BioDelivery Sciences Acquires North American Marketing Authorizations for ONSOLIS from Meda

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Transaction provides BDSI the opportunity to seek a new partner for ONSOLIS in the U.S., Canada and Mexico

RALEIGH, N.C., Jan. 27, 2015 /PRNewswire/ -- BioDelivery Sciences International, Inc. (BDSI) (NASDAQ: BDSI) announced that it has entered into an assignment and revenue sharing agreement with Meda AB (Meda) under which Meda will transfer the marketing authorizations for ONSOLIS® (fentanyl buccal soluble film, CII) for the United States and the right to seek marketing authorizations for ONSOLIS in Canada and Mexico, back to BDSI. BDSI originally licensed such rights to Meda in 2007, and ONSOLIS was approved by the U.S. Food and Drug Administration (FDA) and originally commercially launched in the United States in 2009.

Meda has over the past few years decided to primarily focus on the respiratory area in the U.S., which led to the present agreement that provides BDSI with an opportunity to seek one or more new commercial partners for ONSOLIS. BDSI will have the right to work directly with the FDA to bring ONSOLIS back to the marketplace in the U.S.

Under the agreement, financial terms have been established that enable Meda to share in the proceeds of any new North American partnership for ONSOLIS that may be executed by BDSI, and the execution of such a transaction by BDSI will require execution of a definitive termination agreement embodying those royalty-sharing terms and certain other provisions.

"BDSI is looking forward to the opportunity to secure a new commercial partner and in working directly with the FDA to move ONSOLIS back to the U.S. marketplace," stated Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. "ONSOLIS in our view is a differentiated transmucosal fentanyl product for treating breakthrough cancer pain, and we look forward to finding a new commercial partner to work along side of us to bring it back to the U.S. marketplace. Our first action will be to submit the necessary data requested by FDA that we have generated which we believe will answer the formulation questions raised in the past. We will be preparing to make that submission this quarter. In addition, we are already in discussions with potential commercial partners."

Meda also holds the European rights to ONSOLIS (where it is marketed as BREAKYL) via license from BDSI, and BDSI has also previously licensed certain rights to the product in Taiwan, where it is approved and marketed by TTY Biopharm, and in South Korea where it is licensed to Kunwha Pharmaceutical Company.

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)

INDICATION

ONSOLIS (fentanyl buccal soluble film, CII) is indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, **who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.** Patients considered opioid tolerant are those who are taking at least: 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer.

The most serious adverse reactions associated with all opioids, including ONSOLIS, are respiratory depression (potentially leading to apnea or respiratory arrest), circulatory depression, hypotension, and shock. Follow all patients for symptoms of respiratory depression.

In ONSOLIS trials, the most common adverse reactions (frequency ≥10%) were nausea, vomiting, dehydration, asthenia, dyspnea, fatigue, constipation, dizziness, and somnolence.

WARNINGS: IMPORTANCE OF PROPER PATIENT SELECTION and POTENTIAL FOR ABUSE

ONSOLIS contains fentanyl, an opioid agonist and a Schedule II controlled substance, with abuse liability similar to other opioid analgesics. This should be considered when prescribing or dispensing ONSOLIS in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion. Schedule II opioid substances, which include morphine, oxycodone, hydromorphone, oxymorphone, and methadone, have the highest potential for abuse and risk of fatal overdose due to respiratory depression.

Serious adverse events, including deaths, in patients treated with other oral transmucosal fentanyl products have been reported. Deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients) and/or improper dosing. The substitution of ONSOLIS for any other fentanyl product may result in fatal overdose.

ONSOLIS is contraindicated for use in opioid non-tolerant patients including those using opioids intermittently, on an as needed basis. ONSOLIS is contraindicated in the management of acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients treated with other fentanyl products.

ONSOLIS is contraindicated in patients with known intolerance or hypersensitivity to any of its components or the drug fentanyl. Anaphylaxis and hypersensitivity have been reported in association with the use of other oral transmucosal fentanyl products.

When prescribing, do not convert patients on a mcg per mcg basis from any other oral transmucosal fentanyl product to ONSOLIS. Patients beginning treatment with ONSOLIS must begin with titration from the 200 mcg dose [see *Dosage and Administration*]. When dispensing, do not substitute an ONSOLIS prescription for any other fentanyl product. Substantial differences exist in the pharmacokinetic profile of ONSOLIS compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl. As a result of these differences, the substitution of ONSOLIS for any other fentanyl product may result in fatal overdose.

ONSOLIS is intended to be used only in the care of opioid-tolerant patients with cancer and only by health care professionals who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.

Special care must be used when dosing ONSOLIS. If the breakthrough pain episode is not relieved, patients should wait at least 2 hours before taking another dose [see *Dosage and Administration*].

Patients and their caregivers must be instructed that ONSOLIS contains a medicine in an amount which can be fatal in children, in individuals for whom it is not prescribed, and in those who are not opioid tolerant. All ONSOLIS films must be kept out of the reach of children [see *Patient Counseling Information*].

The concomitant use of ONSOLIS with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations and may cause potentially fatal respiratory depression [see *Drug Interactions*].

Because of the risk for misuse, abuse, addiction, and overdose, ONSOLIS is available only through a restricted program required by the Food and Drug Administration, called a Risk Evaluation and Mitigation Strategy (REMS). Under the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access program, outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors must enroll in the program. *[see Warnings andPrecautions].* Further information is available at www.TIRFREMSAccess.com or by calling 1-866-822-1483.

For more information, please see the full Prescribing Information and Medication Guide.

Cautionary Note on Forward-Looking Statements

This press release and any statements of 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 anticipated benefits of the Company's reacquisition of rights to ONSOLIS as 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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