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Efficacy and Safety of the Asenapine Transdermal Patch, HP-3070, for Schizophrenia: A Phase 3, Randomized, Placebo-Controlled, Inpatient Study

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ABSTRACT: Background: Asenapine is a 2nd-generation antipsychotic currently marketed as a sublingual (SL) tablet in the US for the treatment of schizophrenia. HP-3070, asenapine transdermal system, is a patch for treatment of schizophrenia in adults. Low- and high- HP-3070 doses deliver asenapine concentrations that are similar to SL asenapine 5 mg BID and 10 mg BID, respectively, but with fewer peak and trough fluctuations.

METHODS: In this Phase 3, randomized, double-blind, placebo (PBO)-controlled, 6-week inpatient study, adults with schizophrenia having baseline Positive and Negative Syndrome Scale (PANSS) total score ≥80 and Clinical Global Impression–Severity of Illness Scale (CGI-S) score ≥4 were randomized 1:1:1 to HP 3070 high-dose, HP-3070 low-dose, or PBO.
The primary efficacy objective was Week 6 PANSS score change from baseline (CFB) vs PBO.
The key secondary objective was Week 6 CGI-S CFB vs PBO.
Safety assessments included treatment-emergent adverse events (TEAEs), laboratory results, vital signs, dermal safety, and extrapyramidal symptoms (EPS) assessments.

RESULTS: A total of 616 patients were randomized, with 486 patients completing the study. Discontinuation rates were 23.3%, 18.6%, and 21.4% for HP-3070 high-dose, HP-3070 low-dose, and PBO, respectively; withdrawal of consent and AEs were the most common reasons for discontinuation. Demographics and baseline characteristics were well-balanced among treatment groups.
For PANSS total score, least squares mean (LSM) (standard error [SE]) estimates of the treatment comparison (HP-3070 vs PBO) for CFB at Week 6 were -4.8 (1.634; 95% CI: -8.06, -1.64; p=0.003) and -6.6 (1.630; 95% CI: 9.81, 3.40; p<0.001) for HP-3070 high- and low-dose, respectively. For CGI-S CFB at Week 6, LSM (SE) for the treatment comparison were 0.4 (0.100; 95% CI: 0.55, 0.16; p<0.001) for HP 3070 high-dose and 0.4 (0.099; 95% CI: 0.64, 0.25; p<0.001) for low-dose.
No deaths or serious TEAEs related to study treatment occurred. The HP-3070 safety profile was consistent with SL asenapine. Incidence of TEAEs at the patch application site was higher for HP-3070 (14.2% high-dose, 15.2% low-dose) than for PBO (4.4%); most of these events were mild or moderate in severity. PBO patients had higher rates of psychiatric disorders (24.3% vs 15.7% and 17.6% for HP-3070 high- and low-dose, respectively), with insomnia and anxiety as most common. Study treatment discontinuations due to application site reactions or skin disorders were low (≤0.5%) across treatment groups. There was no marked mean CFB for vital signs or electrocardiogram parameters, nor treatment differences observed on EPS assessments.

CONCLUSIONS: In this study, HP-3070 was efficacious, safe, and well-tolerated for treating schizophrenia in adults; both doses met primary and key secondary endpoints. As the first transdermal antipsychotic patch in the US, HP-3070 will provide patients a novel treatment option.
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Training Forgiveness. A Novel Approach to Reducing Physician Burnout

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ABSTRACT: Study Objective: Psychological risk factors that lead to impaired work performance, negatively impacting mental and physical health, have emerged as a concern across clinical settings. Although depression and anxiety are linked to poor physician mental health, physician burnout characterized by work related stress due to chronic exhaustion from clinical work, cynicism toward meaning of the medical profession, and feelings of inadequacy toward work related accomplishments, may be an even stronger indicator of well-being. Literature suggests

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