BioDelivery Sciences and Collegium Pharmaceutical Announce the Signing of a Licensing Agreement for ONSOLIS® in the U.S.

May 11, 2016

RALEIGH, N.C., May 11, 2016 /PRNewswire/ -- BioDelivery Sciences International, Inc. (Nasdaq: BDSI) and Collegium Pharmaceutical, Inc. (Nasdaq: COLL) today announced the signing of a licensing agreement under which BDSI is granting the exclusive rights to develop and commercialize ONSOLIS® (fentanyl buccal soluble film) in the U.S. to Collegium.

ONSOLIS is an opioid agonist indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

Under terms of the agreement, Collegium will be responsible for the manufacturing, distribution, marketing and sales of ONSOLIS in the U.S. Both companies will collaborate on the ongoing transfer of manufacturing, which includes submission of a Prior Approval Supplement (Supplement) to the U.S. Food and Drug Administration (FDA). Upon approval of the Supplement, the New Drug Application (NDA) and manufacturing responsibility will be transferred to Collegium.

Financial terms of the agreement include:

- $2.5 million upfront non-refundable payment, payable to BDSI within 30 days;
- Reimbursement for a pre-determined amount of the remaining expenses associated with the ongoing transfer of manufacturing of ONSOLIS;
- $4 million upon first commercial sale of ONSOLIS in the U.S;
- Up to $17 million in potential payments based on achievement of performance and sales milestones;
- Upper-teen percent royalties based on various annual U.S. net sales thresholds.

"We are very pleased to enter into this important partnership with a company that has a focus in the pain management area, through their recent FDA approval of Xtampza™ ER, an approved abuse-deterrent opioid and their commitment to the pain category," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. "We believe there remains a significant need for novel delivery technologies for the treatment of breakthrough cancer pain, and we look forward to ONSOLIS potentially returning to the market by mid-2017."

"ONSOLIS is highly complementary to Xtampza™ ER as it allows us to leverage our commercial infrastructure. Many physicians treating patients with cancer-related persistent pain using extended-release oral opioids also need to manage breakthrough pain and can do this effectively with Transmucosal Immediate-Release Fentanyl. Adding this product to our portfolio contributes to our mission of supporting responsible opioid prescribing for patients requiring opioid pain therapies," said Michael Heffernan, Chief Executive Officer of Collegium. "The timing of the potential ONSOLIS launch, expected in mid-2017, allows us to focus the commercial organization on the launch of Xtampza ER for at least the next 12 months."

In January 2015, BDSI entered into an assignment and revenue sharing agreement with Meda, under which Meda transferred the marketing authorizations for ONSOLIS for the United States and the right to seek marketing authorizations for ONSOLIS in Canada and Mexico back to BDSI. ONSOLIS was originally licensed to and launched in the U.S. by Meda. Under the agreement, financial terms were 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 completion of such a transaction by BDSI with Collegium required the execution of a definitive termination agreement between BDSI and Meda embodying those royalty-sharing terms and certain other provisions. Meda continues to commercialize ONSOLIS (marketed under the brand name BREAKYL) in the E.U.

About ONSOLIS®
ONSOLIS is indicated for the management of breakthrough pain in cancer patients (BTPc), 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

Important Safety Information

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 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.

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.

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.

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.

The concomitant use of ONSOLIS with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations and may cause potentially fatal respiratory depression.

Because of the risk for misuse, abuse, and overdose, ONSOLIS is available only through a restricted distribution program.

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 particular area of focus is the development and commercialization of products in the areas of pain management and addiction. For more information, please visit www.bdsi.com.

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 presentation 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 commercialization efforts for ONSOLIS as described herein and the Company's actual receipt of any milestone payments or royalties) 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 presentations or otherwise, except as required by applicable law.

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