BioDelivery Sciences to Develop a Long-Acting Injectable Depot Formulation of Buprenorphine with Evonik for Use in Opioid Dependence and Pain

October 28, 2014

Complementary to BUNAVAIL™; Potential to Leverage Current Addiction Sales Force

RALEIGH, N.C., Oct. 28, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (BDSI) (NASDAQ: BDSI) has entered into an exclusive agreement with Evonik Corporation to develop and commercialize a proprietary, injectable microparticle formulation of buprenorphine potentially capable of providing 30 days of continuous therapy following a single subcutaneous injection.

While BDSI plans to pursue an indication for the maintenance treatment of opioid dependence, the company has also secured the rights and plans to develop a product for the treatment of chronic pain in patients requiring continuous opioid therapy. BDSI has also secured options to license Evonik-owned intellectual property related to these products.

It is estimated that approximately 2.5 million people in the U.S. are dependent on prescription opioids or heroin. Despite the availability of effective treatments, including BUNAVAIL (buprenorphine and naloxone) buccal film, challenges remain regarding patient adherence to long-term buprenorphine treatment, which is critical to successfully manage opioid dependence.

"Given our significant experience with buprenorphine in both opioid dependence and chronic pain, we believe this is an ideal opportunity for BDSI to extend our franchise in both of these areas as the need remains high," said Dr. Andrew Finn, Executive Vice President of Product Development for BDSI. "We look forward to working closely with Evonik to expeditiously complete formulation development work and move the product into the clinic late next year. Since this will be a 505(b)(2) development program, we believe there may be an opportunity to move toward an NDA submission for opioid dependence in approximately three years time."

"Evonik is pleased to work with BDSI on the development of this novel long-acting buprenorphine product," said Dr. Jean-Luc Herbeaux, head of Evonik's Global Health Care Business Line. "With its broad range of competencies in API and drug delivery systems, Evonik strives to support customers in the development and launch of novel medical treatments. Using our proprietary FormEZE® microparticle technology and Resomer® biomaterials, this pharmaceutical will be manufactured at our state-of-the-art facility in Birmingham, Alabama."

"The potential availability of a long-acting formulation of buprenorphine has the opportunity to significantly advance the treatment of opioid dependence and furthers our commitment to this underserved treatment area," said Dr. Mark A. Sirgo, President and Chief Executive Officer. "Not only would a single monthly injection provide an opportunity to substantially improve adherence to buprenorphine treatment, which is a formidable problem for many patients, it could also help to eliminate the problem of diversion. We also believe this will be an outstanding companion product to BUNAVAIL and, if approved, provides another product for our existing sales team."

As part of the agreement, BDSI will have the right to license the product(s) following the attainment of Phase I ready formulations. At that point, Evonik could receive downstream payments for milestones related to regulatory filings and subsequent NDA approvals as well as product royalties. Evonik has the exclusive rights to develop the formulation and manufacture the product(s).

About Evonik

Evonik, the creative industrial group from Germany, is one of the world leaders in specialty chemicals. Profitable growth and a sustained increase in the value of the company form the heart of Evonik's corporate strategy. Its activities focus on the key megatrends health, nutrition, resource efficiency and globalization. Evonik benefits specifically from its innovative prowess and integrated technology platforms.

Evonik is active in over 100 countries around the world. In fiscal 2013, more than 33,500 employees generated sales of around €12.7 billion and an operating profit (adjusted EBITDA) of about €2.0 billion.

For additional information about Evonik in North America, please visit our website: www.evonik.com/north-america

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, the event described herein, 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 Company's collaboration with Evonik and the timing for the development of the product described herein) 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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