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ALKS release on P2 results for its oral OIC drug.

Appears to be a useful link for the companies covered in the database. Coincidentally (in view of the multiple posts on oral Relistor), there was a link to today's press release from ALKS on its OIC drug. The P2 results have prompted ALKS to announce that it will begin a P3 trial mid-year.

>>Alkermes Announces Positive Preliminary Results from Phase 2 Study of ALKS 37 for Treatment of Opioid-Induced Bowel Dysfunction
- Novel Orally Active Compound Targets Gastrointestinal Tract with Limited Systemic Exposure without Affecting Pain Relief from Opioids -
- Company Intends to Proceed into Pivotal Development Program in Mid Calendar 2011 -

WALTHAM, Mass., Feb 15, 2011 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced positive preliminary results from a phase 2, double-blind, randomized, placebo-controlled clinical study of ALKS 37, an orally active, peripherally restricted opioid antagonist for the treatment of opioid-induced bowel dysfunction (OBD), which includes constipation and associated gastrointestinal (GI) abnormalities resulting from chronic use of opioid pain medications. Data from the study showed that ALKS 37 significantly improved GI motility and increased the frequency of bowel movements in patients with OBD, while simultaneously preserving the analgesic effects of opioid treatment. The study also demonstrated that ALKS 37 was generally well tolerated with limited systemic exposure and bioavailability. Based on these results, Alkermes plans to advance ALKS 37 into a pivotal development program in mid calendar 2011.

"OBD is one of the most prevalent side effects of prescription opioid use and a major clinical issue given the widespread utilization of opioids in the treatment of chronic pain," said Anthony Lembo, M.D., Associate Professor of Medicine at Harvard Medical School. "There is significant need for a well tolerated, orally active treatment that enables patients to maintain pain relief without having to experience the debilitating effects of OBD."

In this multi-center, multi-dose study, 87 patients diagnosed with OBD during treatment with opioids for chronic, non-cancer pain were randomized to receive escalating doses of ALKS 37 or placebo pursuant to a pre-defined dose escalation schedule. There was a clear dose-response relationship, with the two highest doses tested (30 mg and 100 mg

once daily) demonstrating a statistically significant increase in the pre-specified primary endpoint of change from baseline in the average number of spontaneous bowel movements (SBMs), compared to placebo. Patients receiving 100 mg ALKS 37 once daily had a mean change from baseline in the average number of SBMs per week of 4.6 versus 0.7 in the placebo group (p=0.003), or a net increase of 3.9 SBMs over placebo.

The study also demonstrated a clinically meaningful and statistically significant increase in the average number of complete spontaneous bowel movements (CSBMs) per week from baseline at the 100 mg dose, as compared to placebo. The mean change from baseline in the average number of CSBMs per week for patients receiving 100 mg ALKS 37 was 3.6 versus 0.8 in the placebo group (p=0.006), or a net increase of 2.8 CSBMs over placebo. Importantly, there was no reversal of analgesia as measured by a change in Numerical Pain Rating Scale (NPRS) scores and no increase in opioid use.

"We set out to design a metabolically stable molecule to target the GI tract with limited systemic exposure to address the medically important condition of opioid-induced bowel dysfunction. We have done just that, and are extremely encouraged by the safety, tolerability and efficacy results seen in this phase 2 study of ALKS 37," said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "Our goal is to develop an oral drug that can normalize bowel function in patients being treated with opioids for chronic pain, without affecting the analgesic effects of prescription opioid medications. Based on these results, we are looking forward to initiating an aggressive pivotal development program in mid calendar 2011." <<

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