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Transdermal Asenapine for Adult Schizophrenics—an old wine in new bottle

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ABSTRACT

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The US food and drug administration (USFDA) approved Asenapine, a once-daily transdermal drug delivery system (TDDS),the first and only patch of its kind, for the treatment of adult schizophrenia patients, on 11 October 2019.[1] The drug is manufactured by Noven Pharmaceuticals, Inc. Asenapine exhibits high affinity for serotonin 5-HT1A, 5-HT1B, 5-HT2A, 5-HT2B, 5-HT2C, 5-HT5A, 5-HT6, and 5-HT7 receptors.[2] Asenapine exhibits minimal affinity for muscarinic cholinergic receptors. TDDS presents a pharmacokinetic profile different from that of the sublingual formulation. Even after drug removal from the application site, apparent elimination half-life is approximately 30 h. The application site (upper arm, upper back, abdomen, and hip area) has no effect on the pharmacokinetic profile of the drug. The application of a heating pad on Asenapine for 8 h has been reported to accelerate the absorption rate compared with that of Asenapine without a heating pad, indicating the apparent effect of heat on absorption in the heating pad application duration.

Schizophrenia patients who prefer a patch instead of an oral medication (owing to its bad taste) or injections are comfortable with transdermal asenapine. Early drug termination can be prescribed if required. Because of its shorter duration of action, daily dosage (i.e., change of patch) is required. Because of the life-long and chronic nature of schizophrenia and difficulty to treat consistently over the long term, transdermal drug delivery with asenapine, which is absorbed into the skin over a 24-h period, has several innate advantages that benefit various patient populations, including those with CNS disorders.

The efficacy of Asenapine in treating schizophrenia patients has been partly established on the basis of efficacy data obtained from trials conducted with the sublingual formulation of asenapine. Additionally, the efficacy of Asenapine was evaluated in a 6-week, fixed-dose, randomised, double-blind, and placebo-controlled trial in adult patients who met the DSM-IV criteria for schizophrenia. In this study, the Positive and Negative Syndrome Scale (PANSS) and clinical global impressions-severity (CGI-S) rating scale were used as primary and secondary efficacy measures, respectively, for assessing psychiatric signs and symptoms. The primary endpoint was change in the PANSS total score from baseline to week 6.(Figure 1). The change from baseline for Asenapine was

compared with that for placebo. In the 6-week trial comparing two fixed doses of Asenapine (3.8 mg/24 h and 7.6 mg/24 h) and placebo, both doses were statistically superior to placebo for both the PANSS total score and CGI-S.(Figure 2)[3]

Safety of Asenapine was evaluated in 315 adult schizophrenia patients who were exposed to Asenapine for up to 6 weeks in a placebo-controlled trial. The most common adverse reaction among Asenapine treated patients was akathisia. The other common adverse reactions (≥5% and at least twice the rate of placebo) were extra-pyramidal disorder, application site reaction, and weight gain.[4]

Almost 50% of the patients with schizophrenia fail to adhere to the treatment course.[5] In such cases, a patient-friendly drug formulation, such as Asenapine transdermal patch, can improve the treatment outcome in adult schizophrenia patients. Further efficacy and safety assessments of this formulation on a larger scale among large number of patients are required to establish the significance of TDDS.

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Treatment Group	Primary Efficacy Measure: PANSS Total Score		
	Mean Baseline Score (SD)	LS Mean Change from Baseline (SE) to Week 6	Placebo-subtracted Difference[a] (95% CI)
SECUADO 3.8 mg/24 hours*	97.0 (9.78)	-22.1 (1.2)	- 6.6 (-9.81, -3.40)
SECUADO 7.6 mg/24 hours*	95.6 (8.68)	-20.4 (1.2)	- 4.8 (-8.06, -1.64)
Placebo	97.4 (10.07)	-15.5 (1.2)	-

SD: standard deviation; SE: standard error; LS Mean: least-squares mean; CI: confidence interval.
[a] Difference (drug minus placebo) in least-squares mean change from baseline. A negative value for the placebo subtracted difference represents improvement.
*: Statistically significant after multiplicity adjustments.

Figure1: Primary efficacy results for change in PANSS total scores from baseline to week 6

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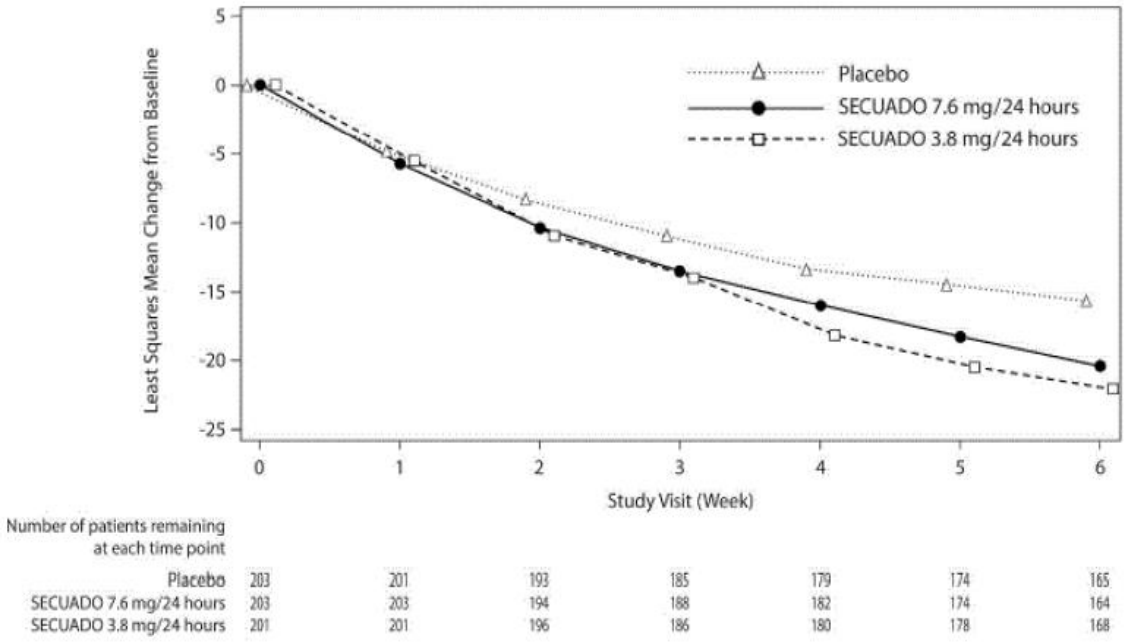

Figure 2: Change in PANSS total score over time (from baseline to week 6) in patients with schizophrenia

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