

**AMENDMENT NO.1
TO THE
MASTER CLINICAL STUDY AGREEMENT
RESTATED AND AMENDED**

This Amendment No. 1 to the Master Clinical Study Agreement (Restated and Amended) (the "Amendment") is hereby made and entered into this 28th day of January, 2020 by and between Astellas Pharma Global Development, Inc., ("Sponsor") and each of The University of Texas at Austin, The University of Texas Health Science Center at Houston, The University of Texas Health Science Center at San Antonio, The University of Texas Medical Branch at Galveston, The University of Texas Southwestern Medical Center, The University of Texas Health Science Center at Tyler, and The University of Texas Rio Grande Valley (each an "Institute" and, collectively, the "Institutes"), and each a member institution of The University of Texas System ("System") that is governed by its Board of Regents ("Board"). Sponsor and Institute and/or Institutes are hereinafter collectively known as the "Parties" or individually as a "Party".

RECITALS:

WHEREAS, the Parties entered into that certain Master Clinical Study Agreement (Restated and Amended) effective as of April 18, 2014 (the "Agreement"); and

WHEREAS, the Parties now desire to amend the Agreement pursuant to the terms and conditions as set forth herein.

NOW THEREFORE, in consideration of the above Recitals, the mutual covenants contained herein and other good and valuable consideration, the receipt, and sufficiency of which are hereby acknowledged, the Parties hereby understand and agree as follows:

1. The Preamble of the Agreement and this Amendment are hereby revised to include **The University of Texas Rio Grande Valley** as another Institute under the Agreement and Amendment.
2. The signature blocks are also hereby revised to include a signature block for **The University of Texas Rio Grande Valley**.
3. The Exhibit B Authorized Representatives or His/Her Designee is deleted in its entirety and replaced with the attached Updated Exhibit B Authorized Representatives or His/Her Designee.
4. Section 20(D) of the Agreement shall be deleted and a new Section 27 (Anti-Corruption) shall be inserted into the Agreement to enable Sponsor to comply with its legal obligations.

"27. Anti-Corruption.

(A) Each Party represents and warrants that:

(1) this Agreement has not been provided as an incentive to, or in exchange or as a reward for, Institute using, purchasing, or prescribing any Sponsor products, or to obtain for or to confer on Sponsor any other improper advantage; and

(2) it shall at all times be bound by and strictly comply with applicable laws and local and applicable industry codes that restrict or prohibit the improper giving of anything of value to, or the receipt of anything of value by, any official, agent or employee of any government, political party or public international organization, any candidate for public office, or any health care professional.

(B) Each Institute represents and warrants that its invoices and any necessary supporting documentation are truthful and accurately describe the nature of any services provided under this Agreement.”

5. Section 2 (Performance) of the Agreement shall be amended to include the following:

“(J) Sponsor may also, from time to time, make changes to the applicable Protocol of the Study. Any such changes may not be implemented at Institute before approval by the Institute’s IRB. If these changes will affect the cost of the applicable Study, Institute will provide Sponsor with a written estimate of the change in the Study cost and Sponsor or designee will discuss in good faith with Institute the option of amending the applicable Work Order to the extent necessary to represent the fair market value for the requested revisions.”

6. A new sentence shall be added to the end of Section 8(B) (Confidential Information) as follows:

“Institute shall be permitted to disclose Confidential Information to Study subjects who are or were enrolled in the Study, or their lawful representatives, solely as the Confidential Information relates to their health or safety during or after completion of the Study.”

7. Section 12 (Agency Access) of the Agreement shall be amended to include the following:

“Sponsor will promptly notify Institute of any monitoring or inspection findings that could affect the safety of Study subjects or their willingness to continue participating in the applicable Study, materially influence the conduct of the Study, or alter the IRB’s approval to continue the applicable Study. Such notice will be given as soon as possible, but always within thirty (30) days of learning of such subject safety issues.”

8. Section 2(G) (Performance) of the Agreement shall be deleted in its entirety and replaced with the following:

“(G) Sponsor, in its role as sponsor of the applicable Study, shall comply with all applicable laws, regulations, and standards of local, state, and federal government agencies, and the International Conference on Harmonization Guidelines for Good Clinical Practice. Sponsor will notify Institute of any subject safety issues that may (i) affect the safety and welfare of current or former Study subjects, (ii) affect the willingness of Study subjects to continue their participation in the applicable Study, (iii) influence the conduct of the applicable Study or

(iv) alter the IRB's approval to continue the applicable Study. Such notice will be given as soon as possible, but no more than thirty (30) days after learning of such subject safety issues. Institute or Principal Investigator will communicate findings to the IRB and Study subjects, as appropriate, pursuant to Institute procedure. In addition, Sponsor will notify the Institute and Principal Investigator of interim findings and post Study results that could affect the Study subjects' safety. Sponsor agrees to register the applicable Study on a clinicaltrials.gov or similar clinical trial registry prior to Study enrollment. Regardless of the outcome of the applicable Study, Sponsor will post the Study results on a publicly available registry, with respect to the primary outcomes."

9. Section 10(A) (Publication) of the Agreement shall be amended to include the following:

"For the purposes of publication otherwise in accordance with the terms of this Agreement, Confidential Information shall not include Study results or Study related methods disclosed in the Protocol reasonably necessary for the appropriate scientific presentation of the Study results."

10. The Parties hereby agree that this Amendment may be executed in counterparts, including pdfs, and all such counterparts shall constitute one agreement, binding upon each Party.
11. Except as expressly modified by this Amendment, all of the terms and conditions of the Agreement shall remain in full force and effect. All capitalized terms used herein shall have the same meaning as ascribed to them in the Agreement, unless otherwise expressly provided herein. To the extent any term or condition of this Amendment conflicts with any term or condition of the Agreement, the terms and conditions of this Amendment shall prevail.

Signatures to follow.

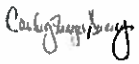
[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties have caused this Amendment to the Agreement to be executed by duly authorized representatives.

ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.

BY: JMMOS LING
NAME: JMMOS LING
TITLE: SR DIRECTOR CLINICAL PROGRAM MGMT
DATE: 04 MARCH 2020

THE UNIVERSITY OF TEXAS AT AUSTIN

BY:  Digitally signed by Courtney Swaney
Date: 2020.02.03 14:52:08 -06'00'
NAME: Courtney Frazier Swaney
TITLE: Associate Director, Office of Sponsored Projects
DATE: 2/3/2020

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

BY: _____
NAME: _____
TITLE: _____
DATE: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

BY: _____
NAME: _____
TITLE: _____
DATE: _____

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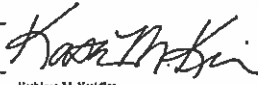
ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.

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DATE: _____

THE UNIVERSITY OF TEXAS AT AUSTIN

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TITLE: _____
DATE: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

BY: _____
NAME:  _____
TITLE: _____
DATE: _____

Digitally signed by Kathleen Kreidler
DN: postalCode=77030,
ou=UTHEALTH.NON.ESCROW, o=The
University of Texas Health Science
Center at Houston, street=7000
Fannin, Suite 1200, st=TX, l=Houston,
c=US, cn=Kathleen Kreidler,
email=kathleen.kreidler@uth.tmc.edu
Date: 2020.02.27 16:14:58 -06'00'

Kathleen M. Kreidler
Associate Vice President
Sponsored Projects Administration

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

BY: _____
NAME: _____
TITLE: _____
DATE: _____

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TITLE: _____
DATE: _____

THE UNIVERSITY OF TEXAS AT AUSTIN

BY: _____
NAME: _____
TITLE: _____
DATE: _____


THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

BY: _____
NAME: _____
TITLE: _____
DATE: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

BY: Chris G. Green
NAME: Chris G. Green, CPA
TITLE: Sr. Director, Office of Sponsored Programs
DATE: 1-30-2020

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

BY: 
NAME: Lori Sinon
TITLE: Director, Office of Clinical Research
DATE: 31-Jan-2020

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

BY: _____
NAME: _____
TITLE: _____
DATE: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

BY: _____
NAME: _____
TITLE: _____
DATE: _____

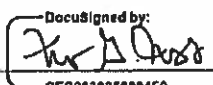

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

BY: _____
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THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

BY: _____
NAME: _____
TITLE: _____
DATE: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

BY:  _____ 
NAME: CFC2638256834F0 Megan G. Marks, Ph.D. _____
TITLE: Asst. VP, Sponsored Programs Administration _____
DATE: 2/6/2020 | 3:48 PM CST _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

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THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

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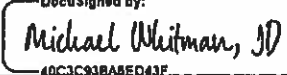
THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

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THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

BY: _____
NAME: _____
TITLE: _____
DATE: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

BY: 
NAME: Michael whitman, JD
TITLE: Director, Office of Sponsored Programs
DATE: 1/30/2020 | 9:23:15 AM CST

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

BY: _____
NAME: _____
TITLE: _____
DATE: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

BY: _____
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TITLE: _____
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THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

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THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

BY: _____
NAME: _____
TITLE: _____
DATE: _____

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

BY: *Karen Martirosyan*
Karen Martirosyan (Feb 4, 2020)
NAME: Dr. Karen Martirosyan
TITLE: AVP for Research Enhancement
DATE: Feb 4, 2020

UPDATED EXHIBIT B
AUTHORIZED REPRESENTATIVES OR HIS/HER DESIGNEE

<p>The University of Texas at Austin</p>	<p>The University of Texas Southwestern Medical Center</p>
<p>Attention: Mark Featherston Assistant Director Office of Sponsored Projects 3925 W. Braker Lane WPRC, Suite 3.340 Austin, Texas 78759 USA Phone: 512-471-6424 Fax: 512-471-6564 Tax ID: 74-6000203 Email: mark.featherston@austin.utexas.edu</p>	<p>Attention: Julia Spesivtseva Director, Clinical Research Services Sponsored Programs Administration 5323 Harry Hines Boulevard Dallas, Texas 75390-9020 USA Phone: 214-648-9877 Fax: 214-648-4671 Email: julia.spesivtseva@utsouthwestern.edu Tax ID: 75-6002868</p>
<p>The University of Texas Health Science Center at San Antonio</p>	<p>The University of Texas Health Science Center at Houston</p>
<p>Attention: Chris Green Senior Director, Office of Sponsored Programs 7703 Floyd Curl Drive, Mail Code 7828 San Antonio, Texas 78229-3900 USA Phone: 210-567-2340 Fax: 210-567-8107 Email: grants@uthscsa.edu Tax ID: 74-1586031</p>	<p>Attention: Kristin L. Parks Director, Clinical Research Finance and Administration Office of Sponsored Projects Administration Fannin Street, UCT1002 Houston, Texas 77030 USA Phone: 713-500-3063 Fax: 713-383-3746 Email: Kristin.Parks@uth.tmc.edu Tax ID: 74-1761309</p> <p>Overnight address: 7000 Fannin Street, Suite UCT 1007-2 Houston, Texas 77030 USA</p>
<p>The University of Texas Health Science Center at Tyler</p>	<p>The University of Texas Medical Branch at Galveston</p>
<p>Attention: Michael S. Whitman Director, Office of Sponsored Programs 11937 U.S. Hwy. 271 Tyler, Texas 75708-3154 USA Phone: 903-877-7392 Fax: 903-877-7689 Email: Grants@uthct.edu</p>	<p>Attention: Lori Simon Director, Office of Clinical Research 6.170 Research Bldg. #6 Galveston, Texas 77555 USA Phone: 409-772-1978 Fax: 409-772-1968 Email: lasimon@utmb.edu Email: clinical.research@utmb.edu</p>

The University of Texas Rio Grande Valley	
Attention: Glorimar Colon Executive Director for Research Compliance and Export Controls Division of Research, Graduate Studies and New Program Development 1201 West University Drive Edinburg, Texas 78539 USA Phone: 956-665-3008 Email: Glorimar.colon@utrgv.edu Dept: sponpro@utrgv.edu Tax ID: 46-5292740	