NEW IBS-C AND CIC TREATMENT CONSTELLA® (LINACLOTIDE) NOW AVAILABLE IN CANADA

CONSTELLA indicated for adults to proactively manage multiple symptoms of irritable bowel syndrome with constipation and chronic idiopathic constipation

Toronto, Ontario – June 27, 2014 – CONSTELLA® (linacotide), approved by Health Canada in December 2013 as a once-daily, first-in-class treatment for both women and men suffering from irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC),1 is now available. Up to 8.9 million Canadians suffer from IBS-C and CIC.2,3,4

IBS-C and CIC are chronic functional gastrointestinal disorders. Symptoms of IBS-C can be debilitating, including abdominal pain, bloating, and altered bowel behaviours.5 CIC is characterized by difficult or infrequent stool passage, but with no underlying physiological abnormalities.6 Of the Canadians with IBS-C or CIC taking prescription medication, 75 per cent are dissatisfied with their current treatment.7

“Some symptoms of CIC and IBS-C, like pain and bloating, can be hard to treat. CONSTELLA alleviates the primary constipation, but also helps with those symptoms too.” says Dr. Paul Moayyedi, gastroenterologist and Acting Director of the Farncombe Family Digestive Health Research Institute. “Patients with chronic constipation often try a number of measures to try to find relief, with varied success – so CONSTELLA® is an important new option.”

CONSTELLA® is the first and only guanylate cyclase-C (GC-C) agonist approved for the treatment of both IBS-C and CIC in adults. CONSTELLA® is a once-daily capsule that helps relieve the chronic abdominal pain and constipation associated with IBS-C, and the constipation and hard stools associated with CIC. The recommended dose is 290 mcg for IBS-C patients and 145 mcg for CIC patients.1

Linaclotide, the active ingredient of CONSTELLA®, binds to GC-C locally in the intestine with minimal systemic exposure.1 Clinical trials for CIC found linaclotide accelerated gastrointestinal transit (increasing bowel movement frequency and reducing constipation). IBS-C clinical trials found that linaclotide reduced abdominal pain and bloating, as well as helping to relieve constipation.1

TRIAL DATA: IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C)
The safety and efficacy of linaclotide for the treatment of IBS-C was established in two double-blind, placebo-controlled Phase III clinical trials of 1,605 patients aged 18 to 87 years old, of which 807 were treated with linaclotide 290 mcg.8,9 Linaclotide 290 mcg significantly reduced abdominal pain; effects were seen within the first week of treatment and improvements were maintained throughout the treatment period. Maximum efficacy in pain relief occurred within six to eight weeks.

Linaclotide also significantly increased the frequency of complete spontaneous bowel movements (CSBM)s, with 20% (Study 1) and 18% (Study 2) of patients treated with linaclotide experiencing at least three CSBM$s and an increase of at least one CSBM from baseline for at least 9 out of 12 weeks versus 6% (Study 1) and 5% (Study 2) of placebo-treated patients. For at least 6 out of 12 weeks, 49% (Study 1) and 48% (Study 2) of linaclotide-treated patients versus 30% (Study 1) and 23% (Study 2) of placebo-treated patients experienced an increase of at least one CSBM from baseline.8,9

Linaclotide-treated patients also had a significant improvement from baseline in the secondary endpoints of abdominal discomfort, bloating, stool consistency and straining, compared to placebo.8,9
The most common adverse events in the clinical trials of IBS-C patients treated with linaclotide were diarrhea (19.8 per cent; versus 3.0 per cent with placebo), abdominal pain (5.1 per cent; versus 3.3 per cent with placebo), and flatulence (4.3 per cent; versus 1.9 per cent with placebo). Severe diarrhea was reported in 2 per cent of linaclotide-treated patients.\textsuperscript{8,9}

**TRIAL DATA: CHRONIC IDIOPATHIC CONSTIPATION (CIC)**

The safety and efficacy of linaclotide for the management of CIC was established in two double-blind, placebo-controlled Phase III clinical trials in which linaclotide met the primary endpoint in both trials. The trials involved 1,272 patients aged 18 to 85 years old, of which 430 received linaclotide 145 mcg and 422 received linaclotide 290 mcg. Prior to treatment, patients reported an average baseline of 0.3 CSBM per week, compared to three or more CSBM per week following treatment.\textsuperscript{10}

At the 145 mcg dose linaclotide significantly increased the frequency of CSBMs in linaclotide-treated patients. At the 145 mcg dose, 21% (Study 3) and 16% (Study 4) of linaclotide-treated patients experienced at least 3 CSBMs and an increase of at least one CSBM from baseline in the same week for at least 9 of the 12 weeks, versus 3% (Study 3) and 6% (Study 4) of placebo patients. Patients taking linaclotide also experienced significant improvement in stool frequency and hardness of stool compared to placebo.\textsuperscript{10}

The most common adverse events in the clinical trials of CIC patients treated with a 145 mcg dose of linaclotide were diarrhea (16 per cent; versus 4.7 per cent with placebo), abdominal pain (4 per cent; versus 3.1 per cent with placebo), and flatulence (5.6 per cent; versus 5.2 per cent with placebo). Severe diarrhea was reported in 1.8 per cent of linaclotide-treated patients.\textsuperscript{10}

**ABOUT CONSTELLA® (LINACLOTIDE)**

Linaclotide binds to GC-C locally in the intestine, resulting in an increase in both intracellular and extracellular concentrations of cyclic guanosine monophosphate (cGMP). Elevations in intracellular cGMP are believed to stimulate secretion of intestinal fluid and accelerate gastrointestinal transit resulting in increased frequency of bowel movements. Elevations in extracellular cGMP are believed to decrease activity of pain-sensing nerves, which is thought to be responsible for a reduction in intestinal pain, according to nonclinical models.\textsuperscript{1}

Linaclotide and its active metabolite are not measurable in plasma following administration of the recommended clinical doses; as such, no systemic drug-drug interactions or drug interactions mediated by plasma protein binding of linaclotide or its metabolite are expected.\textsuperscript{1}

**About Forest Laboratories and Its Products**

Forest Laboratories (NYSE: FRX) is a leading, fully integrated, specialty pharmaceutical company largely focused on the United States market. The Company markets a portfolio of branded drug products and develops new medicines to treat patients suffering from diseases principally in five therapeutic areas: central nervous system, cardiovascular, gastrointestinal, respiratory, and anti-infective. Our strategy of acquiring product rights for development and commercialization through licensing, collaborative partnerships and targeted mergers and acquisitions allows us to take advantage of attractive late-stage development and commercial opportunities, thereby managing the risks inherent in drug development. The Company is headquartered in New York, NY. To learn more, visit [www.FRX.com](http://www.FRX.com).
Except for the historical information contained herein, this release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, and the risk factors listed from time to time in Forest Laboratories’ Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and any subsequent SEC filings. Forest assumes no obligation to update forward-looking statements contained in this release to reflect new information or future events or developments.

Forest Laboratories Canada Inc. is a subsidiary of Forest Laboratories, Inc. and is a member of Rx&D. Canadian operations are based in Vaughan, Ontario. To learn more, visit www.FRX.ca.

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1 CONSTATELLA® (linaclotide) Product Monograph, Forest Laboratories Canada Inc. May 12, 2014.
9 Satish Roa, et al. A 12-Week, Randomized, Controlled Trial with a 4-week randomized withdrawal period to evaluate the efficacy and safety of linaclotide in irritable bowel syndrome with constipation. Am J Gastroenterol, Volume 107, Number 11, November 2012.