BAUSCH Health

US WorldMeds And Salix Pharmaceuticals To Highlight Clinical Data For Opioid Withdrawal Treatment LUCEMYRA™ (lofexidine) At 2018 PAINWeek Conference

September 04, 2018

LOUISVILLE, Ky. and BRIDGEWATER, N.J., Sept. 4, 2018 /PRNewswire/ -- US WorldMeds and Salix Pharmaceuticals, 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 Bausch Health Companies Inc. (NYSE/TSX: BHC), will present data evaluating the efficacy and safety of LUCEMYRA™ (lofexidine) 0.18 mg tablets at the 2018 PAINWeek Conference in Las Vegas from September 4-8. LUCEMYRA is the first and only non-opioid medication indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

The full schedule of research to be presented includes:

- Joseph Pergolizzi, MD. "*Opioid Discontinuation – A New Treatment Option.*" Tuesday, September 4 at 3:40 – 4:30 PM PT in Brera Ballroom, Level 3.
- Joseph Pergolizzi, MD. Poster 56. *"Efficacy of Lofexidine for Opioid Withdrawal Syndrome: Focus on Pain Symptoms."* Thursday, September 6 at 6:30 – 8:30 PM PT in Condesa Commons, Level 2.
- Robert Raffa, PhD. Poster 93. "*Lofexidine: Not just your father's alpha-2 agonist*." Thursday, September 6 at 6:30 – 8:30 PM PT in Condesa Commons, Level 2.
- Mark Pirner, MD, PhD. Poster 80. "*Efficacy and Safety of Lofexidine for Opioid Withdrawal Syndrome: Pooled Analysis of Phase 3 Studies*." Thursday, September 6 at 6:30 – 8:30 PM PT in Condesa Commons, Level 2.
    - Oral Presentation on Friday, September 7 at 7:08 AM PT in Gracia 5, Level 2.

"On the heels of the recent commercial launch and availability of LUCEMYRA, we remain committed to advancing research that helps the healthcare community better understand how to appropriately manage opioid withdrawal symptoms, recognize the role of withdrawal in perpetuating misuse or interfering with recovery, and ultimately help more people successfully discontinue opioid use," said Lee Warren, chief operating officer, US WorldMeds.

"Salix will be sharing various, new data sets across our portfolio at PAINWeek, the nation's largest pain conference. The data to be presented exemplify our commitment to advancing patient care in multiple areas of pain management," said Mark McKenna, president, Salix.

LUCEMYRA is not an opioid drug and is not a treatment for Opioid Use Disorder (OUD) (sometimes known as opioid addiction). For people who have been diagnosed with OUD, withdrawal management alone, with or without LUCEMYRA, is not recommended; LUCEMYRA should be used as part of a comprehensive management program created by a healthcare provider.

Indications

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

Important Safety Information for Patients

- LUCEMYRA will not stop you from craving opioids.
- LUCEMYRA is not an opioid and will not produce the effects seen when taking opioids.
- LUCEMYRA may lessen the severity of symptoms, but it may not completely prevent them.

After a period of not using opioids, you may be more sensitive to the effects of lower amounts of opioids. Taking opioids in amounts that you used before stopping opioid use, whether with or without LUCEMYRA, can lead to overdose and death. It is important that you, your family, and the people closest to you are aware of this increased risk of overdose.

Alcohol, barbiturates, and benzodiazepines should be used with caution while taking LUCEMYRA as serious side effects may occur.

Tell your healthcare provider if you have ever been diagnosed with kidney disease or liver disease.

LUCEMYRA may cause low blood pressure or slower heart rate. Tell your healthcare provider if you have ever been diagnosed with low blood pressure, slow heart rate, any other cardiac abnormality (including prior diagnosis or family history of long QT syndrome), or if you have had a heart attack.

Tell your healthcare provider about all medications you are taking. LUCEMYRA should be used with caution with any medications that decrease pulse or blood pressure.

Watch for signs of a drop in your blood pressure or heart rate, including dizziness, lightheadedness, or feelings of faintness either when sitting or if you quickly stand up. If you experience these symptoms, call your healthcare provider and do not take your next dose of LUCEMYRA until you have talked to your healthcare provider.

It is important to stay hydrated while taking LUCEMYRA during opioid discontinuation or withdrawal.

The most common side effects seen with LUCEMYRA are low blood pressure or symptoms such as lightheadedness, slow heart rate, dizziness, sleepiness, and dry mouth.

Talk to your healthcare provider before taking other medications for individual symptoms of withdrawal (such as pain relievers, sleep aids, or medications for upset stomach). Your healthcare provider will tell you whether it is safe to take LUCEMYRA with other medications you may be

prescribed during opioid discontinuation (such as buprenorphine/naloxone, methadone, naltrexone).

LUCEMYRA should not be stopped abruptly. Consult your healthcare provider before stopping or reducing your LUCEMYRA dose.

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 and Patient Information for LUCEMYRA.

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
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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 healthcare 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 Bausch Health

Bausch Health Companies Inc. (NYSE/TSX: BHC) 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. More information can be found at
www.bauschhealth.com
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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 Bausch Health's most recent annual or quarterly report and detailed from time to time in Bausch Health'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 Bausch Health 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.

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