



Collegium Licenses the U.S. rights to ONSOLIS® from BioDelivery Sciences

May 11, 2016

Breakthrough cancer pain product added to the portfolio

CANTON, Mass., May 11, 2016 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) announced today the licensing of the U.S. rights to develop and commercialize ONSOLIS® (fentanyl buccal soluble film) from BioDelivery Sciences International, Inc. (Nasdaq:BDSI). Collegium expects to launch the product in mid-2017.

ONSOLIS is a Transmucosal Immediate-Release Fentanyl (TIRF) film 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. ONSOLIS incorporates BioDelivery Sciences' BioErodible MucoAdhesive (BEMA®) technology for rapid and controlled delivery of fentanyl, a Schedule II controlled substance, via buccal (inner cheek) administration.

ONSOLIS was originally approved by the U.S. Food and Drug Administration (FDA) in 2009 and voluntarily removed from the market in 2011 to address appearance-related issues. A reformulation of ONSOLIS was approved by the FDA in 2015. Collegium expects to launch the product after the completion of the transfer of manufacturing and submission to the FDA of a Prior Approval Supplement, which requires approval prior to launch. It is currently estimated that approval will occur in 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."

"Breakthrough pain in cancer is different from persistent pain, since it can occur despite adequate therapy for persistent pain, and can significantly affect a patient's well-being and quality of life," said Jeffrey Gudin, MD, Director of Pain Management and Palliative Care at Englewood Hospital and Medical Center. "TIRF products can be effective and safe for management of breakthrough pain in cancer when patients are appropriately assessed and treatment algorithms are followed, which are key goals of the TIRF REMS program. Also, patients with persistent and breakthrough cancer pain who have difficulty swallowing, including oral mucositis, may benefit from appropriate TIRF medications and Xtampza ER due to its flexible dosing and administration."

"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."

Financial terms of the agreement include an upfront payment of \$2.5 million and potential performance and sales milestone payments of up to approximately \$21 million. In addition, Collegium will pay BioDelivery Sciences annual net sales royalties based on achieving certain annual net sales targets.

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.

For Important Safety Information Visit, <http://www.bdsi.com/Onsolis.aspx>

About Xtampza™ ER

Xtampza ER is an opioid agonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

For Important Safety Information Visit, <http://www.xtampzaer.com/>

About Collegium Pharmaceutical, Inc.

Collegium is a specialty pharmaceutical company focused on developing a portfolio of products that incorporate its patent-protected DETERx® technology platform for the treatment of chronic pain and other diseases. The DETERx oral drug delivery technology is designed to provide extended-release delivery, unique abuse-deterrent properties, and flexible dose administration options.

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.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the company's current expectations. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors, including the following: our ability to commercialize our products and product candidates; the existence of any patent infringement or similar litigation relating to any of our products or product candidates, and costs and delays associated with such litigation; the size and growth potential of the markets for our product and product candidates, and our ability to service those markets; our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of our product and product candidates; the success, cost and timing of our product development activities, studies and clinical trials; the success of competing products that are or become available; and our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for our product candidates. These and other risks are described under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015, and those risks described from time to time in other reports which we file with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Contact:

Douglas Carlson
Vice President, Corporate Development
dcarlson@collegiumpharma.com



Collegium Pharmaceutical, Inc