Reviva Pharmaceuticals Announces Completion of Patient Enrollment in Phase 2 Clinical Trial of RP5063 for the Treatment of Schizophrenia and Schizoaffective Disorder

SAN JOSE, Calif.--(BUSINESS WIRE)--Reviva Pharmaceuticals,Inc., a privately held drug discovery and development company, today announces completion of patient enrollment in the phase 2 clinical trial of RP5063 for the treatment of schizophrenia and schizoaffective disorder. It is a randomized, double-blind, placebo-controlled, four-arm, global multi-center Phase 2 study to assess the efficacy, safety and tolerability of RP5063 in male and female patients with schizophrenia. A total of 234 schizophrenia patients were enrolled in this phase 2 study from USA, Asia and Europe. Top-line results from this trial are expected to be announced by the end of February 2013 (For more details please visit: www.ClinicalTrials.gov and identifier: NCT01490086).

“Schizophrenia is a devastating mental disease with much unmet treatment need,” said Dr. Laxminarayan Bhat, President and Chief Executive Officer of Reviva Pharmaceuticals. “We are optimistic that the results of this trial will establish clinical proof of concept on safety and efficacy to reveal RP5063 as a promising therapeutic option for treating schizophrenia and schizoaffective disorder.”

About Schizophrenia and Schizoaffective Disorder

Schizophrenia is a serious lifelong mental disease whose symptoms are generally divided into three categories - Positive, Negative, and Cognitive. Major positive symptoms include delusions, hallucinations, disordered thoughts and speech. Negative symptoms commonly include emotional flatness or lack of expression, an inability to start and follow through with activities, speech that is brief and devoid of content, and a lack of pleasure or interest in life. Cognitive Symptoms are across multiple domains including inattention and poor memory. Many schizophrenia patients also suffer from depression, mood swings and some even bipolar-like states as schizoaffective disorder. Current antipsychotics may help relieve the positive symptoms of schizophrenia but are poorly effective for treating negative and cognitive symptoms. Approved pharmacological treatments have dose limiting side effects, including troublesome actions on motor function (movement), weight gain, and metabolic symptoms (diabetes and hyperlipidemia), diminished sexual function, sedation, constipation, dizziness, and loss of bladder control. Many patients do not take their prescribed medications due to the side effects. Few patients are able to regain normal psychosocial function with currently available pharmacological and rehabilitation treatments. Therefore, the unmet need for a safer and more effective alternative treatment for schizophrenia and schizoaffective disorder is enormous.

About RP5063

RP5063 is an orally active new chemical entity (NCE) having effective patent life until September 2030 with possibility of patent term extension up to additional 5 years. RP5063 is a dopamine-serotonin system stabilizer with a potent partial agonist activity at the dopamine D2, D3 and D4, and serotonin 5-HT1A and 5-HT2A receptors, and antagonist activity at the serotonin 5-HT6 and 5-HT7 receptors. RP5063 is also under development for the treatment of a brain disorders as from major depressive disorder (MDD), manic-depressive bipolar disorder, psychosis in Parkinson’s and Alzheimer’s diseases, autism and Tourette’s syndrome.

About Reviva Pharmaceuticals Inc

Reviva Pharmaceuticals Inc. (Reviva), located in San Jose, California, is a clinical stage pharmaceutical company focused on developing a portfolio of internally discovered next generation safe and effective novel (NCE) therapeutic drugs by using an
integrated chemical genomics approach and proprietary chemistries. Reviva is currently focused on developing best in class new drugs for the central nervous system (CNS), metabolic, cardiovascular (CV), inflammation and pain indications.

Reviva’s leadership team has a strong background and a track record in successful rapid product development, regulatory approval and commercialization. Reviva was founded in 2006 and financed by angel investors including medical doctors, successful entrepreneurs, and professionals associated with the pharmaceutical and high-tech industries. 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, the availability of top-line-data-delays in enrollment, delays caused by institutional review boards or regulatory agencies, shortage of clinical trial supplies, dependence on clinical trial collaborators, loss of any executive officers or key personnel or consultants. Undue reliance should be placed on forward-looking statements, which speak only as of the date 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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