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Treating Psychosis in Schizophrenia: Could a Non-D2-Receptor Binding Drug Be the Key?

Dr. Birnholz:
You're listening to *NeuroFrontiers* on ReachMD sponsored by Sunovion. I'm Dr. Matt Birnholz. On today's audio abstract, we'll dive into a study exploring the use of a non-D2 receptor binding drug for the treatment of psychosis in schizophrenia.

The oral compound, code named SEP-363856, acts on trace amine-associated receptor 1 and serotonin 5-HT type 1A receptors.

A randomized controlled safety and efficacy study was conducted over 4 weeks; 245 patients were split into two groups, 120 receiving the experimental drug once daily at flexible doses of 50 or 75 mg, while 125 patients received placebo. Baseline eligibility characteristics for patients included being between 18 and 40 years of age, meeting the DSM-5 diagnostic criteria for schizophrenia for at least 6 months, and having had an acute exacerbation of psychotic symptoms with the duration of 2 months or less. Severity of psychotic symptoms was assessed with a positive and negative syndrome scale, or PANSS, with a minimum eligibility score of 80 set against the reference range of 30 to 210. The higher scores indicating more severe psychotic symptoms.

Patients receiving SEP-363856 began the trial with a mean baseline total PANSS score of 101.4. At the 4-week mark, this group's score had reduced by 17.2 points compared to only a 9.7-point reduction in the placebo group.

This represented a clinically significant reduction in severe psychosis symptoms from baseline over placebo.

Additionally, improvements in other symptoms severity scores were also observed in the SEP-363856 group such as with negative symptoms and symptoms of depression.

The incidence of adverse events was generally similar between both groups, and included extrapyramidal symptoms and changes in lipid, glycated hemoglobin, and prolactin levels. Gastrointestinal symptoms and somnolence were more common in the SEP-363856 group, and one treated patient experienced worsening of schizophrenia and acute cardiovascular insufficiency resulting in sudden death. There were no clinically significant electrocardiographic abnormalities after baseline between study groups.

Based on these results, the study authors suggest that SEP-363856 could represent a new class of psychotropic agent with a non-D2 receptor binding mechanism of action for the treatment of psychosis in schizophrenia. More clinical trials will be needed to further understand its efficacy and safety.

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