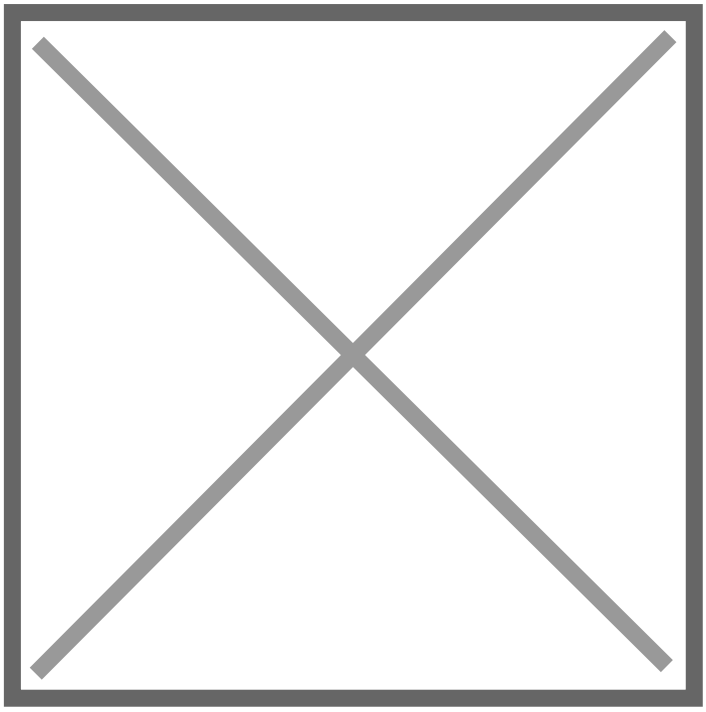
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Sunovion, PsychoGenics announce grant of Breakthrough Therapy Designation for SEP-363856

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SEP-363856 offers an innovative approach to the treatment of schizophrenia including the potential to be the first agent for the treatment of schizophrenia that does not bind to dopamine 2 (D2) receptors.



Sunovion Pharmaceuticals and PsychoGenics have announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for SEP-363856, a novel agent for the treatment of people with schizophrenia.

Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on one or more clinically significant endpoints.[1]

“Schizophrenia is a major public health challenge associated with persistent abnormalities in thinking, perception and behavior, as well as impairments in quality of life and functional skills, that affects approximately 2.4 million people in the U.S.,”[2] said Antony Loebel, M.D., President and Chief Executive Officer at Sunovion. “Breakthrough Therapy Designation underscores the potential of SEP-363856 as a novel treatment for patients with schizophrenia, for whom few major advances in treatment have occurred since the advent of antipsychotic pharmacotherapy in the 1950s. Investigational studies to further evaluate the clinical benefit of SEP-363856 are in progress, and we look forward to working closely with the FDA on this important potential new therapy."

SEP-363856 does not bind to dopamine 2 (D2) or serotonin 2A (5-HT2A) receptors, which are thought to mediate the effects of currently available antipsychotic medicines. Although the exact mechanism of action is unknown, SEP-363856 is believed to activate TAAR1 (trace amine-associated receptor 1) in addition to 5-HT1A (serotonin 1A) receptors.

The FDA granted Breakthrough Therapy Designation for SEP-363856 based on pivotal, Phase 2 data from Study SEP361-201, which were presented by Sunovion at the 57th Annual Meeting of the American College of Neuropsychopharmacology (ACNP) in December 2018, as well as data from Study SEP361-202, a six-month, open-label, safety and tolerability extension study.

With this Breakthrough Therapy Designation SEP-363856 is eligible for intensive guidance from the FDA on the drug development program and priority review.[1]

About SEP 361-201

SEP 361-201, a randomized, placebo-controlled, double-blind, registration study, met its primary endpoint, demonstrating that hospitalized patients with acute exacerbation (worsening) of schizophrenia treated with SEP-363856 showed statistically significant and clinically meaningful improvement in the Positive and Negative Syndrome Scale (PANSS) total score compared to placebo after four weeks of treatment (-17.2 vs. -9.7, respectively; p=0.001). Patients treated with SEP-363856 also showed improvement in the overall severity of illness as assessed by the Clinical Global Impression Scale - Severity (CGI-S) ($p<0.001$). In addition, improvement was found in all major PANSS (positive, negative and general psychopathology)

subscales ($p<0.02$).

SEP-363856 was found to be generally well tolerated with notable similarities to placebo treatment in discontinuation rates; proportion of patients experiencing extrapyramidal symptoms or akathisia (restlessness); and change in metabolic parameters such as weight, lipids, glucose and prolactin.

About SEP-363856

SEP-363856 is a psychotropic agent with a novel, non-D2 mechanism of action, distinct from currently marketed antipsychotics. Sunovion discovered SEP-363856 in collaboration with PsychoGenics based in part on a mechanism-independent approach using the in vivo phenotypic SmartCube platform and associated artificial intelligence algorithms. SEP-363856 was optimized for antipsychotic activity by Sunovion medicinal chemists based on quantitative structure-activity relationship analysis, in collaboration with PsychoGenics. SEP-363856 is jointly owned by Sunovion and PsychoGenics. Sunovion has exclusive rights to develop and commercialize SEP-363856 globally.

SEP-363856 is being studied in a global development program for schizophrenia as well as for Parkinson's disease psychosis, with additional indications under consideration. Clinical trial results to date demonstrate a predictable pharmacokinetic (PK) profile suitable for once daily use.

About Schizophrenia

Schizophrenia is a chronic, serious and often severely disabling brain disorder that affects more than 23 million people worldwide[2] and approximately one in 100 adults (about 2.4 million people) in the United States.[3] It is characterized by positive symptoms, such as hallucinations, delusions and disorganized thinking as well as negative symptoms, such as lack of emotion, social withdrawal, lack of spontaneity and cognitive impairment that includes problems with memory, attention and the ability to plan, organize and make decisions.[3]

References

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