Request for Proposal: Regulatory Strategy for Fake Hats Co.

Company Overview

Company Name	Fake Hat Co
CEO	Bob Sacamano
CTO (PI)	Elaine Benes
Company website	FakeHats.Net
Technology Description	Small molecule therapeutic targeting Purple Ear Syndrome
Major market(s)	Adults with Purple Ear Syndrome
Technology stage	Pre-clinical testing
Primary regulatory path	Orphan Indication, NDA (New Drug Application)

Context of Service Request:

Fake Hat Co is requesting support in the area of Regulatory Affairs. Fake Hat is developing a small molecule therapy for Purple Ear Syndrome - excessive blood flow to the eardrum - a debilitating condition that affects up to 60,000 Americans. Excessive blood flow can obstruct auditory processing of external sounds, resulting in accidents, disrupted motor skill function, increased mortality, and social isolation.

We are asking for regulatory support to help us understand the FDA requirements for getting PES-456 to patients. We want to talk with FDA and get their approval to start our clinical trials. We have already been talking with the PEdeStrian Forum (an advocacy group for people living with PES and their families) and these families are very concerned about how frequently they need to repeat themselves, and how often their family members bump into things (household furniture, car accidents, etc.), and how the lack of ability to hear clearly causes them to withdraw from family (and life) functions. PEdeStrian has accumulated a lot of natural history data about PES, and we believe FDA will let us use this instead of placebo in our clinical trials.

Deliverables and Reporting Requirements:

Fake Hats is requesting support in the area of Regulatory Affairs to help us file our IND for our Phase 1 human clinical trials. Our SBIR project has demonstrated a safe and effective small molecule therapeutic for PES in pre-clinical models. We expect to work with a vendor who will explain the regulations to us, help us write our Phase 1 MAD/SAD clinical protocols, and submit our IND to FDA. The expected outcome is submission of our IND. This is an important time for Fake Hats to begin regulatory discussions because we still have the flexibility to align our clinical trial outcomes with the

regulatory path and supporting marketing claims. This support will help us to prepare for our FDA filing, which in turn will accelerate our path to market and increase the probability of FDA approval of the first-in-human use of PES-456.

Existing Information Available for Engaged Vendor:

Fake Hats has optimized the synthesis of PES-456 and has synthesized (at 500 mg scale) very pure PES-456. We have identified and optimized formulation and conducted ADMET studies in PES-symptomatic cats (there is no mouse model of PES). We have begun talking with CMOs to scale production of formulated PES-456 to support our clinical trials. We have talked with representatives for FDA at multiple scientific meetings, all conversations have been very encouraging about the need for a therapy and the people we spoke with are excited about our results. Fake Hats has also talked with PEdeStrian Forum members to increase awareness of the imminent clinical trials.

Vendor Qualifications:

- Experience submitting INDs for auditory therapeutics