News Release

AstraZeneca

ASTRAZENECA ANNOUNCES RESULTS FROM LONG-TERM SAFETY TRIAL OF NALOXEGOL IN PATIENTS WITH OPIOID-INDUCED CONSTIPATION

26 February 2013

AstraZeneca today announced high-level results from KODIAC-08, an open-label, randomised, 52-week, long-term safety trial of naloxegol versus usual care (UC) in patients with non-cancer related pain and opioid-induced constipation (OIC). UC was defined as the investigator's choice of an existing laxative treatment regimen for OIC. This is the fourth trial in the naloxegol Phase III development programme, and was designed to evaluate the long-term safety and adverse event (AE) profile of naloxegol in patients taking 25 mg once daily, as compared to UC.

In the trial, a total of 534 patients received naloxegol once daily for up to 52 weeks, while 270 patients received UC for OIC during the same treatment period. The most commonly reported AEs occurring more frequently on naloxegol than on usual care included abdominal pain, diarrhoea, nausea and headache. The trial reported no imbalances in serious adverse events (SAEs). In addition, there were a low number of major adverse cardiovascular events (MACE), as adjudicated by an independent external committee, and there was no imbalance of these events across naloxegol and UC arms.

There were no increases from baseline levels in mean daily pain scores or mean total daily opioid dose in either the naloxegol or the UC arm. Additionally, there were no reports of opioid withdrawal AEs which could be attributed to naloxegol. A full assessment of the safety and tolerability findings is ongoing.

"These high-level results are similar to the safety results seen in the Phase III studies previously reported and provide further confidence in the data we've seen to date for naloxegol," said Briggs Morrison, M.D., Executive Vice President, Global Medicines Development, AstraZeneca. "We have now completed our core Phase III programme and we are pleased to advance naloxegol toward a regulatory submission later this year." A New Drug Application (NDA) filing in the US and a Marketing Authorisation Application (MAA) filing in the EU are planned for the third quarter of 2013, pending AstraZeneca's final preparation of the registration package and a pre-NDA meeting with the FDA.

The core Phase III KODIAC programme for naloxegol is comprised of four clinical trials, designed to investigate the safety and efficacy of naloxegol for the treatment of OIC in patients with non-cancer related pain. Three trials reported high level results in November 2012, including KODIAC-04, -05 and -07. KODIAC-04 and -05 were pivotal 12-week efficacy and safety trials, while KODIAC-07 was a 12-week safety extension of KODIAC-04.

Full results from KODIAC-04 and -05 will be presented at Digestive Disease Week (DDW), 18-21 May, 2013. Full results from KODIAC-07, along with KODIAC-08, will be presented at a scientific meeting later in 2013.

Naloxegol is part of the exclusive worldwide license agreement announced on 21 September 2009, between AstraZeneca and Nektar Therapeutics.

Naloxegol is currently considered a Schedule II controlled substance by the US Drug Enforcement Administration (DEA) based on structural relatedness to noroxymorphone. AstraZeneca has conducted the studies necessary to evaluate the abuse potential and dependence-producing properties of naloxegol in support of obtaining decontrol. A petition for the decontrol of naloxegol was submitted to the DEA in March 2012 and subsequently accepted for review. Commercialisation and launch in the US will be subject to both FDA approval and DEA schedule determination.

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NOTES TO EDITORS

About Naloxegol
Naloxegol is a peripherally-acting mu-opioid receptor antagonist being investigated for the treatment of constipation as a side effect of prescription opioid pain medicines.

Top-line results of the Phase II study of naloxegol (formerly NKTR-118) were previously presented at the American College of Gastroenterology Annual Clinical Meeting and the American Academy of Pain Management Annual Meeting. Naloxegol was developed using Nektar's oral small molecule polymer conjugate technology.

About Opioid-Induced Constipation
Opioids attach to specific proteins called opioid receptors. When the opioids attach to certain opioid receptors in the gastrointestinal tract, constipation may occur. Opioid-induced constipation is a result of decreased fluid absorption and lower gastrointestinal motility due to opioid receptor binding in the gastrointestinal tract.

Globally, approximately 40–50% (28-35 million) of patients taking opioids for long-term pain develop constipation. About 40–50% (11-18 million) of those OIC sufferers achieve the desired treatment outcomes with current options that include over-the-counter and prescription laxatives.

About Nektar
Nektar Therapeutics (NASDAQ: NKTR) is a clinical-stage biopharmaceutical company developing novel therapeutics based on its PEGylation and advanced polymer conjugate technology platforms. Nektar has a robust R&D pipeline of therapeutic candidates in oncology, pain and other areas. The company is headquartered in San Francisco, California, with additional R&D operations in Huntsville, Alabama and Hyderabad, India. Further information about Nektar and its drug development programs and capabilities may be found online at www.nektar.com

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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