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# US FDA accepts Actavis' New NDA

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The US Food and Drug Administration (US FDA) has accepted Actavis' Supplemental New Drug Application (sNDA) for Saphris (asenapine) for the acute treatment of manic or mixed episodes associated with bipolar I disorder in paediatric patients aged 10 to 17 years. The company's sNDA for Saphris has been granted priority review status by the FDA.

"The sNDA filing of Saphris speaks to our commitment to ongoing research and development of our mental health portfolio. We are pleased that the FDA has accepted this sNDA, marking the first step towards our goal of bringing this important antipsychotic treatment option to paediatric patients,"said Mr C David Nicholson, senior vice president, Actavis Global Brands R&D.

The sNDA submission for asenapine is based on the results of a three-week monotherapy trial in 403 paediatric patients (10 to 17 years of age), of whom 302 received asenapine. In the trial, asenapine was shown to be statistically superior to placebo in the reductions of both the Young Mania Rating Scale (YMRS) total score and Clinical Global Impression-Bipolar (CGI-BP) score at fixed doses of 2.5 mg, 5 mg and 10 mg twice daily. The most commonly observed adverse reactions (incidence = 5 per cent and at least twice that for placebo) were somnolence, dizziness, dysgeusia, oral hypoesthesia, oral paresthesia, nausea, increased appetite, fatigue and increased weight.

SAPHRIS is indicated for the treatment of schizophrenia in adults, and for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults, as monotherapy or as adjunctive therapy with either lithium or valproate.