimus (LCPT) in African American kidney transplant recipients." (the "**Study**"); and

WHEREAS, Veloxis wishes to support Institution and the Principal Investigator in the conduct of the Study.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Scope of Agreement. This agreement establishes the general terms and conditions for Veloxis support of the investigator initiated research study specified above.

2. Principal Investigator.

2.1 The Principal Investigator shall be responsible for the conduct, supervision and management of the Study in accordance with applicable Law.

2.2 The Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff only to the extent permitted by any applicable statute, law, ordinance, regulation, rule, code, order, constitution, treaty, common law, judgment, decree, other requirement or rule of law of any federal, state, local or foreign government or political subdivision thereof, or any arbitrator, court or tribunal of competent jurisdiction ("**Law**"). If the Principal Investigator is not qualified to prescribe drugs (e.g., a Principal Investigator who is a PhD or PharmD), the Principal Investigator will ensure oversight of drug administration and subject safety by a medically qualified sub-investigator.

2.3 Investigator will provide Veloxis quarterly enrollment status, beginning one (1) month from the enrollment of the first patient/subject. Quarterly enrollment to include the total number of patient/subjects enrolled and general demographic information. Investigator will provide Veloxis with quarterly safety review; to include all adverse and serious adverse events regardless of relationship to test article, and to include start/stop date, relationship to test article, severity of event, and outcome until such time as the study is concluded and the final study report/manuscript is completed.

2.4 Institution will ensure that the Principal Investigator complies with the terms of this Agreement and Institution's policies and procedures in the conduct of the Study, including any applicable financial policies. Institution will notify Veloxis promptly of any conflict between the terms of this Agreement and any such policy or procedure. In the event of a conflict, the parties will negotiate in good faith to reach an appropriate accommodation.

3. Study Protocol.

3.1 The Study shall be conducted in accordance with the written protocol developed by the Principal Investigator (the "**Protocol**"), attached hereto as Exhibit A.

3.2 If the Principal Investigator modifies the Protocol in any material way that affects: (a) the administration or use of Veloxis Product (e.g., dosage or duration of treatment), (b) the objectives of the Study or (c) in case of interventional studies, potential risks to Study subjects, the Principal Investigator will promptly inform Veloxis in writing. Continued support by Veloxis will be contingent on Veloxis's and the IRB's review and acceptance of such protocol modifications.

4. Conduct of the Study.

4.1 Sponsorship. Institution, not Veloxis, will be the sponsor of the Study. Neither Institution nor Principal Investigator will represent to any third party, including Study subjects, that Veloxis is sponsoring the Study.

4.2 Regulatory. Institution and Principal Investigator will be solely responsible for any and all safety reporting and regulatory obligations associated with the conduct of the Study, including, but not limited to, obtaining and maintaining an Investigational New Drug application, as well as promptly notifying Veloxis of any safety reporting involving the use of any Veloxis product.

4.3 Applicable Standards. The Principal Investigator shall conduct the Study in accordance with the Protocol and all applicable Laws. For clinical studies, this includes compliance with International Conference on Harmonization Good Clinical Practices guidelines as adopted by the FDA.

4.4 IRB Approval. Institution shall ensure that the Study is approved by and subject to continuing oversight by an appropriate Institutional Review Board ("**IRB**").

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4.5 Informed Consent. Principal Investigator shall obtain informed consent for each subject in accordance with applicable Law and will inform Study subjects that Veloxis is providing support for the Study. Veloxis has no obligation to participate in the development of, or to review or comment on, the informed consent form.

4.6 No Monitoring or Data Collection. Veloxis will not monitor the conduct of the Study with the exception of quarterly reports as detailed in Section 2.3 of this agreement. Veloxis will not receive any subject-level data from the Study except for certain adverse event reports from clinical studies involving a Veloxis product.

4.7 Risk Reporting. If the Study is an ongoing clinical study involving a Veloxis product, Veloxis will notify Institution of any unexpected Serious Adverse Event (as defined below) report associated with such Veloxis product from clinical studies or other sources that results in a change to the benefit/risk profile of the Veloxis product.

4.8 Adverse Event Reporting:

(a) Reporting of Serious Adverse Events. Within 24 hours of first awareness of the event (immediately if the event is fatal or life-threatening), Principal Investigator will report to Veloxis by facsimile certain Serious Adverse Events ("**SAEs**," as defined below) that occur during the SAE reporting period (as defined below) in a Study subject assigned to receive the Veloxis Product. The subset of SAEs to be reported for this Study are those that fit into either of the following categories: (1) a death, regardless of whether it is considered related to treatment with the Veloxis Product, or (2) an SAE that is assessed by the Principal Investigator as both related to treatment with the Veloxis Product and unexpected for that Product. An event should be considered "related" to the Veloxis Product if a relationship is at least a reasonable possibility, and "unexpectedness" should be based upon current Product labeling. Principal Investigator will report such SAEs using either Institution's Internal Adverse Event Report form or an FDA MEDWATCH form together with the *Veloxis-UBC SAE Reporting Form v1.0* provided by Veloxis. SAEs should be reported as soon as they are determined to meet the definition, even if complete information is not yet available.

(i) SAE Definition. An SAE is any adverse event that is life-threatening or that results in any of the following outcomes: death; in-patient hospitalization or prolongation of existing hospitalization; persistent or significant disability or incapacity; or a congenital anomaly or birth defect. Any other medical event that, in the medical judgment of the Principal Investigator, may jeopardize the subject or may require medical or surgical intervention to prevent one of the outcomes listed

above is also considered an SAE. A planned medical or surgical procedure is not, in itself, an SAE. Also specifically excluded from this definition of SAE is any event judged by the Principal Investigator to represent progression of the malignancy under study, unless it results in death within the SAE Reporting Period.

(ii) SAE Reporting Period. The SAEs that are subject to this reporting provision are those that occur from after the first dose of the Veloxis Product through 72 hours after discontinuation of the Veloxis Product. In addition, any and all related SAEs that occur after the reporting period of which the Principal Investigator becomes aware should also be reported.

(iii) Follow-Up Information. Institution will assist Veloxis in investigating any SAE and will provide any follow-up information reasonably requested by Veloxis.

(b) Regulatory Reporting. Reporting an SAE to Veloxis does not relieve Institution of responsibility for reporting it to FDA, as required.

(c) Veloxis-Provided Training. Veloxis will make available training material that provides information about the SAE reporting requirements for the Study. Principal Investigator will review this material and share it with any Study staff engaged in the reporting of SAEs.

(d) Study Subject Safety. To the extent required by applicable law, rule or regulation, Veloxis agrees to notify Institution of any findings of which Veloxis becomes aware, including any results arising from a Study, which may affect the safety of the Study subjects or their willingness to continue as Study subjects, alter the risk/benefit ratio of a Study, alter the conduct of a Study, involve a present or imminent danger or health risk to the public or patients (including the Study subjects) or otherwise affect the IRB's approval to continue a Study, including copies of any data safety monitoring reports related to the Study. Upon receipt of any findings from Veloxis contemplated by this Section 4.8(d), the Principal Investigator shall review such findings with Institution's IRB and Principal Investigator and the IRB shall determine whether such findings should be communicated to past and/or present Study subjects in accordance with IRB policy. In the event the Principal Investigator and the IRB determine that such findings should be communicated to the Study subjects, the findings

may be communicated to the Study subjects to the extent deemed necessary.

(e) In the event of a research related injury, Institution will arrange care for the Study subject. Institution agrees Veloxis will not be responsible for costs, expenses and/or damages due to a research related injury(ies).

4.9 Protected Health Information. Data collected in the Study may include Protected Health Information ("PHI") as that term is defined in the Privacy Rule enacted pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA Privacy Rule"). Institution will comply with the HIPAA Privacy Rule in its conduct and reporting of a Study. Veloxis does not request any subject-level data that could include PHI from clinical Studies that it supports with the IIS agreement. However, should Veloxis ever gain access to Study data that includes PHI, Veloxis will take appropriate measures to protect the confidentiality and security of that PHI in compliance with HIPAA. Veloxis acknowledges that Institution is a patient care facility and considered a covered entity under HIPAA. As a patient care facility and covered entity, Institution must protect and secure patient care areas as well as PHI. Veloxis and its agents hereby acknowledge that they will be asked to comply with Institution's security policies and procedures in order to access any Study facilities and records and that failure to follow such policies and procedures may result in a denial of such access. In the event Veloxis or its agents come into contact or otherwise have access to a Study subject's medical records or any PHI, then Veloxis shall ensure such information and the identity of such Study subject is held in confidence and treated in accordance with all applicable laws and regulations as well as the HIPAA Authorization provided by the subject. Veloxis shall only have access to that portion of the Study subject's medical record that is directly related to the Study. If Veloxis or its agents gain access to medical records and PHI of a patient not participating in the Study, Veloxis shall ensure that such information and the identity of such patient is held in confidence. Veloxis shall also ensure that if any records containing such information are removed from Institution's facilities, such records will be immediately returned to Institution.

5. Veloxis Support.

5.1 Basis of Support. Veloxis may support the Study by providing money and/or Veloxis product to Institution. Support of the Study is not conditioned on any pre-existing or future clinical research or business relationship between Institution, Principal Investigator or Veloxis. Support is also not conditioned on any clinical research, business relationship, or other decision the Principal Investigator or Institution has made, or may make relating to Veloxis or Veloxis products.

5.2 Funding. Except as otherwise expressly provided in this Agreement, in consideration of Institution's performance of its obligations hereunder with respect to the

Study, Sponsor will pay to Institution $55,096 according to the schedule and terms set forth below:

Payment schedule:

(A) Initial Milestone payment of 75% of budget ($41,322) payable 60 days following execution of this Agreement, and approval from the IRB and Regulatory authorities;

(B) Final milestone payment of 25% of budget ($13,774) payable 60 days following receipt of the Study Report/manuscript by Veloxis no more than 6 months following termination of the study.

5.3 Use of Funds. The Principal Investigator and Institution will use any funds received pursuant to this Agreement ("**Veloxis Funds**") solely for the purposes of the Study. If the Study is a prospective clinical trial, Institution and Principal Investigator will not use Veloxis Funds to pay physicians for referring potential subjects for enrollment in the Study. At the completion of the Study, Principal Investigator will confirm in writing that Veloxis funds have been used only to support the Study, by certifying the same in writing upon completion of the Study.

6.0 Study Close Out. In the event this Agreement is terminated prior to completion of the Study, for any reason, Institution shall: (a) notify the IRB that the Study has been terminated; (b) immediately cease enrolling subjects in the Study; and (c) terminate, as soon as practicable, all other Study activities. In the event of early termination, in accordance with Section 15.3, the Institution shall be reimbursed for all work completed, on a pro-rata basis, and for non-cancelable commitments properly incurred through that date.

7. Product Support.

7.1 Veloxis Product. If the Study involves the use of Veloxis product, Veloxis may choose to provide, free of charge, sufficient supplies of such product ("**Veloxis Product**") to conduct the Study as specified below:

Veloxis Product will not be supplied as part of this agreement

If Veloxis Product is provided for a Study, Veloxis represents and warrants that such product has been manufactured in accordance with US current Good Manufacturing Practices ("**cGMPs**").

7.2 Custody and Dispensing. Not applicable

7.3 Destruction of Expired, Returned, or Unused Supplies. Not applicable

7.4 Ownership and Permitted Use. Except for, and limited to, the use specified in the Protocol for the applicable Study, Veloxis grants Principal Investigator or Institution no express or implied intellectual property rights in the Veloxis Product or in any methods of making or using the Veloxis Product. Principal Investigator will use the Veloxis Product only as specified in the Protocol for the applicable Study. Any other use of the Veloxis Product shall constitute a material breach of this Agreement.

8. Study Data. "Study Data" shall mean all data and information generated by Institution as a result of conducting the Study in accordance with the IRB approved Protocol. Institution shall own the Study Data. Data does not include original Study subject or patient medical records, research notebooks, source documents, or other routine internal documents kept in the Institution's ordinary course of business operations, which shall remain the sole and exclusive property of the Institution or medical provider. Principal Investigator and Institution are free to publish the results of the Study ("**Study Data**"), subject to the provisions in Section 9 (Publications), and to use Study Data generated from the Study for their own research and educational purposes and programs and in accordance with the informed consent form and HIPAA authorization. Institution, however, will not use or permit others to use non-public or unpublished raw Study Data from any Study that involves the use of a Veloxis Product for the commercial benefit of any third party.

9. Study Report. Within six months after completion or termination of the Study, whichever occurs first, Principal Investigator will provide Veloxis with a written report of the Study results ("**Study Report**"). The Study Report may take the form of a manuscript for publication. If a Study is terminated early, the Study Report should include, at minimum, the results of the Study Data up until the date of termination.

9.1 Right of First Publication. Institution and Principal Investigator will have the first opportunity to publish the results of the Study and the Study Data subject to Section 7 above. Consequently, Veloxis will not, and will ensure that its affiliates, research collaborators, employees, agents, and representatives do not make any public presentation of the results, Study Report, Study Data or other Study information provided by Institution and Principal Investigator until the earlier of: (i) 12 months following completion of the Study; or (ii) the results or information have been publicly disclosed by Institution or the Principal Investigator (as permitted under Section 9 of this Agreement).

(a) Request for Earlier Disclosure. If Veloxis wishes to disclose results or other Study information, Study Data or parts or all of the Study Report earlier than indicated above, Veloxis may submit a request to Institution in writing. Institution will consider any such request in good faith. Any such request must identify the results or other Study information, Study Data or parts of the Study Report that Veloxis wishes to disclose and how and where it would be disclosed.

(b) Acknowledgment by Veloxis. In any publication by Veloxis of the results of the Study, Veloxis will acknowledge the roles and efforts of Institution and Principal Investigator in the Study.

10. Publications.

10.1 Institution and Principal Investigator shall have publication privileges subject to the provisions of section 8 and provided that such manuscript and/or abstract does not disclose Confidential Information as described in Section 10, and ensure against inadvertent disclosure of unprotected Inventions that relate to a Veloxis Product (see Section 11, Intellectual Property) hereof, other than the results of the Study, and provided that such manuscript and/or abstract is submitted to Veloxis for review and comment thirty (30) days prior to submission or other public disclosure.

10.2 Institution and Principal Investigator further agree to delete information identified by Veloxis as Confidential Information, except Institution's Study results, prior to submitting such manuscript and/or abstract for publication or, alternatively, defer publication of such manuscript and/or abstract for an additional period of time, not to exceed sixty (60) days at the request of Veloxis, to permit the filing of any desired patent applications by Veloxis. Veloxis shall also have the right to publish the study subject to the terms of Section 8.

10.3 Standards. Institution and Principal Investigator will comply with recognized ethical standards concerning publications and authorship, including the *Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (located at* http://www.icmje.org/recommendations/) established by the International Committee of Medical Journal Editors.

10.4 Unapproved Ad-hoc Analysis. This section intentionally left blank

10.5 Disclosure of Support. Institution and Principal Investigator will disclose Veloxis support of the Study in any publication of Study results.

11. Confidential Information

11.1 Definition. "**Veloxis Confidential Information**" shall mean all proprietary or non-public information (including financial information), ideas, concepts, data, data compilations, research, reports, protocols, techniques, methods, processes, plans, strategies, know-how, materials and documents which, by appropriate marking, are identified as confidential and proprietary at the time of disclosure, or if disclosed orally, are identified in a marked writing within thirty (30) days as being confidential and disclosed to the Institution by Veloxis for the purpose of conducting the Study. Veloxis will make reasonable efforts to mark Confidential Information as described above. However, if in the absence of written markings, the information disclosed is such that a

reasonable person familiar with the Study would consider it to be confidential or proprietary from the context or circumstances of disclosure it shall be deemed as such. Notwithstanding the foregoing, Study Data and results generated in the course of conducting the Study are not the Confidential Information of Veloxis. Institution agrees, for a period of five (5) years following the termination or expiration of this Agreement, to use reasonable efforts, no less than the protection given to their own Confidential Information, to use Veloxis Confidential Information in accordance with this Section 10.

11.2 "**Institution Confidential Information**" shall mean all proprietary or non-public information (including financial information), ideas, concepts, data, data compilations, research, reports, protocols, techniques, methods, processes, plans, strategies, know-how, materials and documents, including the Study Data and results, which, by appropriate marking, are identified as confidential and proprietary at the time of disclosure, or if disclosed orally, are identified in a marked writing within thirty (30) days as being confidential and disclosed to Veloxis by Institution for the purpose of conducting the Study. Institution will make reasonable efforts to mark Confidential Information as described above. However, if in the absence of written markings, the information disclosed is such that a reasonable person familiar with the Study would consider it to be confidential or proprietary from the context or circumstances of disclosure it shall be deemed as such. Veloxis agrees, for a period of five (5) years following the termination or expiration of this Agreement, to use reasonable efforts, no less than the protection given to their own Confidential Information, to use Institution Confidential Information in accordance with this Section 10.

11.3 The obligations of nondisclosure above do not apply with respect to either Party's Confidential Information that:

(i) is or becomes public knowledge (through no fault of the receiving Party);

(ii) is lawfully made available to receiving Party by an independent third party owing no obligation of confidentiality to the disclosing Party with regard thereto (and such lawful right can be properly demonstrated by the receiving Party through contemporaneous written record);

(iii) is already in the receiving Party's possession at the time of receipt (and such prior possession can be properly demonstrated by the receiving Party through contemporaneous written record);or

(iv) which was independently developed by the receiving Party (and such independent development can be properly demonstrated by receiving Party through contemporaneous written record).

11.4 The Receiving party may disclose Confidential Information to the extent it is required by law, regulation, rule, act or order of any governmental authority or agency; provided, however, that to the extent permitted by law, the receiving Party agrees to promptly notify the disclosing Party in writing of such legally mandated disclosure promptly after receipt of such legally mandated disclosure and to provide the disclosing Party with an opportunity to seek an appropriate protective order to prevent such disclosure.

11.5 Subject to applicable federal, state or local legal and regulatory requirements, the receiving Party agrees to promptly return to the disclosing Party, upon its request all Confidential Information obtained from the disclosing Party or belonging to the disclosing Party pursuant to this Agreement; provided, however, that receiving Party may retain one (1) copy of Confidential Information in a secure location for purposes of identifying receiving Party's obligations under these confidentiality provisions.

11.6 Unless the disclosing Party provides prior written consent, the receiving Party may not use the disclosing Party's Confidential Information for any purpose except to conduct the Study, nor may the receiving Party disclose the disclosing Party's Confidential Information to any third party (other than its employees and agents involved in the Study, who need to know such information and are subject to obligations of confidentiality and non-use no less stringent than those contained herein) except as authorized in this Agreement or as required by Law (including FDA regulations). Disclosure of Confidential Information is specifically authorized in the following circumstances:

(i) Required disclosure of Veloxis Confidential Information to the IRB or to FDA representatives.

(ii) If necessary in order to seek or enforce a patent, provided, however, that Institution will disclose Veloxis Confidential Information only to the extent necessary and will make reasonable efforts to limit public disclosure by seeking a protective order or other appropriate protection with respect to such disclosure.

(iii) If necessary in order to obtain consent from patients or subjects who may wish to enroll in a Study, but the information will be disclosed only to the extent necessary and Veloxis Confidential Information will not be provided in answer to unsolicited inquiries by telephone or to individuals who are not eligible Study candidates.

(iv) If necessary to adequately inform a Study subject of a potential risk with regard to the subject's safety and wellbeing.

11.7 Disclosure Required by Law. Notwithstanding any other provision of this Agreement, Institution may disclose Veloxis Confidential Information to the extent required by Law. If disclosure of Veloxis Confidential Information other than as expressly permitted under this Agreement to any party other than the FDA or IRB is required by law, Institution will:

(i)notify Veloxis in writing as far as possible in advance of the disclosure so as to allow Veloxis to take legal action to protect its Veloxis Confidential Information;

(ii) disclose only that Veloxis Confidential Information required to comply with the legal requirement; and

(iii) continue to maintain the confidentiality of the Veloxis Confidential Information with respect to all other third parties.

12. Intellectual Property. Without compromising Veloxis's rights in Section 12.2, all documents, Confidential Information and materials provided to the Institution and/or the Principal Investigator pursuant to this Agreement are and shall remain Veloxis property.

12.1This section intentionally left blank.

12.2 Inventions and discoveries arising from Institution's performance of the Study that are conceived and reduced to practice solely by Institution's employees or agents, shall be the sole and exclusive property of Institution ("Institution Inventions"). Institution shall offer Veloxis the first right to obtain an exclusive, world-wide license subject to Subsection E below. Inventions made jointly by employees or agents of Veloxis and Institution shall be the joint property of Veloxis and Institution ("Joint Inventions").

12.3 Institution and Veloxis shall notify the other of all Joint Inventions made in the course of carrying out the Study. If Veloxis requests, and at Veloxis's sole expense, Institution will file patent applications to any such Institution Invention, and will provide Veloxis reasonable assistance in obtaining patents to any such Joint Inventions, including executing any invention document.

12.4 Institution will offer Veloxis a time-limited first-option to enter into an exclusive, world-wide royalty-bearing license for commercial purposes, including the right to grant sublicenses, to Institution Inventions and to Institution's entire right, title and interest in and to all Joint Inventions. Veloxis will have sixty (60) days following receipt of the option offer to advise Institution, in writing, of its interest in obtaining an exclusive license to any Institution Invention or Joint Invention. Any such exclusive license will be negotiated in good faith by the Parties for an additional 120 days and will include a reasonable royalty and other terms typical in licenses of similar technology. In the event that Veloxis fails to exercise its option within said 120 day option period, or the Parties

fail to reach mutual agreement as to the terms of a license within said 120 day negotiation period, Institution will be free to license said inventions and/or discoveries of Institution in accordance with Institution's policy and practice.

12.5 Ownership. It is expressly agreed that this Agreement does not transfer to either Party any intellectual property, patent right, copyright, or other proprietary right, whether or not protected by patent or other intellectual property right, the other Party owns as the effective date of this Agreement, except as specifically set forth herein.

12.6 Disclosure. Institution shall promptly disclose to Veloxis, in writing, any Inventions.

12.7 Institution shall ensure that all individuals working on the study, including the Investigator, have assigned to the Institution or have a legal obligation to the Institution to assign all their rights to Inventions.

12.8 Assignment and Delegation. Parties may not assign its rights or delegate or subcontract any duties under this Agreement or any Study Order without prior written consent of other Party. Any attempt to so assign, delegate, or subcontract is invalid. Notwithstanding the foregoing, Veloxis may assign this Agreement, without the prior consent of Institution, to an affiliated company or to a successor of substantially all of Veloxis's business interests by a merger, acquisition or transfer of assets, provided that Veloxis promptly notifies Institution of the new transferee, including contact details for the person(s) in the transferee organization responsible for administering Veloxis's obligations under this Agreement. In the event Veloxis assigns this agreement to an entity that has not purchased substantially all of the business assets or stock of Veloxis, Veloxis shall remain liable to Institution for all of the obligations under this Agreement.

13. Indemnification. The Study for which Veloxis provides support are not designed, sponsored, or managed by Veloxis, and Veloxis provides no indemnification for Study conduct. However, Veloxis shall indemnify, defend and hold Institution, its affiliates, and their respective Regents, Institutions, Principal Investigators, directors, officers, agents, and employees, including the IRB (collectively, "**Indemnified Parties**") harmless from any liability, claims, lawsuits, actions, demands, losses, costs and expenses (including reasonable attorneys' fees and costs) arising from or relating to Veloxis's use of the results from the Study, Study data, the Study Reports or other Study information provided to Veloxis. In addition, Veloxis will indemnify, defend and hold harmless the Indemnified Parties from any losses (including reasonable attorneys' fees and costs of defense) from claims that arise from or relate to defects in the manufacture of the Veloxis Product, except to the extent that the losses result from (a) failure to use the Veloxis Product in accordance with the Protocol, (b) negligence or willful misconduct on Indemnified Parties' part, or (c) a breach of any applicable law or regulation by any Indemnified Party.

13.1 Institution shall promptly notify Veloxis of any such claim relating to any loss subject to this indemnification, and will reasonably cooperate with Veloxis in the defense of the claim. The obligation to indemnify shall not be limited by late notice of any claim unless such notice prejudices Veloxis's ability to properly defend against such a claim. Veloxis shall not enter into any settlement or admit fault or liability on behalf of any Indemnitee without the prior written consent of Institution, which shall not be unreasonably withheld or delayed.

14. Insurance. Institution shall, at its sole cost and expense, procure and maintain comprehensive general liability insurance in amounts not less than $1,000,000 per incident and $3,000,000 annual aggregate. Institution shall also maintain professional liability insurance on behalf of itself and the Principal Investigator in amounts as required under current Pennsylvania law. Veloxis warrants that it maintains a policy or program of insurance or self-insurance for no less than $1,000,000 for each occurrence of bodily injury, personal injury or death and $3,000,000 in the aggregate.

15. Term and Termination.

15.1 Term of Agreement. This Agreement will remain in effect until 31 May 2022.

15.2 Extensions to Agreement. This Agreement may only be extended by mutual agreement of the Parties. Any extension will be executed as a written Amendment to this Agreement.

15.3 Early Termination of Agreement. This Agreement may be terminated early:

(a) By thirty (30) days advance written notice by either party for any reason; or

(b) by notification from either party of a material uncured breach by the other party. The party alleging breach must first provide notice that specifically identifies the breach and must provide the breaching party thirty (30) days to cure the breach.

15.4 Survival. All provisions of this Agreement that by their terms require performance by one or both parties following expiration or termination of this Agreement shall survive such expiration or termination. Such provisions shall include, but not be limited to, sections 4.8(e), 4.9, 9, 10, 11, 13, 14, 16, 20, 23 and 24.

16. Modifications. Any modification to this Agreement must be in writing, signed by both parties, and identified as an 'Amendment' to this Agreement.

17. Debarment and Exclusion. Institution represents that it is not debarred under subsections 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act and that is has not and will not use in any capacity the services of any person debarred under such law with

respect to services to be performed under this Agreement. Institution also represents that it is not excluded from any federal health care program, including but not limited to Medicare and Medicaid. Institution or Principal Investigator will notify Veloxis immediately if either of these representations needs to be amended in light of new information.

18. Entire Agreement and Counterparts. This Agreement and its Attachments constitute the entire agreement between the Parties with respect to subject matter. This Agreement may be executed and delivered in one or more counterparts, each of which when executed and delivered shall be deemed to be an original but all of which when taken together shall constitute one and the same Agreement.

19. Conflict with Attachments. If there is any conflict between this Agreement and any Attachments to it, or between the Agreement and the Protocol, the terms the Protocol shall govern and control with respect to all clinical or medical matters, and the terms of this Agreement shall govern and control with respect to all other matters.

20. WARRANTY DISCLAIMER. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, VELOXIS DISCLAIMS ALL WARRANTIES OF ANY KIND, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, SAFETY, NON-TOXICITY, EFFICACY, ABSENCE OF ERRORS, ACCURACY, COMPLETENESS OF RESULTS, THE PROSPECTS OR LIKELIHOOD OF SUCCESS (FINANCIAL, REGULATORY OR OTHERWISE) OF THE STUDY.

21. Relationship of the Parties. The relationship between the parties is that of independent contractors. Nothing contained in this Agreement shall be construed as creating any agency, partnership, joint venture or other form of joint enterprise, employment or fiduciary relationship between the parties, and neither party shall have authority to contract for or bind the other party in any manner whatsoever.

22. Notices. Any notice required or permitted hereunder shall have binding legal effect only if in writing and addressed to a Party in accordance with this Section. Any notice shall be deemed given as of the date it is (i) delivered by hand or (ii) received by Registered or Certified Mail, postage prepaid, return receipt requested, or received by facsimile and addressed to the Party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

If to Veloxis:

Veloxis Pharmaceuticals, Inc.
1001 Winstead Drive Suite 310
Cary, NC 27513
Facsimile: (919) 678-8026

E-mail: DRS@veloxis.com

Attention: Daniel R. Stevens,
Director, Medical Affairs

With a copy to:

Veloxis Pharmaceuticals, Inc.
1001 Winstead Drive Suite 310
Cary, NC 27513

Attention: Legal

If to Temple University :

Temple University
Temple University Clinical Research Institute
3440 N. Broad Street, Kresge Hall East Room 229
Philadelphia, PA 19140
Attention: Director, Clinical Research Administration

With a copy to :

Adam Diamond, PharmD, BCPS
Temple University Hospital
Adam.Diamond@tuhs.temple.edu
3401 N. Broad Street
Philadelphia, PA 19140

With a copy to:

Temple University Health System, Inc.
Office of Counsel
Attn: Chief Counsel
2450 W. Hunting Park Ave. 4th Floor
Philadelphia, PA 19129

23. Force Majeure. Noncompliance by either Party with the obligations of this Agreement due to circumstances reasonably beyond such Party's control, including, without limitation, labor disturbances or labor disputes of any kind, failure of any governmental approval required for full performance, civil disorders or commotions, acts

of aggression, acts of terrorism, acts of God, energy or other conservation measures imposed by law or regulation, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, accidents, fire, failure of transportation, or any similar cause beyond the reasonable control of either Party, shall not constitute a breach of this Agreement. Such Party shall be excused from performance hereunder to the extent and for the duration such force majeure event persists, provided it first notifies the other Party in writing of such force majeure event.

24. Use of Name. Neither Party shall, without the prior written consent of the other, use, or authorize others to use, the name, trademark, logo, symbol, or other image or trade name of the other Party, or that Party's employees or agents, in any form of advertising, publicity, news release or any other promotional material in connection with the Study or that in any way implies endorsement of the Party whose name is being used; provided, however, that such consent will not be unreasonably withheld. This shall not include legally required disclosure by the Institution or Veloxis that identifies the existence of the Agreement. Notwithstanding the foregoing, Institution may acknowledge Veloxis's financial support as may be required by academic journals, professional societies, funding agencies, and applicable regulations, and Veloxis agrees to allow Institution to list the Study title, Veloxis's name and Investigator(s) on the Institution's website or in Institution's internal reports and also in association with a listing of the Protocol in publicly available listings of ongoing clinical trials or other subject recruitment services or mechanisms.

25. Governing Law; Submission to Jurisdiction. This Agreement shall remain silent on the issue of governing law.

[SIGNATURE PAGE FOLLOWS]

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IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the Effective Date.

Veloxis Pharmaceuticals, Inc.
By_____
Name:
Title:

Temple University – Of The Commonwealth System Of Higher Education
DocuSigned by:
By
Name: Jason G. Kuriem
Title: Vice President, Budget

Read and Acknowledged:

Principal Investigator
By
Name: Adam Diamond, PharmD, BCPS
Title:

Principal Investigator
By_____
Name:
BCPS
Title:

DocuSign Envelope ID: E151518B-1B93-427F-80ED-7E439DE2608F

EXHIBIT A

[INSERT STUDY PROTOCOL]