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MOVANTIK™ (Naloxegol) Tablets For The Treatment Of Opioid-Induced Constipation In Adult Patients With Chronic Non-Cancer Pain Launched In The US

WILMINGTON, Del., March 31, 2015 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) reported that partner AstraZeneca announced today that MOVANTIK™ (naloxegol) has launched in the United States. On September 16, 2014, the US Food and Drug Administration (FDA) approved MOVANTIK as the first once-daily oral peripherally-acting mu-opioid receptor antagonist (PAMORA) medication for the treatment of opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain.

"At AstraZeneca, patients are at the core of what we do every day, and it's this focus that drives us to bring first-in-class oral medicines like MOVANTIK to the market," said Dave Fredrickson, Vice President, Specialty Care, AstraZeneca. "We know many patients taking opioids for chronic non-cancer pain often experience OIC, and we believe MOVANTIK is an important treatment option for those unable to effectively manage their symptoms."

Opioids work by binding to mu-receptors in the brain and other parts of the central nervous system (CNS), but they also bind to mu-receptors in the bowel, which may cause OIC. OIC is one of the most common side effects of opioids and typically persists for the duration of treatment.

The FDA approval of MOVANTIK was based on data from the KODIAC clinical program.

In the KODIAC04 and KODIAC05 trials, response rates at 12 weeks were significantly higher with MOVANTIK 25 mg compared with placebo. The most common adverse reactions with MOVANTIK were abdominal pain, diarrhea, nausea, flatulence, vomiting, headache, and hyperhidrosis.

"MOVANTIK provides an oral treatment option that's specifically designed for patients struggling with opioid-induced constipation. When administered at recommended dose levels, MOVANTIK decreases the constipating effect of opioids by blocking opioids from binding to mu-receptors in the bowel," said Cathy Datto, US Medical Lead at AstraZeneca. "And because of its design, at recommended doses, the central nervous system penetration of MOVANTIK is expected to be negligible, limiting the potential for interference with opioid pain relief."

On March 19, 2015, AstraZeneca announced a co-commercialization agreement with Daiichi Sankyo, Inc. for MOVANTIK in the US, in line with the Company's strategy of delivering value through its own development and commercial capabilities, as well as through external collaboration. The Daiichi Sankyo sales force will join AstraZeneca in the promotion of MOVANTIK in the US by May 2015. AstraZeneca will be responsible for manufacturing, will book all sales and will make sales-related commission payments to Daiichi Sankyo, Inc.

AstraZeneca is committed to supporting patient access to MOVANTIK and connecting patients and physicians with the information and support they need. Please visit www.movantik.com for more information.

IMPORTANT SAFETY INFORMATION ABOUT MOVANTIK

- MOVANTIK is contraindicated in:
  - Patients with known or suspected gastrointestinal (GI) obstruction and patients at increased risk of recurrent obstruction due to the potential for GI perforation
  - Patients receiving strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole) because these medications can significantly increase exposure to naloxegol which may precipitate opioid withdrawal symptoms
  - Patients with a known serious or severe hypersensitivity reaction to MOVANTIK or any of its excipients
- Cases of GI perforation have been reported with the use of another peripherally acting opioid antagonist in patients with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the GI tract. Monitor for severe, persistent, or worsening abdominal pain; discontinue if this symptom develops
- Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, irritability, and yawning, occurred in patients treated with MOVANTIK. Patients receiving methadone as therapy for their pain condition in the clinical trials were observed to have a higher frequency of GI adverse reactions that may have been related to opioid withdrawal than patients receiving other opioids. Patients with disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal or reduced analgesia. These patients were not enrolled in the clinical studies. Take into account the overall risk-benefit profile when using MOVANTIK in such patients. Monitor for symptoms of opioid

withdrawal when using MOVANTIK in such patients
- Avoid concomitant use of moderate CYP3A4 inhibitors (eg, diltiazem, erythromycin, verapamil) because they may increase the risk of adverse reactions. Use of strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort) is not recommended because they may decrease the efficacy of MOVANTIK, Avoid use of MOVANTIK with another opioid antagonist due to the increased risk of opioid withdrawal
- The use of MOVANTIK during pregnancy may precipitate opioid withdrawal in a fetus due to the immature fetal blood-brain barrier. MOVANTIK should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Due to the potential for serious adverse reactions, including opioid withdrawal in nursing infants, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother
- The most common adverse reactions with MOVANTIK as compared to placebo in clinical trials were abdominal pain (21% vs. 7%), diarrhea (9% vs. 5%), nausea (8% vs 5%), flatulence (6% vs 3%), vomiting (5% vs 4%), headache (4% vs. 3%), and hyperhidrosis (3% vs. > 1%)

Please see full US Prescribing Information
http://www.azpicentral.com/movantik/movantik.pdf

NOTES TO EDITORS

About MOVANTIK™ (naloxegol) Tablets

MOVANTIK™ (naloxegol) Tablets is the first FDA approved once-daily oral peripherally-acting mu-opioid receptor antagonist (PAMORA) specifically designed for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. In the Phase III clinical studies, MOVANTIK was administered as a once-daily tablet and was designed to block the binding of opioids to opioid receptors in tissues such as the gastrointestinal (GI) tract.

MOVANTIK is part of the exclusive worldwide licence agreement announced on 21 September 2009 between AstraZeneca and Nektar Therapeutics. MOVANTIK was developed using Nektar's oral small molecule polymer conjugate technology.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit www.astrazeneca-us.com.

About Daiichi Sankyo, Inc.

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, dyslipidemia and bacterial infections used by patients around the world, the Group has also launched treatments for thrombotic disorders and is building new product franchises. Furthermore, Daiichi Sankyo research and development is focused on bringing forth novel therapies in oncology and cardiovascular-metabolic diseases, including biologics. The Daiichi Sankyo Group has created a 'Hybrid Business Model' to respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit: www.daiichisankyo.com. Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit www.dsi.com.

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