BioDelivery Sciences Announces the Availability of BUNAVAIL™ in the U.S.

November 3, 2014

BUNAVAIL Is the First and Only Buccal Film Formulation of Buprenorphine and Naloxone for the Maintenance Treatment of Opioid Dependence

BUNAVAIL Shipped to Wholesalers; Pharmacy Availability Anticipated by End of This Week

RALEIGH, N.C., Nov. 3, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (BDSI) (NASDAQ: BDSI) announced that BUNAVAIL™ (buprenorphine and naloxone) buccal film (CIII) is now commercially available. FDA-approved for the maintenance treatment of opioid dependence and to be used as part of a complete treatment plan to include counseling and psychosocial support, BUNAVAIL has been shipped to wholesalers and is anticipated to be available by prescription at retail pharmacies across the U.S. by the end of this week, thus commencing the full U.S. launch.

"Today marks a significant organizational milestone as BDSI transitions to a commercial entity with the launch of BUNAVAIL," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. "We are very pleased to introduce the first and only FDA-approved buccal film formulation of buprenorphine and naloxone. For the over two and a half million people dependent on opioids, the introduction of BUNAVAIL represents a valuable addition to currently available treatment options for the appropriate patients and their healthcare professionals."

"As expressed during our investor call a few weeks ago, the extra time we have had in the field, has given our sales force the opportunity to make a significant number of visits to our target customers and to give them the information and tools needed to initiate prescribing of BUNAVAIL, while simultaneously increasing our available product stock," said David Acheson, Vice President of Sales and Managed Markets. "We are very encouraged by the initial receptivity to BUNAVAIL's attributes, which are driven by the BEMA delivery technology, as well as by the early wholesaler orders that are being shipped this week."

In March 2014, BDSI entered into an agreement with Quintiles to support the launch and subsequent commercialization of BUNAVAIL in the U.S. BUNAVAIL is supported by an experienced, sixty person field sales team as well as a team of Medical Science Liaisons (MSLs). Separately, BDSI has entered into an agreement with Ashfield Market Access to provide managed markets and trade support for BUNAVAIL. Ashfield Market Access is actively in the process of executing a payer strategy aimed at maximizing patient access to BUNAVAIL. At launch, it is anticipated that BUNAVAIL will be available to approximately 165 - 175 million covered commercial lives.

BUNAVAIL was designed using BDSI's patented, thin film drug delivery technology, BioErodible MucoAdhesive (BEMA®), allowing for the efficient and convenient delivery of buprenorphine while potentially overcoming some of the administration challenges presented by the sublingual (under the tongue) dosage forms currently available.

BUNAVAIL is the first and only formulation of buprenorphine and naloxone for buccal (inside of the cheek) administration. The ability of BUNAVAIL to stick on the inside of the cheek, unlike sublingual products that need to be kept in place under the tongue until they dissolve, allows patients to talk, swallow and go about normal daily activities while the medication is being consistently absorbed.

BUNAVAIL was assessed in a Phase 3 clinical study in 249 patients who were converted from Suboxone sublingual tablet or film to BUNAVAIL. In this study, BUNAVAIL demonstrated favorable safety and efficacy in the maintenance treatment of opioid dependence as demonstrated by the high study retention rate and the low frequency of patients with positive urine tests for non-prescribed opioids over the 12-week period. The majority of patients who participated found BUNAVAIL easy to use and pleasant in taste. Additionally, prior to conversion to BUNAVAIL, about 40 percent of patients were experiencing constipation while receiving Suboxone tablet or film, a common problem with chronic opioid use, and more than two-thirds of these patients reported resolution of symptoms when they switched from Suboxone to BUNAVAIL.

BUNAVAIL is the first film formulation of buprenorphine to compete directly with Suboxone sublingual film. In 2013, sales of Suboxone sublingual film increased to more than $1.3 billion in the U.S. according to data from Symphony Health Solutions.

About Opioid Dependence

Opioid dependence is a significant and undertreated condition in the U.S., with 2.5 million people dependent on opioids in 2012 according to the National Institute on Drug Abuse (NIDA). Suboxone, which was approved for the treatment of opioid dependence in 2002, has been shown to be a highly effective treatment option and, as a result, currently generates annual sales of more than $1.3 billion according to data from Symphony Health Solutions. According to the World Health Organization, opioid dependence is a complex health condition that often requires long-term treatment and care. The treatment of opioid dependence is important to reduce its health and social consequences and to improve the well-being and social functioning of people affected. The main objectives of treating and rehabilitating persons with opioid dependence are to reduce dependence on illicit drugs; to reduce the morbidity and mortality caused by the use of illicit opioids, or associated with their use, such as infectious diseases; to improve physical and psychological health; to reduce criminal behavior; to facilitate reintegration into the workforce and education system and to improve social functioning. The achievement of a drug free state is the ideal and ultimate objective.

About BioDelivery Sciences International

BioDelivery Sciences International, Inc. (NASDAQ:BDSI) is a specialty pharmaceutical company with a focus in the areas of pain management and addiction medicine. BDSI is utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA®) technology and other drug delivery technologies to develop and commercialize, either on its own or in partnership with third parties, new applications of proven therapies aimed at addressing important

unmet medical needs.

BDSI's development strategy focuses on utilization of the FDA's 505(b)(2) approval process. This regulatory pathway creates the potential for more timely and efficient approval of new formulations of previously approved therapeutics.

BDSI's particular area of focus is the development and commercialization of products in the areas of pain management and addiction. These are areas where BDSI believes its drug delivery technologies and products can best be applied to address critical unmet medical needs. BDSI's marketed products and those in development address serious and debilitating conditions such as breakthrough cancer pain, chronic pain, painful diabetic neuropathy and opioid dependence.

BDSI's headquarters is located in Raleigh, North Carolina.

For more information visit www.bdsi.com.

BDSI can now be followed on Facebook (Facebook.com/BioDeliverySI) and Twitter (Twitter.com/BioDeliverySI)

About BUNAVAIL

INDICATION

BUNAVAIL (buprenorphine and naloxone) Buccal Film (CIII) is a prescription medicine indicated for the maintenance treatment of opioid dependence. BUNAVAIL should be used as part of a complete treatment plan to include counseling and psychosocial support.

Prescription use of this product is limited under the Drug Addiction Treatment Act (DATA).

IMPORTANT SAFETY INFORMATION

Keep BUNAVAIL (buprenorphine and naloxone) Buccal Film (CIII) out of the sight and reach of children. Ingestion of BUNAVAIL by a child may cause severe breathing problems and death. If a child takes BUNAVAIL, get emergency help right away.

Do not take BUNAVAIL if you are allergic to buprenorphine or naloxone, as serious negative effects including anaphylactic shock, have been reported.

Do not take BUNAVAIL before the effects of other opioids (e.g., heroin, methadone, oxycodone, morphine) have lessened as you may experience withdrawal symptoms.

Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how BUNAVAIL affects you.

BUNAVAIL contains buprenorphine, an opioid that can cause physical dependence. Your doctor can tell you more about the difference between physical dependence and drug addiction. Do not stop taking BUNAVAIL without talking to your doctor. You could become sick with uncomfortable withdrawal symptoms because your body has become used to this medicine.

Do not switch from BUNAVAIL to other medicines that contain buprenorphine without talking with your doctor. The amount of buprenorphine in a dose of BUNAVAIL is not the same as the amount of buprenorphine in other medicines. Your doctor will prescribe a dose of BUNAVAIL that may be different than other buprenorphine-containing medicines you may have been taking.

BUNAVAIL can cause serious life-threatening breathing problems, overdose and death, particularly when taken by the intravenous (IV) route in combination with benzodiazepines, sedatives, tranquilizers or alcohol. You should not drink alcohol while taking BUNAVAIL, as this can lead to loss of consciousness or even death.

Like other opioids (e.g., heroin, methadone, oxycodone, morphine), BUNAVAIL may produce orthostatic hypotension ('dizzy spells') in ambulatory individuals.

Common side effects of BUNAVAIL include headache, drug withdrawal syndrome, lethargy (lack of energy), sweating, constipation, decrease in sleep (insomnia), fatigue and sleepiness.

Because BUNAVAIL contains naloxone, injecting BUNAVAIL may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

BUNAVAIL can be abused in a manner similar to other opioids, legal or illicit. Keep BUNAVAIL in a safe place. Do not give your BUNAVAIL to other people, it can cause them harm or even death. Selling or giving away this medicine is against the law.

BUNAVAIL is not recommended in patients with severe hepatic impairment. BUNAVAIL may be used with caution for maintenance treatment in patients with moderate hepatic impairment.

Before taking BUNAVAIL, tell your doctor if you are pregnant or plan to become pregnant. If you become pregnant while taking BUNAVAIL, tell your doctor immediately as there may be significant risks to you and your baby; your baby may have symptoms of withdrawal at birth.

Before taking BUNAVAIL, talk to your doctor if you are breast-feeding or plan to breast-feed your baby. BUNAVAIL can pass into your breast milk and may harm your baby. Monitor your baby for increased sleepiness and breathing problems. Your doctor should tell you about the best way to feed your baby if you are taking BUNAVAIL.

This is not a complete list of potential adverse events associated with BUNAVAIL Buccal Film. Please see full Prescribing Information for a complete list.

To report negative side effects associated with taking BUNAVAIL Buccal Film, please call 1-800-469-0261. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information, please see full Prescribing Information and Medication Guide for BUNAVAIL™ Buccal Film (CIII)

Cautionary Note on Forward-Looking Statements

This press release and any statements of employees, representatives and partners of BioDelivery Sciences International, Inc. (the "Company") related thereto (including, without limitation, at the presentations described herein) contain, or may contain, among other things, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the results of the commercial launch of BUNAVAIL) may differ significantly from those set forth in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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