Renexxion Achieves Positive FDA Guidance for Phase 3 ready GI Drug Naronapride

Cardiovascular outcome safety study requirement dropped, limited trials required for NDA filing

Menlo Park, California – November 16, 2016 - Renexxion today announced positive guidance on the design of the final pivotal trials required for NDA filing for naronapride, a potentially best-in-class 5HT-4 agonist for treatment of GI motility disorders.

At a recent meeting of the FDA's Division of Gastroenterology and Inborn Errors Products (DGIEP), and the Center for Drug Evaluation and Research's (CDER) new Safety Outcomes Trials (SOT) Subcommittee, it was agreed that the necessary safety database for naronapride development for chronic idiopathic constipation (CIC) and other functional GI disorders does not require statistical powering for cardiovascular outcomes. Furthermore, Renexxion was advised that two randomized, blinded placebo-controlled clinical trials of 1000 subjects each of 12 weeks duration in this indication would be sufficient for filing of an NDA for naronapride. The safety trials would be limited to 12 months total exposure in these 2000 subjects in addition to the 982 subjects already exposed in the four positive Phase II studies.

Peter Milner M.D., CEO, said "As a result of cooperative interactions between Renexxion management and the FDA, the agency formally dropped its requirement for preapproval CV safety outcome studies so that there is now a clear pathway to approval in CIC, the largest functional GI market. By agreement with the FDA, the additional 2000 total further exposures in two randomized clinical trials would be NDA-enabling. This path to approval is consistent with some of the other recently approved drugs in constipation indications and is familiar to large pharmaceutical companies."

About GI motility disorders:

GI motility disorders encompass a wide range of disorders of the esophagus, the stomach, the small and large intestines. Disorders associated with these organs include chronic idiopathic constipation (CIC), gastroesophageal reflux disease (GERD) especially those forms resistant to treatment with a proton pump inhibitor (PPI), delayed gastric emptying – gastroparesis (GP), and constipation due to irritable bowel syndrome (IBSc). Such disorders may be primary or associated with other diseases such as diabetes, or Parkinson's Syndrome. Cisapride (Propulsid®) and tegaserod (Zelnorm®), the two most successful motility agents, each sold over $1B annually, but were withdrawn over 10 years ago due to unexpected cardiac safety concerns discovered after marketing; since then no safe and effective motility agent has been approved.

About naronapride:

Naronapride is a new generation of potentially best-in-class 5HT-4 agonist that stimulates gastrointestinal motility. Naronapride was engineered to avoid any risk of cardiac arrhythmia seen in the older agents in this drug class, such as cisapride and tegaserod, and to reduce undesirable off-target pharmacological effects. In addition to the chronic oral formulation enabled by the recent FDA interaction, an intravenous formulation (or single use oral solution formulation) can be developed for

the growing and important unmet needs in ICU and ventilator units of enteral feeding intolerance (EFI), acute GP, short bowel syndrome (SBS) and post operative ileus (POI). Today there are currently no FDA-approved treatment options available and these indications impact several millions of Americans with EFI alone affecting one million Americans.

About Renexxion:

Renexxion, LLC is a privately held biopharmaceutical company committed to delivering benefits to patients with GI motility disorders by developing naronapride to approval and to becoming a leading GI biopharmaceutical company. www.renexxion.com

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