



## Reviva Pharmaceuticals Announces Successful End-of-Phase 2 Meeting With FDA for RP5063

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SAN JOSE, Calif.--(BUSINESS WIRE)--Reviva Pharmaceuticals, Inc., (Reviva), a privately held pharmaceutical company focused on the discovery and development of new, safer and highly effective therapies for chronic indications, announced today the successful completion of an End-of-Phase 2 meeting with the Food and Drug Administration (FDA) for its lead, new investigational antipsychotic drug, RP5063. The FDA indicated that the data from the completed Phase 2 clinical studies of RP5063 support the start of pivotal Phase 3 studies. During the meeting, FDA provided clear guidance related to the proposed Phase 3 development plan: overall size and design of the planned phase 3 studies, the primary endpoints, statistical analysis, non-clinical toxicology, clinical pharmacology and manufacturing plans for both drug substance and drug products for the proposed filing of a New Drug Application (NDA) for schizophrenia.

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“This meeting was a critical milestone for advancing Reviva’s lead product,” said Laxminarayan Bhat, Ph.D., President and Chief Executive Officer of Reviva. “We are very pleased with the positive outcome and the clear feedback from the FDA at our End-of-Phase 2 meeting.”

Reviva plans to initiate Phase 3 trials in early 2014 and anticipates filing a NDA in 2016. “There is a major unmet medical and public health need for a well-tolerated and highly effective therapy for schizophrenia,” said Marc Cantillon, M.D., Chief Medical Officer of Reviva. “The encouraging safety and efficacy results from the Phase 2 clinical trial of RP5063 provide strong support for the successful Phase 3 clinical development.”

## **About Schizophrenia**

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 such as schizoaffective disorder. Current antipsychotics may help relieve the positive symptoms of schizophrenia but their effectiveness for treating negative and cognitive symptoms tends to be poor. Approved treatments also have serious 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, with many patients failing to take their prescribed medications because of these side effects. As a consequence, few patients are able to regain their normal psychosocial function with these currently available pharmacological and rehabilitation treatments. Hence, there is still a major unmet medical and public health need for safer and more effective alternative treatments of schizophrenia.

## **About RP5063**

RP5063 is a ‘best-in-class’ new chemical entity (NCE) that is taken orally and has an effective patent life until September 2030, with the possibility of a patent term extension for up to 5 additional years. RP5063 is a dopamine-serotonin system stabilizer with an optimum balance of potent partial agonist activity at the dopamine D<sub>2</sub>, D<sub>3</sub>, D<sub>4</sub>, serotonin 5-HT<sub>1A</sub> and 5-HT<sub>2A</sub> receptors, and antagonist activity at the serotonin 5-HT<sub>6</sub> and 5-HT<sub>7</sub> receptors.

Earlier this year, Reviva reported that the RP5063 global phase 2 clinical trial results showed a robust remission level efficacy for acute schizophrenia in addition to promising efficacy signals for comorbid conditions cognition impairment and mood disorders. RP5063 showed a very good safety and tolerability profile with no weight gain, metabolic, cardiac or movement side effects, leading to good acceptance and compliance with the treatment.

As a result of its favorable balance of agonism and antagonism of key dopaminergic and serotonergic receptors, as well as minimal off-target activities, RP5063 is also under development for the treatment of major depressive disorder, bipolar disorder, Tourette syndrome, autism, attention-deficit/hyperactivity disorder (ADHD), and psychosis in Alzheimer's and Parkinson's disease.

### **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 highly 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 is financed by high-net-worth 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](http://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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