MEMORANDUM OF UNDERSTANDING
BETWEEN
NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES
NATIONAL INSTITUTES OF HEALTH
AND
[INSERT COMPANY NAME]
CONCERNING
NIH-INDUSTRY PROGRAM: DISCOVERING NEW THERAPEUTIC USES FOR EXISTING MOLECULES

This Memorandum of Understanding ("MOU") is between the National Center for Advancing Translational Sciences ("NCATS"), part of the National Institutes of Health ("NIH"), U.S. Department of Health & Human Services ("HHS"), and [Pharmaceutical Company] ("COMPANY"). NCATS and COMPANY are referred to herein individually as a Party and collectively as the Parties.

WHEREAS industry, academic, and government partnerships have always been important to the process of developing new medicines, and the need for partnerships is growing because many areas of unmet medical need are in complex or poorly understood disease areas;

WHEREAS the mission of NCATS is to catalyze the development of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions;

WHEREAS NCATS intends to work with experts in academia and the biotechnology and pharmaceutical industries to consider how extant technologies, know-how, and Assets can be used to better understand human biology, mechanisms of disease, and novel therapeutic indications ("NIH-Industry Program: Discovering New Therapeutic Uses for Existing Molecules");

WHEREAS COMPANY, a global corporation dedicated to the discovery, development, and manufacturing of [INSERT unique text, e.g., (drugs and vaccines) OR (therapeutics and diagnostics)] to improve health and well-being,owns or controls certain small molecules and biologics (as more specifically defined below, the "COMPANY Assets") that have been advanced to clinical studies;

WHEREAS COMPANY Assets, because of their potential as therapeutics, have been the subject, collectively, of extensive research and development efforts funded by COMPANY, which provide an extensive base of knowledge regarding their safety profiles, pharmacology, pharmacokinetics and mechanism of action;

WHEREAS COMPANY seeks to develop novel collaborative relationships or partnerships with the public sector that include a robust and rigorous process to jointly assess the feasibility of new ideas, identify and fill critical knowledge gaps, and thereby enable the best opportunities to be pursued;

WHEREAS COMPANY, to support public health by advancing science and potential new therapeutic understanding, approaches, and indications, is willing to make the COMPANY

Assets available for translational research through the collaboration described in the project plan provided for in, and subject to the terms and conditions of, this Memorandum of Understanding ("Project Plan");

WHEREAS the discovery of new therapeutic indications for, or new human biology and disease insights regarding, any of the COMPANY Assets could facilitate the development of novel therapeutics and/or diagnostics to benefit public health;

WHEREAS NIH is uniquely able to: i) solicit and receive proposals for investigator-initiated research that will explore new, unanticipated therapeutic uses of the COMPANY Assets, ii) evaluate such proposals for scientific merit using its peer review system, iii) distinguish and determine projects of high public health relevance and benefit, and iv) fund research of high scientific merit and public health relevance;

WHEREAS COMPANY, in support of public health and academic research goals, expects to structure Collaborative Research Agreements ("CRAs") (as described below) under the NIH-Industry Program: Discovering New Therapeutic Uses for Existing Molecules to permit dissemination of research results and the right of the participants to grant non-exclusive research use licenses to non-profit and government entities, as more fully provided under such CRAs;

WHEREAS NCATS and COMPANY agree that a public-private collaboration using Assets currently owned or controlled by private pharmaceutical companies and involving government, academia and industry for the purpose of advancing science and identifying new therapeutic indications would serve the best interests of the public, and that this program could serve as a model for other similar collaborations;

WHEREAS, pursuant to the terms and conditions defined below, NCATS and COMPANY expect that a collaboration between the Parties will take the form of an opportunity for research funding, the NIH-Industry Program: Discovering New Therapeutic Uses for Existing Molecules, that will be funded and administered by NCATS or other NIH Institute or Center and for which COMPANY will provide COMPANY Assets to NIH funding recipients ("NIH Grantees") under separate agreements between COMPANY and prospective NIH Grantees;

NOW, THEREFORE, the Parties agree as follows:

A. Activities

1. NCATS Activities

a. <u>NIH-Industry Program: Discovering New Therapeutic Uses for Existing Molecules</u>. NCATS continues to develop, fund and administer the NIH-Industry Program: Discovering New Therapeutic Uses for Existing Molecules, consistent with this MOU through a grant program, NIH-Industry Program: Discovering New Therapeutic Uses for Existing Molecules ("Grant Program"), utilizing cooperative agreements focusing on COMPANY Assets. This Grant Program is for the purpose of discovering new

therapeutic uses for or information regarding COMPANY Assets in order to develop new treatments for significant public health problems. Under the NIH-Industry Program: Discovering New Therapeutic Uses for Existing Molecules, NCATS intends to seek additional drug candidates or biologics from other sources, including other pharmaceutical companies. Regarding the additional drug candidates or biologics potentially received from other pharmaceutical companies, NCATS intends to negotiate separate MOUs with said companies, which may be managed in a similar manner as this NCATS-COMPANY MOU but not requiring any COMPANY participation.

b. Procedures to be followed. NIH previously published a Request for Information ("RFI") to invite public input, including input from COMPANY, outside experts and other stakeholders on the Grant Program, and subsequently issued a Funding Opportunity Announcement (FOA) to initiate the pilot phase of the Grant Program. NCATS anticipates issuing a future FOA that will include information with respect to each COMPANY Asset so as to allow potential investigators to construct meaningful applications. The type of information COMPANY will provide includes: the targets/pathways affected by each drug candidate, whether the drug candidate is a small molecule or a biologic, its route of administration, and prominent safety and tolerability properties that may limit its utility, provided, however, that COMPANY may determine at its sole discretion what additional information will be provided in the case of any specific COMPANY Asset. We anticipate that the FOA will have multiple receipt dates (e.g. two (2) annually for the three (3) years). COMPANY may add additional Assets two (2) times per year. COMPANY may also resubmit Assets, should said Assets still be available. It is understood that Assets should not be removed 90 days prior to a pre-application (X02) receipt date, unless something unanticipated (e.g., new safety information from FDA) becomes available.

NCATS expects to conduct its activities under the Grant Program in two phases as follows:

i. Pre-applications. Pre-applications submitted by applicants in response to a Funding Opportunity Announcement will be programmatically reviewed. Applications that meet programmatic criteria will be put in contact with pharmaceutic companies. They may submit a full application for funding, subject to obtaining access to the relevant COMPANY Asset and confidential information from COMPANY and other program requirements. These applicants will be notified to engage with COMPANY to develop and submit a full proposal, which will include documentation of access to the relevant COMPANY Assets and confidential information pursuant to a CRA and related Project Plan, as specified below. No formulated molecule or Good Manufacturing Practice ("GMP") biopharmaceutical/biologic for the selected COMPANY Assets will be transferred to the applicants unless and until the applicant is awarded the NIH Grant.

ii. NIH Review of Full Proposals and Grant Award. Each full application submitted in response to the FOA will undergo NIH peer review. After a second level of review b y the appropriate NIH Advisory Council, applications will be selected for funding based on scientific merit, program priorities, the availability of funds, and whether a CRA (including a Project Plan) has been executed with COMPANY. Any revisions in go/no go milestones (the "Go-Forward Decision Criteria"), based on feedback from peer review, and the Terms and Conditions of the cooperative agreement will be incorporated

into the NIH Notice of Award.

c. Administration in accordance with Law. NCATS intends to administer the Grant Program in accordance with applicable law and agency policy, including the use of peer review to determine and ensure scientific excellence. NCATS will not disclose confidential information of COMPANY or applicant without appropriate permission.

2. COMPANY Activities

a. Forms of Confidential Disclosure Agreement ("CDA") and CRA. Forms of the CDA and the CRA are or will be attached as Exhibits A and B, respectively, to this MOU upon the Parties reaching agreement on the form of the CDA and CRA. The Parties agree that NCATS will publish Exhibits A & B on the NCATS website. Applicants who submit a full application ("Applicant(s)") are expected to enter a CDA and duly negotiated CRA with COMPANY. Financial terms applicable to a specific CRA may be specified in the related Project Plan. Changes may be made to the standard form of CDA or CRA by mutual agreement of COMPANY, the Applicant, and NIH. A copy of any revised form shall be substituted for the respective Exhibit. Following the award of any grant, COMPANY and the NIH Grantee may modify or amend the Project Plan of the CRA upon written agreement of the NIH Grantee and COMPANY and the approval of NIH as specified in the NIH Notice of Award.

b. COMPANY Assets. COMPANY Assets will consist of particular drug or biologic candidates, which will be announced prior to any FOA or award cycle. COMPANY will not add or remove any Assets 90 days prior to a pre-application (X02) receipt date, except for safety reasons. COMPANY may add or remove Assets twice a year. Please note that resubmitted applications (resubmissions) will not be considered for funding without an updated letter of support from COMPANY, which is under no obligation to make an Asset available for longer than a single application cycle. A resubmission is defined as an unfunded application that has been modified following initial peer review and resubmitted for a subsequent peer review cycle and funding consideration.

c. Execution of CDA. COMPANY and each Applicant will execute the standard CDA prior to COMPANY reviewing any confidential information of the Applicant or providing any COMPANY Material or COMPANY confidential information to the Applicant.

d. Preparing Full Proposal. Under the CDA, COMPANY and Applicants will share such information as they each deem necessary to provide in order for the Applicant to prepare, with the COMPANY's advice if the Company so provides, a full proposal. COMPANY or the Applicant may determine at any time prior to submission of a full proposal to NIH not to proceed with the full proposal and COMPANY shall have no further obligations with respect to such application. Each full proposal will include:

   i. An executed CRA providing for the Project Plan to be conducted under the NIH Grant (as defined in the CRA form, attached hereto as Exhibit B) requested by the full proposal, to become effective upon award of the NIH Grant, containing as an exhibit of the Project Plan described below.

ii. A Project Plan describing the proposed research, the specific activities to be undertaken by each of COMPANY and the Applicant, and support to be provided by the Applicant and COMPANY under the Project Plan, including the COMPANY Assets and any of the other support that may be provided by COMPANY, the funding to be provided by NIH, and any specific Go-Forward Decision Criteria applicable to the Project Plan.

e. COMPANY Support for Research Programs. COMPANY's support for any research program will be described in the Project Plan covered by a CRA. The types of support which may be included in a Project Plan may include those listed below. Not all forms of support may be provided in regard to any particular Project Plan. COMPANY's support will generally be provided by COMPANY directly to the NIH Grantee and, except as otherwise provided in any CRA or Project Plan, will generally be provided on an "in kind" basis at no cost to NIH or the NIH Grantee. In some circumstances, COMPANY may determine to provide additional support for the Project Plan, beyond the categories of support listed below, including additional in-kind support or direct funding. In regard to any particular Project Plan, COMPANY may provide, as and to the extent provided in the applicable Project Plan:

i. Supplies of formulated molecule or GMP biopharmaceutical/biologic for the selected COMPANY Assets and placebo;

ii. COMPANY data regarding the COMPANY Asset for inclusion in regulatory data packages for the selected COMPANY Asset including (if applicable) data for inclusion in an Investigational New Drug ("IND") application for a drug or biologic that uses the COMPANY Asset;

If COMPANY drug or biologic is an Asset for which a prior IND has not been filed with the FDA (e.g., clinical trials were conducted overseas), and for which clinical trials are proposed for the first year of the COMPANY will work with the investigator to ensure that an IND can be filed within one (1) month of the NIH providing support for the clinical trial phase of an award. In such cases, for example, the COMPANY will need to provide the IND filer with data required for the IND; and if needed, submission of a Drug Master File ("DMF") to the FDA and authorization for the PI to cross reference the COMPANY's DMF.

iii. Appropriate research and drug development expertise and enabling technologies for the selected COMPANY Asset; and/or

iv. Pharmacokinetics data analysis, pharmacokinetics modeling to calculate bioequivalence and drug exposure data, and biomarker Standard Operating Procedures ("SOP") information for the selected COMPANY Asset to support any pre-clinical and clinical studies that the NIH Grantee conducts in accordance with the Project Plan.

B. General Provisions

1. Effective Date. This MOU becomes effective on the date of the last signature and shall remain in full force and effect for seven (7) years, unless modified or terminated. Either Party may terminate this MOU by providing written notice to the other Party of its intent to terminate the MOU, not later than sixty (60) days before the proposed effective date of

termination.

2. **Effect of Termination**. Termination of this MOU shall not terminate any grant, CDA or CRA entered into prior to the termination of this MOU. The terms of the applicable grant or CRA, as appropriate, shall govern the rights of the NIH Grantee and COMPANY under such circumstances.

3. **No Prohibition on Similar Arrangements**. Nothing in this MOU restricts, in any way, the United States, HHS, NIH, NCATS, or other NIH Institute or Center from participating in similar activities or arrangements with other public or private agencies, organizations, or individuals. Nothing in this MOU restricts, in any way, COMPANY or its affiliates from participating in similar activities or arrangements with other public or private agencies, organizations or individuals, provided that COMPANY and its affiliates allow the United States, HHS, NIH, NCATS, or other NIH Institute or Center, and NIH Grantee continued access to the COMPANY Asset.

   This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the **Pharma Partner's Affiliate(s)** without the prior written consent of **NCATS**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable. Should the Pharma Partner transfer or sublicense the asset to a third party, that party shall be expected to execute required program agreements with NCATS.

4. **No Endorsement**. Nothing in this MOU may be interpreted to imply that the United States, HHS, NIH, NCATS, or other NIH Institute or Center endorses COMPANY, COMPANY Assets, COMPANY's products, or COMPANY's services. COMPANY

will not take any action or make any statement that suggests or implies such an endorsement.

5. **Contingent on Availability of Funds**. It is understood that the award of any NIH grant under the Grant Program is contingent upon the availability of funds and the discretion of NIH to engage in the activities enumerated herein. It is understood and agreed that NIH has no obligation under this MOU to award any grant. Any monies allocated by NIH for purposes covered by this MOU shall be obligated and expended by NIH in accordance with the terms and the manner prescribed by the fiscal regulations and/or administrative policies of NIH. Transfers of funds, goods or services from NIH to COMPANY are not authorized by this MOU.

6. **Governing Law**. This MOU shall be governed by U.S. Federal Law as applied in the Federal Courts of the District of Columbia.

7. **Entire Agreement; Amendment**. This MOU incorporates all Exhibits and Schedules (if any) hereto and constitutes the entire agreement and understanding between the Parties in respect of the subject matter hereof and replaces in its entirety any prior discussions, negotiations, agreements or other arrangements in relation to the subject matter, whether written or oral, all of which are replaced by the terms of this MOU. No amendment or modification of this MOU shall be valid or binding unless made in writing and signed by authorized representatives of both parties.

8. **Counterparts**. This MOU may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall constitute a single document. The Parties acknowledge and agree that the exchange of electronic or fax signatures will have the same legal validity as the Parties' signatures would have if signed in hard copy form.

9. **Authority**. Sections 301, 402, and 479 of the Public Health Service Act, 42 U.S.C. §§ 241, 282, 287.

10. **Notices and Meetings**. All notices pertaining to or required by this MOU will be in writing, signed by an authorized representative of the notifying Party, and delivered by registered, certified or by an express/overnight delivery service and sent to the other Party at the address designated below. The contacts listed below will establish a schedule of periodic meetings for the Parties to discuss the administration of this MOU and the progress and coordination of the Grant Program.

INSERT COMPANY Contact.

Name:

Title:

Address:

Phone number:

Fax number:

INSERT NCATS Contact.

Name:

Title:

NCATS Address:

Phone number:

Fax number:

Email address:

SIGNATURES BEGIN ON NEXT PAGE

In witness whereof, each Party has caused this MOU to be executed by its duly authorized representative, as of the dates set forth below.

INSERT COMPANY name	**NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES, NATIONAL INSTITUTES OF HEALTH**
By:	**By:**
Printed Name:	**Printed Name:**
Title:	**Title:**
Date:	**Date:**