



Reviva Pharmaceuticals Announces Successful Completion of Pre-IND Meeting with FDA on Brilaroxazine for the Treatment of Idiopathic Pulmonary Fibrosis (IPF)

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CUPERTINO, Calif.--([BUSINESS WIRE](#))--Reviva Pharmaceuticals, Inc. (Reviva), a privately held, clinical stage pharmaceutical company today announced that it has successfully completed a pre-Investigational New Drug (IND) Application meeting with the U.S. Food and Drug Administration (FDA) for its drug candidate brilaroxazine, which is being developed for the treatment of idiopathic pulmonary fibrosis (IPF). The FDA has recently granted Orphan Drug Designation to brilaroxazine for treating patients with IPF.

A pre-IND meeting provides an opportunity for an open communication between the sponsor and the FDA to discuss the IND development plan and to obtain the agency's guidance for clinical studies for the sponsor's new drug candidate. The FDA has reviewed brilaroxazine IND enabling preclinical data, and clinical phase 1 study results and phase 2 study plan for IPF. The FDA addressed Reviva's questions and provided guidance on the brilaroxazine clinical development plan for IPF.

"We are very pleased with the outcome of the pre-IND meeting with the FDA," said Laxminarayan Bhat, PhD, Reviva's Founder, President and Chief Executive Officer. "We look forward to initiating brilaroxazine phase 2 study for IPF soon."

About Idiopathic Pulmonary Fibrosis (IPF)

IPF is a progressive, debilitating and fatal lung disease that affects approximately 3 million people worldwide. IPF is characterized by inflammation and fibrosis of the lungs, hindering the ability to process oxygen and causing shortness of breath. Mortality from IPF is increasing steadily worldwide with a median survival time from diagnosis of 2-5 years. It is estimated that there will be between 28,000 and 65,000 deaths in Europe and between 13,000 and 17,000 deaths in the United States from IPF per year. Currently, the treatment options are limited and there is no cure for IPF.

About Brilaroxazine

Brilaroxazine is a new chemical entity (NCE) that acts on serotonin signaling pathways. Whilst dysfunctional serotonin (5-HT) signaling in the brain contributes to the pathophysiology of neuropsychiatric and neurological diseases, in the lung it leads to IPF and pulmonary arterial hypertension (PAH). Serotonin signaling derived from activated 5-HT_{2A/2B/7} receptors in the lung has been reported to mediate inflammation, fibrosis and proliferation, and pulmonary hypertension that are hallmarks of IPF and PAH. Brilaroxazine is a potent inhibitor of the 5-HT_{2A/2B/7} receptors and, consequently, attenuates these functional changes in a series of highly recognized translational animal models proven to emulate IPF and PAH conditions in humans.

PAH and neuropsychiatric symptoms are among the major comorbidities in patients with IPF. Reviva has already successfully completed a multicenter, multinational phase 2 clinical study for brilaroxazine in patients with schizophrenia and schizoaffective disorders where it demonstrated robust efficacy with remission in acute schizophrenia and promising efficacy for comorbid negative, cognition, depression and mood symptoms. Moreover, brilaroxazine showed an excellent safety and tolerability profile compared to the placebo with no weight gain, metabolic, cardiac or movement side effects, which resulted in good acceptance and compliance. Data from preclinical and clinical studies with brilaroxazine are currently available in several published research articles in peer reviewed journals (<http://revivapharma.com/publications/>).

About Reviva Pharmaceuticals

Reviva is located in Cupertino, California and is a clinical stage pharmaceutical company focused on developing a portfolio of internally discovered next generation therapies that address unmet medical needs in the therapeutic areas of the central nervous system (CNS), metabolic and inflammatory diseases. Reviva has a strong patent portfolio and several products in the pipeline at various stages of development.

Reviva's leadership team has a proven background and a track record in successful product development, regulatory approval and commercialization. For additional information, please visit our website at www.revivapharma.com.

Forward Looking Statements

This press release contains forward-looking statements made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events, they give no assurance that such expectations will prove to be correct. Forward-looking statements are subject to a number of risks and uncertainties, but not limited to, our liability to obtain additional capital on acceptable terms, or at all, including additional capital which will be necessary to complete the clinical trials, delays caused by institutional review boards or regulatory agencies, enrollments, shortage of clinical trial supplies, dependence on clinical trial collaborators, loss of any executive officers or key personnel or consultants. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made, and the facts and assumptions underlying the forward-looking statements may change. Except as required by law, Reviva disclaims any obligation to update these forward-looking statements to reflect future information, events or circumstances.

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