Inhaled Dihydroergotamine Well Tolerated in Long-Term Use for Acute Migraines in Adults

An open-label 12-month study in adult migraineurs reveals that Levadex was well tolerated, with no new safety concerns associated with inhaled administration of the active, dihydroergotamine.

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June 03, 2011 (Washington, DC) — Levadex, an orally-inhaled formulation of dihydroergotamine mesylate, was well tolerated in adult migraineurs participating in a 12-month open-label extension to the FREEDOM-301 trial. No new safety concerns were associated with inhaled administration.

Dr. Kellerman and colleagues presented the findings at the 53rd meeting of the American Headache Society, here on Thursday.

The open-label phase of the Phase 3 FREEDOM-301 trial was conducted over 12 months, during which adult migraineurs self-administered Levadex (1.0 mg nominal dose) when required to treat acute migraines.

Safety was assessed through adverse events (AEs) reporting, laboratory tests, vital signs, physical examination, cardiopulmonary function (electrocardiogram, echocardiography and forced expiratory volume in 1 second [FEV1]), lung capacity for diffusion of carbon monoxide (DLco) and chest X-ray. A group of untreated subjects was followed to assess underlying variability of echocardiography, FEV1, DLco and chest X-ray results.

During the 12 months of the study, no significant respiratory effects or serious treatment-related AEs were observed. Upper respiratory tract infection (14.6%), nausea (12.2%) and nasopharyngitis (10.5%) were the most common AEs reported. Abnormal results for echocardiography, diffusion capacity and spirometry were infrequent and reported with similar incidence between the Levadex and control groups.

In total, 458 patients completed the study with 12-months' follow-up (263 received Levadex and 195 served as controls). Levadex was used to treat over 9,500 migraines. The proportion of asthmatics was higher in the Levadex group compared to the control group (24% vs. 9%), whereas the mean age and proportion of females were similar (40 and 37 years; 91% and 87% were female in the Levadex and control groups, respectively).

Levadex is a novel orally-inhaled formulation of dihydroergotamine mesylate in hydrofluoroalkane propellants. The drug is delivered to the patient using the breath-actuated TEMPO inhaler.

A New Drug Application for Levadex has been submitted to the United States Food and Drug Administration (FDA) for the potential acute treatment of migraine in adults.

The study was sponsored by MAP Pharmaceuticals, Inc.

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