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Reviva Pharmaceuticals Reports Positive Top-Line Results from a Phase 2 Clinical Trial of RP5063 for the Treatment of Schizophrenia and Schizoaffective Disorder

SAN JOSE, Calif.--(BUSINESS WIRE)--Reviva Pharmaceuticals, Inc., (Reviva), a privately held drug discovery and development company, today announces top-line results from REFRESH, a phase 2 clinical trial of RP5063 for the treatment of schizophrenia and schizoaffective disorder. REFRESH is a randomized, double-blind, placebo-controlled, dose ranging, global and 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 from USA, Asia and Europe in this phase 2 study (for more details please visit: www.clinicaltrials.gov and identifier: NCT01490086). These top-line results will be followed with more details following completion of the data analysis at New Clinical Drug Evaluation Unit (NCDEU) annual meeting on May 28-31, 2013. An earlier Phase 1b trial had been conducted in patients with stable schizophrenia in the United States reported at NCDEU 2012.

Patients with acute exacerbation of schizophrenia or schizoaffective disorder were randomized to be treated for a month with either RP5063 at doses of 15 mg, 30 mg, or 50 mg/day or placebo or a control arm of aripiprazole (15 mg). RP5063 showed overall broad efficacy across the Positive and Negative Syndrome Scale (PANSS) total scores as well as subscales: Positive, Negative and General Psychopathology. RP5063 also showed efficacy in the Clinical Global Impression Severity (CGI-S) Scale further strengthening the efficacy shown in the PANSS.

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In this REFRESH trial; RP5063 was well-tolerated with a very favorable safety profile as demonstrated in the earlier trial. There were no clinically important differences in systematic side effects between RP5063 and placebo, including motor function (movement) side effects, cardiac, metabolic parameters, or in prolactin related sexual problems, which are common side effect of current antipsychotic treatments. Laboratory testing revealed no clinically significant changes in normal blood chemistries, hematology or urine parameters.

“These results confirm that the dopamine serotonin stabilizer, RP5063, has great promise, since it is both effective and with a potentially excellent safety profile, particularly with regards to metabolic problems,” said Oliver Freudenreich, MD, Director of Schizophrenia Program at Massachusetts General Hospital and Associate Professor at Harvard Medical School.

“These results confirm that RP5063 promises to be a ‘best in class’ dopamine serotonin stabilizer that has the potential to improve the treatment of schizophrenia and schizoaffective disorder, filling a much unmet medical need. The favorable tolerability data also lends support to trials in even more fragile populations, such as geriatrics and pediatrics,” said study investigator Mark Novitsky, MD, Principal Investigator, CRI Lifetree Philadelphia Research Center.

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 with 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 the 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 D_2, D_3 and D_4, and serotonin 5-HT_{1A} and 5-HT_{2A} receptors, and antagonist activity at the serotonin 5-HT_6 and 5-HT_7 receptors. RP5063 is also under development for the treatment of brain disorders such as from major depressive disorder (MDD), manic-depressive bipolar disorder, psychosis in Parkinson's and Alzheimer's diseases, Tourette's syndrome, autism and attention deficit hyperactivity disorder (ADHD).

About 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 and rapid product development, regulatory approval and commercialization. Reviva was founded in 2006 and financed by angel investors comprising of 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

The forward-looking statements in this press release speak only as of the date of this document. Reviva cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. We caution investors, potential investors, and others not to place considerable reliance on the forward-looking statements contained in this press release. 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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