

2.1.2019 Final

AMENDMENT NO. 4 TO MASTER CLINICAL TRIAL AGREEMENT BETWEEN NOVARTIS AND UT SYSTEM INSTITUTIONS

This **Amendment No. 4** (“Amendment #4”) to the Master Clinical Trial Agreement between Novartis Pharmaceuticals Corporation (Novartis) and certain institutions of The University of Texas System is made and entered into as of January 25, 2019 (“Effective Date”) by and between Novartis and the following member institutions (each an “Institution” or collectively, “Institutions”) of the University of Texas System (“UT System”): The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Houston, The University of Texas Health Science Center at Tyler, The University of Texas Medical Branch at Galveston, The University of Texas Southwestern Medical Center, and The University of Texas at Austin.

RECITALS

- A. Novartis and the following member Institutions of The University of Texas System entered into a Master Clinical Trial Agreement having an Effective Date of May 1, 2009 (the “Master Agreement”): The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Houston, The University of Texas Health Science Center at Tyler, The University of Texas Medical Branch at Galveston, The University of Texas M. D. Anderson Cancer Center, The University of Texas Southwestern Medical Center, and The University of Texas at Austin.
- B. The parties have executed the following three (3) amendments to the Master Agreement:
1. **Amendment #1** having an effective date on or around June 5, 2013 which amended
 - Section 9 A. Inventions and Patents;
 - Section 14A Clinical Trial Subject Injury; and
 - Added two Addenda: the first Addendum was entitled “Master Clinical Trial Agreement HCI/HCP Contract Addendum” and the second Addendum was entitled “**Attachment A: Clinical Trial Request Form**”
 2. **Amendment #2** having an effective date on or around April 10, 2014 which extended the term of the Master Agreement until April 30, 2019
 3. **Amendment #3** having an effective date on or around January 3, 2019 which
 - Added “The University of Texas System” (for the benefit of Clinical Trials Xpress) and “The University of Texas Rio Grande Valley” as parties to the Master Agreement;
 - Amended Section 1 **Scope of Work** to include Clinical Trials Xpress (“CTX”) [www.clinicaltrialsxpress.org], a wholly-owned initiative of UT

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System and to outline certain activities that CTX will perform if Novartis approves and selects at least one CTX network site;

- Amended Section 1 **Scope of Work** to outline the costs that Novartis will pay UT System for the services provided by CTX;
- Amended Section 1 **Scope of Work** to outline CTX Central Coordinating Office Roles and Responsibilities by adding a new **Attachment C**;
- Amended Section 1 **Scope of Work** to outline CTX Network Services by adding a new **Attachment D**;
- Amended Section 2 **Agreement Term** to extend the term of the Master Agreement until August 31, 2023.

C. Novartis and The University of Texas M.D. Anderson Cancer Center now wish to further amend the terms of the Master Agreement to specifically **delete** The University of Texas M. D. Anderson Cancer Center as a party to the Master Agreement.

NOW, THEREFORE, it is agreed that the Amendment #4 is amended as follows:

1. "The University of Texas M. D. Anderson Cancer Center" is hereby **deleted** as a party to the Master Agreement effective as of April 30, 2019.
2. Any ongoing and then-current individual CTRF as of April 30, 2019 between Novartis and The University of Texas M. D. Anderson Cancer Center shall continue to be governed and controlled by the terms, conditions and provisions of the Master Agreement and its amendments.
3. Except as expressly provided in this Amendment #4, all other terms, conditions and provisions of the Master Agreement and its amendments shall continue in full force and effect as provided therein.

THIS AMENDMENT #4 IS EXECUTED by the authorized representatives of Novartis and The University of Texas M.D. Anderson Cancer Center as of the Effective Date.

<p><i>SIGNED for and on behalf of</i> Novartis Pharmaceuticals Corporation</p> <p>DocuSigned by: <i>Melissa Shivas</i> 1A0CF5CB4EE64B2...</p> <hr/> <p>Name: Melissa Shivas</p> <p>Title: Head of Country Trial Operations</p> <p>Date: 05-Feb-2019 5:09:28 PM EST</p>	<p><i>SIGNED for and on behalf of</i> The University of Texas M. D. Anderson Cancer Center</p> <p><i>Jaine Farios</i></p> <hr/> <p>Name: Farios, MBA Assistant Director, Sponsored Program</p> <p>Title:</p> <p>Date: 2/2/19</p>
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