BioDelivery Sciences Announces Patent Litigation Settlement Agreement with Teva

October 12, 2017

RALEIGH, N.C., Oct. 12, 2017 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a specialty pharmaceutical company with a focus in pain management and addiction medicine, today announced that it has entered into a Settlement Agreement with Teva Pharmaceuticals USA, Inc., Actavis Laboratories UT, Inc. and Teva Pharmaceuticals Industries, Ltd. (Teva) that resolves BDSI's previously reported BUNAVAIL® patent litigation against Teva pending in the United States District Court for the District of Delaware.

"We are pleased to have resolved this lawsuit with Teva regarding BUNAVAIL®, as it provides additional certainty to our patent portfolio, and allows us to move forward while averting future costs associated with this litigation," said Dr. Mark A. Mark Sirgo, Vice Chairman, President and Chief Executive Officer of BioDelivery Sciences.

BDSI alleged in the lawsuits that the generic form of BUNAVAIL® (buprenorphine and naloxone) buccal film, which Teva is seeking approval to market in the United Statespursuant to two Abbreviated New Drug Application (ANDA) filings with the U.S. Food and Drug Administration (FDA), infringed upon several U.S. patents owned by BDSI. As part of the Settlement Agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, BDSI has entered into a non-exclusive license agreement with Teva that permits Teva to first begin selling its generic version of BUNAVAIL® in the U.S. on July 23, 2028 or earlier under certain circumstances. Other terms of the agreement are confidential.

About BioDelivery Sciences International, Inc.

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 marketed products and those in development address serious and debilitating conditions such as breakthrough cancer pain, chronic pain and opioid dependence. BDSI's headquarters is in Raleigh, North Carolina.

For more information, please visit or follow us:

Internet: www.bdsi.com
Facebook: Facebook.com/BioDeliverySI
Twitter: @BioDeliverySI

BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) and BELBUCA® (buprenorphine) buccal film (CIII) are marketed in the U.S. by BioDelivery Sciences. *ONSOLIS*® (fentanyl buccal soluble film) (CII) is licensed in the U.S. to Collegium Pharmaceutical pursuant to the U.S. licensing and development agreement between BDSI and Collegium. For full prescribing information and important safety information on BDSI products, including BOXED WARNINGS for ONSOLIS, please visit www.bdsi.com where the Company promptly posts press releases, SEC filings and other important information or contact the Company at (800) 469-0261. For full prescribing and safety information on BELBUCA, please visit www.belbuca.com and for full prescribing and safety information on BUNAVAIL, please visit www.bunavail.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 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, any anticipated benefits of the Company's settlement with Teva 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 presentations or otherwise, except as required by applicable law.

SOURCE BioDelivery Sciences International, Inc.

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