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AZ safety data on opioid-constipation drug is out

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Singapore: AstraZeneca released results from its Kodiac-08 open-label, randomized, 52-week, long-term safety trial of naloxegol versus usual care (UC) in patients with non-cancer related pain and opioid-induced constipation (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 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 adverse effects 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. 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.

Dr Briggs Morrison, executive vice president, global medicines development, AstraZeneca, said that, "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. 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 Authorization 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.

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. Commercialization and launch in the US will be subject to both FDA approval and DEA schedule determination.