Request for Proposal: Pre-IND Regulatory Strategy for Fake Hats Co.

Company Overview

Company Name	Fake Hats Company
CEO	Bob Sacamano
CTO (PI)	Elaine Benes
Company website	www.FakeHats.net
Technology Summary	Small molecule therapeutic (PES-456) is being developed as a first line therapy for Purple Ear Syndrome
Major market(s)	Purple Ear Syndrome patients (400,000 world-wide)
Technology stage	Pre-clinical safety & efficacy with lead compound
Primary regulatory path	Orphan Indication, NDA (New Drug Application)

Context of Service Request:

Fake Hats Co. needs assistance with the development of an initial FDA interaction to support the development of its first therapeutic molecule PES-456. PES-456 is being developed to resolve the symptomology of Purple Ear Syndrome – a condition where excessive blood flow to the tympanic membrane results in a characteristic purple color and which impacts the lives of effected people in one or more of the following ways: difficulty hearing; tinnitus; inability to "clear" ears during changes in altitude (leading to increased potential for ruptured ear drums); and challenges in balance (due to unequal pressure in eustachian tubes). Purple Ear Syndrome is an intermittent condition that can affect one or both ears, individually or simultaneously.

Fake Hats Co. has not had any documented interactions with the US FDA, though we have spoken with FDA representatives at scientific meetings they were excited about our early data. We have identified an optimized synthetic scheme for and are able to produce up to 500 mg of material in our company labs. We have explored both topical and systemic dosing approaches and believe our drug will be delivered as ear drops. There are no animal models for PES, therefore, we modeled PES using organ-on-a-chip technology. We need to understand what, if any, animal data FDA will require before we can begin human trials. We are seeking regulatory support to assist in the development and submission of a pre-IND meeting with FDA.

Deliverables and Reporting Requirements:

The expected deliverable is a documented plan, validated in a pre-IND meeting with FDA, describing the data required to successfully submit an allowable IND and begin clinical evaluation of PES-456. Interim milestones to achieve this deliverable might include:

- A review of documentation developed by Fake Hats to support the pre-IND meeting
- Collaborative development of pre-IND questions and briefing packet for PES-456
- Submission of the pre-IND request and briefing packet for PES-456
- Support reviewing FDA's pre-IND response comments, revising the meeting agenda to address questions, and debriefing the company after the meeting to clarify required activities to support successful IND filing.

Vendor Qualifications:

- Recent experience (within the past 3 years) working with the relevant office in FDA
- Extensive expertise working with small companies to guide early FDA interactions
- Experience supporting pre-IND meetings for auditory therapeutics