PFIZER’S CTI REQUESTS PROPOSALS FOR BIOTHERAPEUTIC TARGETS

Pre-Proposal Deadline: April 21, 2017

Pfizer’s Centers for Therapeutic Innovation, or CTI, is a unique program that collaborates with leading academic medical centers, the NIH, and foundations to speed the translation of novel targets to the clinic.

Advantages to Collaborating with CTI

A partnership with CTI may include collaborative use of Pfizer’s technologies, publishing rights, and financial awards in the form of milestone and royalty payments for successful programs, in addition to providing appropriate funds for carrying out the collaborative work.

Foundations collaborating with CTI include:
- Lupus Research Alliance
- Alzheimer’s Drug Discovery Foundation
- Crohn’s and Colitis Foundation of America
- Foundation for Sarcoidosis Research
- Juvenile Diabetes Research Foundation
- Jeffrey Modell Foundation

Pre-proposal Submission Process

Submission entails a brief, non-confidential 2-3 page overview of the target, mechanism (including evidence for disease linkage), and the proposed therapeutic drug. At a high level, the pre-proposal should suggest how the therapeutic hypothesis could be tested in the clinic.

For Information

Please contact Mary Faris at Mary.Faris@pfizer.com and Jeanne Heschele at jheschel@stanford.edu

What We Look For

- **Strong project rationale**, demonstrated association between target biology and disease mechanism
- **Novel drug targets** with potential to lead to differentiated drugs
- **Link between target pathway and human disease**
- **Ability to address unmet medical needs**
- **Feasibility**: tractable target, discovery/development plan

Modalities

- **Large Molecules** (antibodies, proteins, peptides, ADCs, Fusions)

Therapeutic Areas of Interest for Spring 2017

- **Oncology**: Immuno-oncology, targets that promote immune response, targets involved in oncogenic signaling and tumorigenesis, novel tumor-specific cell surface antigens or tumor targeting approach, tumor metabolism and epigenetics
- **Inflammation and immune disorders**: Rheumatoid Arthritis, lupus, Crohn’s Disease and colitis, NASH, atopic dermatitis, cytokines and their signaling pathways, regulatory cells and tolerance induction, microbiome with an interest in epithelial barrier
- **Cardiovascular and metabolic diseases**: Cardiovascular disease and heart failure, NAFLD/NASH, and obesity/eating disorders
- **Neuroscience**: Alzheimer’s Disease, Parkinson’s Disease, chronic neuroinflammation mechanisms and mitochondrial biology impacting the pathologies of AD and PD, cerebral amyloid angiopathy and vascular impairment associated with neurodegeneration
- **Rare monogenic genetic diseases**: Hematologic (non-malignant), neuromuscular and pulmonary diseases, including PAH and cystic fibrosis

Eligibility: Stanford faculty with PI eligibility and CE Faculty (with an approved CE faculty PI waiver). Please submit non-confidential pre-proposals to Jeanne Heschele per the attached guidelines by **April 21, 2017**.
CTI looks for projects that have:

- **Strong Project Rationale**
  - Demonstrated association between target biology, pathway and disease mechanism
  - Target validation as demonstrated by genetic or pharmacologic evidence

- **Therapeutic Area Opportunity**
  - Unmet medical needs, opportunity for novel therapeutic mechanism or modality in in-scope therapeutic areas

- **Therapeutic Drug Target**
  - Novel target, novel therapeutic strategy or new insight into target patient population
  - Defined target
  - Demonstrated cause/effect relationship to disease mechanism
  - Understanding of desired pharmacology
  - Tractability of target relative to drug modalities (e.g., monoclonal antibodies, peptides, proteins or, where applicable, small molecules), available reagents, assays and technologies

- **Project Feasibility**
  - Clear path to candidate development (biochemical/cell-free/cellular assays, disease models, preclinical testing, etc.)
  - Clear path to FIH clinical trial (approach for proof-of-mechanism in humans, accessible patient population, timeframe, safety issues, etc.)

- **Ability to Translate Basic Biological Research into the Clinic**
  - From molecular mechanism to therapeutic opportunity
  - Therapeutic strategies may include personalized medicine, patient stratification, molecular signatures, genetic associations, biomarkers

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*Platform technologies and exploratory research (e.g., target discovery, development of animal models, cell line models, indication expansion or mechanism of action for existing drugs) are generally out of scope for CTI. In-licensing opportunities are also generally out-of-scope although CTI may consider proposals for pre-existing drug candidates based upon discussions with the PI and TTO.*
CTI PRE-PROPOSAL GUIDELINES

By Friday, April 21, 2017, 5 p.m., submit one PDF file containing (1) the pre-proposal and (2) your NIH Biosketch to Jeanne Heschele in the Research Management Group at jheschele@stanford.edu.

Required Contents of the Pre-Proposal

Please use the following template to submit your pre-proposal. Please also include data (tables, graphs) or cartoons, as appropriate. Maximum length of your pre-proposal should be three pages.

INVESTIGATOR NAME (First and last name):
Academic Title, Department
Address
Phone #
Email address

PROJECT TITLE
Subject of CTI Research Project

EXECUTIVE SUMMARY
In four sentences or less, please provide a BRIEF statement summarizing of the following:
- Overall goal & impact of the mechanism
- Desired characteristics
- Patient stratification & evidence of PoM

SCIENTIFIC RATIONALE AND BACKGROUND
This section should contain:
1) a brief description of the target/pathway and link to human disease and disease mechanism(s). What is/are the unmet medical need(s) this target/pathway could address? Is this pathway targetable with a biotherapeutic?
2) please indicate the novelty/differentiation of this target or approach relevant to disease mechanism (if there are other treatments available, please describe why this is different – greater efficacy/safety etc.)
3) key evidence available to support the hypothesis above (i.e. human genetic, human tissue, preclinical proof of mechanism/concept models)
PROPOSED BIOTHERAPEUTIC DRUG CANDIDATE
Please describe any available potential biotherapeutic molecule(s) the PI has generated against the target and its mechanism of action. If available, please describe the characteristics of said molecule (affinity, humanization, PK etc.) (Please be sure to communicate within limits of any Intellectual Property constraints). If unavailable, please indicate the characteristics of the preferred biotherapeutic agent.

PROPOSED (or concept) FOR FIRST BIOLOGICAL READOUT IN CLINIC (PROOF OF MECHANISM)
Brief description of potential therapeutic indications expected to be impacted by this mechanism. Describe the first potential clinical study to demonstrate proof of mechanism including:

1) Patient stratification/selection for the study (i.e. molecular signature, SNP, genetic deficiency etc.)
2) Clinical study endpoints that would allow for testing mechanism in patients.
3) Will this allow for clinical differentiation from other therapies?

RESEARCH PLAN AND REAGENTS
Provide a brief description of research plan to be carried out (objectives, specific aims) leading to demonstration of PoM. Please list the available reagents and assays to support research plan. Alternatively, please describe reagents and assays that may need to be developed, and any gaps in the plan (and how Pfizer scientists may contribute, i.e. complete mechanistic studies in vitro, develop cellular assays, discover biomarkers, etc.)