

New data on Aloxi® presented at the ASCO Annual Meeting, Chicago 1-5 June 2007

Lugano-Chicago, 5th June 2007 – New data on Aloxi® were presented at this year's ASCO Annual Meeting held in Chicago from 1-5th June. Together with two posters, Aloxi® (palonosetron hydrochloride) Injection was the subject of a published abstract describing study results that differentiate the molecular interaction of Aloxi® with the 5-HT₃ receptor. These data provide new insight into the receptor binding mechanisms that may explain the improved protection from chemotherapy-induced nausea and vomiting (CINV) observed with Aloxi® in clinical trials.

Aloxi® Injection

Study Results on Receptor Interactions of Aloxi® versus Other 5-HT₃ Receptor Antagonists

The results of a study characterizing the molecular ligand-receptor interactions for Aloxi® and the other 5-HT₃ receptor antagonists, ondansetron and granisetron, were reported. Competitive versus allosteric interactions between these agents and the 5-HT₃ receptor were examined in binding experiments using each unlabeled antagonist in competition with [³H]-antagonist. Concentrations of [³H]-antagonists were representative of the probable concentrations of each antagonist at the receptor site in vivo. Based on a plot of the

concentration of unlabeled antagonist needed to observe half maximal binding (IC₅₀) as a function of [³H]-antagonist concentration, Aloxi® demonstrated dual action suggesting competitive and allosteric interactions with the 5-HT₃ receptor. In contrast, ondansetron and granisetron exhibited strictly competitive antagonism. The Aloxi® allosteric interaction with the 5-HT₃ receptor indicates that it has additional inhibitory potential at the primary receptor binding site compared to the other 5-HT₃ receptor antagonists studied.

Study of a Single Day Combination of Aloxi®, Dexamethasone and Aprepitant in Patients Receiving Moderately Emetogenic Chemotherapy (MEC) Regimens

The results of a study evaluating the efficacy of Aloxi® in combination with dexamethasone and aprepitant given only on Day 1 for the prevention of acute and delayed CINV in patients receiving MEC were presented in a poster session on Saturday, June 2, 2007. Forty-one patients (40 female, 1 male) with solid tumors received a 1-day, 3-drug regimen of intravenous Aloxi® 0.25 mg, oral dexamethasone 20 mg and aprepitant 285 mg prior to their first cycle of chemotherapy. Endpoints of the study included complete response (no emesis or rescue

medication), no emesis, and no significant nausea (Visual Analogue Score (VAS; 0-100) <25) on Day 1, during the delayed period of Days 2-5, and during the overall period of Days 1-5. On Day 1, 100% of patients had no emesis and at least 95% of patients had no emetic episodes in the delayed and overall time periods. A complete response was demonstrated in 75% of patients on Day 1 and in 67% of patients in the delayed time period. Based on VAS, the majority of patients had no significant nausea in the acute, delayed or overall phases. The most commonly observed adverse events were headache and fatigue.

Phase 3 Results of Aloxi® in Pediatric Patients

The results of a phase 3, multicenter, randomized, double-blind study to assess the safety, efficacy and pharmacokinetics of single intravenous doses of Aloxi® in pediatric patients were presented in a poster session on Sunday, June 3, 2007. Sixty patients (2-17 years of age) were randomized to receive either 3 mcg/kg or 10 mcg/kg with a maximum total dose of 0.25 mg and 0.75mg, respectively, prior to moderately (n=21) or highly (n=39) emetogenic chemotherapy. Twelve additional patients, age 28 days-23 months, were studied in open-label design at the same doses. The majority of patients had received previous chemotherapy. Day 1 complete response (CR: no emetic episodes and no rescue medication) rates of 7.1% (CI: 22.0-55.1%) and 54.1% (CI: 37.1-

70.2%) were reported in the 3 mcg/kg (n=35) and 10 mcg/kg (n=37) groups, respectively. The percentage of patients who were emesis-free and who had no nausea was numerically higher in the 10 mcg/kg group; however, as with CR, these differences were primarily seen in children < 2 years. Both doses showed a similar time to treatment failure (time to first emetic episode and/or first administration of rescue medication). The pharmacokinetic data show that total body clearance and volume of distribution of Aloxi® increased with age-related body weight, as expected. The long half-life (21-37 hours) of Aloxi® in this pediatric population was consistent with that in adults. There were no cardiac safety concerns or serious treatment related adverse events.

About Aloxi® (palonosetron hydrochloride) Injection

Aloxi® is approved by the U.S. FDA for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy and for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. Aloxi® is the first and only 5-HT₃ receptor antagonist to be indicated for the prevention of delayed CINV caused by moderately emetogenic cancer chemotherapy. The most common adverse reactions related to Aloxi® were headache (9%) and constipation



(5%). Aloxi® is contraindicated in patients known to have hypersensitivity to the drug or any of its components. Please see more information at www.aloxi.com.

About HELSINN HEALTHCARE

HELINN HEALTHCARE SA, a privately owned pharmaceutical group with headquarters in Switzerland, is the worldwide licensor of palonosetron. HELINN's core business is the licensing of pharmaceuticals in therapeutic niche areas. The company's business strategy is to in-license early stage new chemical entities and complete their development from the performance of pre-clinical/clinical studies and CMC development to the attainment of market approvals in strategic markets (U.S. and Europe). HELINN's products are eventually out-licensed to its marketing partners for distribution. The active pharmaceutical ingredients and the finished dosage forms are manufactured at HELINN's cGMP facilities and supplied worldwide to its customers. For more information on HELINN, please visit the company's Web site at www.helsinn.com.

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