AstraZeneca Initiates Phase III Clinical Programme Evaluating NKTR-118 for Treatment of Opioid-Induced Constipation

15th March 2011

AstraZeneca today announced enrolment of the first patient in the Phase III clinical programme for NKTR-118, an oral peripherally-acting opioid antagonist being investigated for the treatment of opioid-induced constipation (OIC). The Phase III clinical programme is designed to investigate the safety and efficacy of NKTR-118 as a medicine to relieve opioid induced constipation, a common side effect of prescription opioids when used for chronic pain management. NKTR-118 is part of the exclusive worldwide license agreement announced on September 21, 2009, between AstraZeneca and Nektar Therapeutics.

The Phase III clinical programme will consist of two 12-week, randomized, placebo-controlled efficacy studies (with approximately 630 randomized patients each) and an open-label, randomized, long-term safety study with a "usual care" comparator arm. The 12 week efficacy studies will compare response rate among placebo and two different doses of NKTR 118 with primary endpoint at 4 weeks. There is a three month safety extension following one of the two 12 week studies.

The long-term safety study will include patients from the 12-week efficacy studies, as well as new patients not previously enrolled. All patients will be randomly assigned to open-label treatment of either NKTR-118 or physician's choice (usual care) laxative regimen. Safety assessments will also be collected throughout the trials.

"This is a key milestone for NKTR-118," said Anders Ekblom, Executive Vice President of Global Medicines Development, AstraZeneca. "We will put our knowledge and our effort into studying NKTR-118 as a potential effective new treatment option for Opioid Induced Constipation, which continues to be an area of unmet need in patients needing effective pain treatment."

The first regulatory filings based on the programme are planned for 2013.

NOTES TO EDITORS:

About NKTR-118
NKTR-118 is an investigational drug candidate being developed as a once-daily oral tablet for the treatment of opioid-induced constipation. It combines Nektar's advanced small molecule polymer conjugate technology platform with naloxol, a derivative of the opioid antagonist drug, naloxone. Top line results of the Phase II study of NKTR-118 were presented in October 2009 at the American College of Gastroenterology Annual Clinical Meeting and the American Academy of Pain Management. In addition, the company is also developing NKTR-119, a co-formulation of oral NKTR-118 and an opioid analgesic.

About Opioid-Induced Constipation
Clinically, OIC is the most prevalent side effect of opioid therapy[9]. For those patients who take opiates for long term pain management, approximately 40-50 percent will develop constipation[6]. Only about 40-50 percent of those patients experience effective relief from the treatment options that include prescription and over-the-counter laxatives and stool softeners[7,8,9].

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation 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

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 programmes and capabilities may be found online at www.nektar.com

Media Enquiries:

Neil McCrae
+44 20 7604 8236 (24 hours)

Sarah Lindgreen
+44 20 7604 8033 (24 hours)

Abigail Baron
+44 20 7604 8034 (24 hours)

Investor Enquiries UK:
Jonathan Hunt
+44 20 7604 8122
mob: +44 7775 704032

Karl Hård
+44 20 7604 8123
mob: +44 7789 654364

Nicklas Westerholm
+44 20 7604 8124
mob: +44 7585 404950

Investor Enquiries US:
Ed Seage
+1 302 886 4065
mob: +1 302 373 1361

Jorgen Winroth
+1 212 579 0506
mob: +1 917 612 4043

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