Usona Institute

Dear Supporters,

As spring has blossomed into summer, Usona Institute has been growing and progressing on numerous fronts. In this inaugural newsletter, we're excited to share with you recent advances across the multiple disciplines in our work. We appreciate your interest as all of these complexities are defined and developed for our studies.

Following an informative and encouraging preliminary meeting with the FDA in February, we have decided to focus our research efforts on major depressive disorder (MDD)—both in cancer patients and in the population more generally—and plan to pursue next-stage, multi-site clinical trials building on the promising data from previous psilocybin studies at other institutes.

Work toward this goal is progressing across multiple streams, including pharmaceutical-grade drug synthesis and manufacture, regulatory affairs, protocol writing, site selection, and guiding program development. We are fortunate to have expert guidance in each area. Additional detail on several of these streams is included below.

Pharmaceutical-grade Drug Synthesis and Manufacture

This branch of our work involves the synthesis and production of the API (Active Pharmaceutical Agent) for planned clinical trials in psilocybin as well as developmental research with other compounds.

In 2016, we embarked on a large-scale cGMP (current Good Manufacturing Practices) psilocybin synthesis project, which is estimated for completion in early 2018. Recently, a vendor was selected to perform the encapsulation of the bulk psilocybin. At the end of May, members of our team visited the vendor on-site to meet their staff, tour their manufacturing facilities, and begin working out the logistical details.

We are also in the process of hiring two staff chemists to work on synthesis optimization and developmental chemistry on a variety of other compounds. One will be based in San Luis Obispo, California and the other will be based in Madison, Wisconsin. Both chemists will work within leased professional lab facilities designed to support both the required scientific rigor required and the precise protocols needed to manage sensitive materials.

Regulatory Affairs

Our Regulatory Affairs work focuses on all aspects of engagement with regulatory agencies such as the FDA, and ensures that all aspects of our research complies with federal, state, and local regulations pertaining to the development and implementation of clinical trials.

Information is being assembled for the CMC (Chemistry, Manufacturing, and Controls) section of our IND. An important upcoming step is to request a CMC-only meeting with the FDA to review and discuss plans for the cGMP manufacture of our drug substance (bulk API) and drug product (encapsulated API).

We are also continuing work on an Investigator's Brochure for psilocybin which will be made available to the psilocybin research community, and are currently recruiting for a Regulatory Affairs Manager to be positioned at our headquarters in Madison, WI.

Study Design and Implementation

This area of our work centers upon engagements related to protocol development and implementation, including the site selection process.

Dr. Chuck Raison has made significant progress on drafting the MDD (major depressive disorder) protocols, and discussions with our biostatistician are ongoing. The site evaluation process for both MDD study protocols has been underway as well.

Additionally, the Usona team has selected a firm to provide centralized independent rating services, and is evaluating Contract Research Organizations (CROs) for support with study data monitoring, electronic database development, and pharmacovigilance. Consideration is also being given to a national recruitment effort, incorporating digital and social media tools.

Guiding

Preparation and setting are a critical part of this research. This aspect of our work is focused on serving as facilitators of communication amongst guiding experts and the gathering of best (or most ideally suited) guiding practices for the Phase III studies, which will ultimately be woven into a guiding protocol and a guiding manual for the multi-site pivotal trials planned.

We have been in communication with researchers (including guides/therapists) at many research sites and have received a great deal of helpful information to review. The next phase of our work will be reaching out to key collaborators to receive and refine their specific input on critical questions for the guiding protocol. With each site having its own unique and valuable approach, our shared challenge will be to discern which practices will be best suited to these first Phase III, multi-site trials in MDD.

Thank You

All of us at Usona Institute would like to extend our gratitude for your interest in the furtherance of our mission. If you'd like any additional information, please feel free to email us at info@usonainstitute.org.

Warmly,

The Usona team

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