**CTI PRE-PROPOSAL**

***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:**

**INVESTIGATOR EMAIL ADDRESS:**

**INVESTIGATOR HOSPITAL/ACADEMIC AFFILIATION:**

**TECH TRANSFER OFFICER AND EMAIL:**

**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/SMALL MOLECULE 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 characteristic s 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.

For small-molecule projects, list any tool compounds, if available.

**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 prood 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.)

**BIOGRAPHICAL SKETCH OF PRINCIPAL INVESTIGATOR**

Please provide a brief bio-sketch of the PI and key publications. Attachment of NIH biosketch is acceptable.