BAUSCH Health

Salix And US WorldMeds Enter Into Exclusive Co-Promotion Agreement For Opioid Withdrawal Treatment LUCEMYRA™ (lofexidine)

June 26, 2018

Salix Sales Force to Begin Promoting LUCEMYRA to Primary Care and Pain Management Physicians

LUCEMYRA is the First and Only Non-Opioid Medication Approved for Mitigation of Opioid Withdrawal Symptoms

LOUISVILLE, Ky. and BRIDGEWATER, N.J., June 26, 2018 /PRNewswire/ -- US WorldMeds, LLC and Salix Pharmaceuticals, a division of Valeant Pharmaceuticals North America LLC ("Salix"), one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases and a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX) ("Valeant"), today announced that they have entered into an exclusive agreement to co-promote US WorldMeds' LUCEMYRA™ (lofexidine). The U.S. Food and Drug Administration ("FDA") approved LUCEMYRA on May 16, 2018 as the first and only non-opioid medication for the mitigation of withdrawal symptoms to facilitate abrupt discontinuation of opioids in adults.

Opioid withdrawal is an often-overlooked medical challenge in the current opioid epidemic, which has reached dangerous levels. More than 115 people in the United States die each day after overdosing on opioid-based products, according to a 2017 report from the Centers for Disease Control and Prevention.[1]

"Partnering with Salix, which has a strong commercial presence in primary care and pain management, will provide greater momentum and broader reach for the launch and uptake of LUCEMYRA – including the critical need for education around opioid withdrawal and the appropriate use of LUCEMYRA," said P. Breckinridge Jones, chief executive officer, US WorldMeds. "We look forward to making LUCEMYRA available to health care providers and their patients who urgently need help discontinuing opioid use."

From a clinical standpoint, symptoms of withdrawal are one of the most powerful drivers of opioid dependence and addictive behaviors. Many people have such difficulty tolerating these symptoms that the desire to avoid them can perpetuate their opioid use.[2]

"Research indicates that withdrawal fear is contributing to the U.S. opioid public health issue.[2] We believe an important step in addressing this epidemic is to empower patients with the ability to endure opioid withdrawal and provide a starting point towards recovery," said Mark McKenna, senior vice president and general manager, Salix. "We have developed a national sales footprint in pain management with RELISTOR® (methylnaltrexone bromide), a treatment for opioid-induced constipation, and with the addition of LUCEMYRA, we can now offer a second solution in our portfolio to address the complexities of treatment with opioid-based pain medications."

The approval of LUCEMYRA was supported by two randomized, double-blind, placebo-controlled clinical trials, an open-label study and several clinical pharmacology studies with concomitant

administration of either methadone, buprenorphine or naltrexone. The FDA reviewed the New Drug Application for LUCEMYRA under Priority Review, which is granted to submissions for medications that would provide significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions.

LUCEMYRA is expected to be commercially available in the United States in August.

LUCEMYRA INDICATIONS

LUCEMYRA is indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

LUCEMYRA SAFETY INFORMATION

LUCEMYRA may cause hypotension, bradycardia, and syncope. Avoid using LUCEMYRA in patients with severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, or marked bradycardia. LUCEMYRA should be used with caution with any medications that decrease pulse or blood pressure to avoid the risk of excessive bradycardia and hypotension. Patients using LUCEMYRA should be monitored for symptoms related to bradycardia and orthostasis.

LUCEMYRA prolongs the QT interval and should be avoided in patients with congenital long QT syndrome. Monitor ECG in patients using LUCEMYRA who have renal or hepatic impairment, known QT prolongation, metabolic disturbances, pre-existing cardiovascular disease, relevant family history, or those taking drugs known to prolong the QT interval.

LUCEMYRA potentiates the depressant effects of benzodiazepines and may potentiate the CNS depressant effects of alcohol, barbiturates, and other sedating drugs.

During and after opioid discontinuation, patients are at an increased risk of fatal overdose should they resume opioid use; patients and caregivers should be informed of this increased risk. In patients with opioid use disorder, LUCEMYRA should be used in conjunction with a comprehensive treatment program.

LUCEMYRA treatment should be discontinued with gradual dose reduction.

The most commonly reported adverse reactions associated with LUCEMYRA treatment (incidence ≥10% and notably more frequent than placebo) are orthostatic hypotension, bradycardia, hypotension, dizziness, somnolence, sedation, and dry mouth.

Dose adjustment of LUCEMYRA is required in patients with hepatic or renal impairment. Before prescribing, see dosage recommendation tables in Full Prescribing Information.

There are no contraindications for taking LUCEMYRA.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact US WorldMeds at 1-833-LUCEMYRA or FDA at 1-800-FDA-1088 or
www.fda.gov/medwatch
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Please click
here
to access the full U.S. Prescribing Information for LUCEMYRA.

RELISTOR Indications

- RELISTOR® (methylnaltrexone bromide) is a prescription medicine used to treat constipation in adults that is caused by prescription pain medicines called opioids.
- RELISTOR tablets and RELISTOR injection are used to treat constipation caused by opioids in adults with long-lasting (chronic) pain that is not caused by active cancer.
- RELISTOR injection is also used to treat constipation caused by opioids in adults with advanced illness or pain caused by active cancer and who need increases in their opioid dose for pain management.

RELISTOR SAFETY INFORMATION

- Do not take RELISTOR if you have a bowel blockage (called an intestinal obstruction) or have a history of bowel blockage.
- RELISTOR can cause serious side effects such as a tear in your stomach or intestinal wall (perforation). Stomach pain that is severe can be a sign of a serious medical condition.
- Stop using RELISTOR if you get diarrhea that is severe or that does not go away during treatment with RELISTOR.
- You may have symptoms of opioid withdrawal during treatment with RELISTOR including sweating, chills, diarrhea, stomach pain, anxiety, and yawning.
- Tell your health care provider if you have: any stomach or bowel (intestines) problems, including stomach ulcer, Crohn's disease, diverticulitis, cancer of the stomach or bowel, or Ogilvie's syndrome; kidney or liver problems.
- Taking RELISTOR during pregnancy may cause opioid withdrawal symptoms in your unborn baby. Breastfeeding is not recommended.
- The most common side effects are:
  - Adult patients with chronic non-cancer pain: abdominal pain, diarrhea, headache, abdominal distention, vomiting, hyperhidrosis, anxiety, muscle spasms, rhinorrhea, hot flush, tremor and chills
  - Adult patients with advanced illness: abdominal pain, flatulence, nausea, dizziness and diarrhea.

You are encouraged to report side effects of prescription drugs to FDA. Visit
www.fda.gov/medwatch
, or call 1-800-FDA-1088.

For product information, adverse event reports, and product complaint reports, please contact:

Salix Product Information Call Center
Phone: 1-800-321-4576
Fax: 1-510-595-8183
Email:
salixmc@dlss.com

Please click
here
for full Prescribing Information for RELISTOR tablets and RELISTOR injection.

About LUCEMYRA (lofexidine)

LUCEMYRA (lofexidine), an oral tablet, is a central alpha 2-adrenergic agonist that reduces the release of norepinephrine to suppress the neurochemical surge that produces opioid withdrawal. It is indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults. In clinical trials, LUCEMYRA significantly reduced the severity of withdrawal symptoms compared to placebo, as reported by patients experiencing opioid withdrawal. LUCEMYRA is administered in three 0.18 mg tablets taken orally four times daily at

five- to six-hour intervals during the period of peak withdrawal symptoms (generally five to seven days following last use of opioids); total treatment may continue for up to 14 days, with dosing guided by symptoms. LUCEMYRA should be discontinued with gradual dose reduction over two to four days.

About Opioid Withdrawal

Opioids lower norepinephrine, a brain chemical that supports vital functions like respiration and consciousness. With continued opioid use, the brain establishes a new equilibrium by increasing compensatory norepinephrine production in order to maintain normal functioning. When opioids are removed, or the dose is significantly reduced, the brain's increased norepinephrine levels are no longer offset by the presence of the opioids. This results in a norepinephrine surge that produces the acute and painful symptoms of withdrawal.

About US WorldMeds

US WorldMeds is a specialty pharmaceutical company whose products are making a difference in the lives of the patients and communities it serves. US WorldMeds takes an agile and personal approach to pharmaceuticals – pioneering research and product development in therapeutic areas that desperately need new solutions. Headquartered in Louisville, Kentucky, US WorldMeds has global presence and more than 15 years of experience in the development, licensure, and commercialization of unique products. For more information about US WorldMeds, visit http://www.usworldmeds.com/ . Follow US WorldMeds on Twitter , LinkedIn and Facebook .

About Salix

Salix is one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases. For almost 30 years, Salix has licensed, developed, and marketed innovative products to improve patients' lives and arm health care providers with life-changing solutions for many chronic and debilitating conditions. Salix currently markets its product line to U.S. health care providers through an expanded sales force that focuses on gastroenterology, hepatology, pain specialists, and primary care. Salix is headquartered in Bridgewater, New Jersey.

About Valeant

Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health.

Forward-looking Statements

This news release may contain forward-looking statements which may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of

management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, risks and uncertainties discussed in Valeant's most recent annual or quarterly report and detailed from time to time in Valeant's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Neither Valeant nor US WorldMeds undertakes any obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

References

[1] CDC/NCHS, National Vital Statistics System, Mortality. CDC Wonder, Atlanta, GA: US Department of Health and Human Services, CDC; 2017. https://wonder.cdc.gov.

[2] Kosten TR, George TP. The Neurobiology of Opioid Dependence: Implications for Treatment. *Science & Practice Perspectives. 2002*;1(1):13-20.

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