BioDelivery Sciences Announces Commercialization Agreement with Quintiles to Support the Launch of BUNAVAIL in the U.S.

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Ashfield Market Access to provide managed markets and trade support

RALEIGH, N.C., March 27, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that it has entered into an agreement with Quintiles to provide a range of services to support the anticipated launch of BUNAVAIL (buprenorphine and naloxone buccal film), BDSI's proposed maintenance treatment for opioid dependence.

BUNAVAIL is currently under review at the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) date of June 7, 2014. Assuming BUNAVAIL is approved, BDSI intends to launch BUNAVAIL in the latter part of third quarter 2014.

Under terms of the agreement, Quintiles will provide a range of services to support the launch and subsequent commercialization of BUNAVAIL in the U.S., including a field sales force. Under the direction of BDSI, Quintiles will support the recruitment, training and deployment of a competitively sized sales force capable of reaching the physician base treating the majority of patients with buprenorphine for opioid dependence. In the U.S., nearly 5,000 physicians are responsible for approximately 90% of prescriptions for buprenorphine products for the treatment of opioid dependence according to most recent data from Symphony Health Solutions.

Separately, BDSI has entered into an agreement with Ashfield Market Access to provide managed markets and trade support for BUNAVAIL. Ashfield Market Access, which is led by industry veterans including Steve Stefano, who led GlaxoSmithKline's managed markets group for more than 20 years, will be responsible for executing a payer strategy aimed at maximizing patient access to BUNAVAIL.

"We have been working with and have formed strong relationships with these two companies over the past year, and in conjunction with them have developed a commercial plan that will support what we believe will be a successful launch of BUNAVAIL in the U.S. later this year," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. "Both Quintiles and Ashfield Market Access have an excellent history of supporting companies like BDSI in successfully launching and commercializing important new products. We are very pleased to now formalize our collaborations. We will provide greater details around our plans for the launch of BUNAVAIL as we approach our June 7th PDUFA date and the product's potential approval."

"As part of our collaboration with Quintiles, BDSI will have input in the selection of a newly developed sales force that will be dedicated solely to support the introduction of BUNAVAIL," said David Acheson, Vice President of Sales and Managed Markets for BDSI. "Leading this collaborative effort with Quintiles, BDSI will be in a position to build an experienced and highly committed sales force. Additionally, the added strength of Ashfield Market Access provides us critical access to trade and managed markets by tapping into the resources of individuals with significant experience and long-term relationships with payers. We believe the combined resources of Quintiles and Ashfield Market Access, along with our other partners, our internal commercial experience, and a well differentiated product in BUNAVAIL, will help support a strong introduction."

About BioDelivery Sciences International

BioDelivery Sciences International (NASDAQ: BDSI) is a specialty pharmaceutical company that is leveraging its novel and proprietary patented drug delivery technologies to develop and commercialize, either on its own or in partnerships with third parties, new applications of proven therapeutics. BDSI is focusing on developing products to meet unmet patient needs in the areas of pain management and addiction.

BDSI's pain franchise consists of three products, two of which utilize the patented BioErodible MucoAdhesive (BEMA) drug delivery technology. ONSOLIS (fentanyl buccal soluble film) is approved in the U.S., Canada, E.U. (where it is marketed as BREAKYL) and Taiwan (where it will be marketed as PAINKYL), for the management of breakthrough pain in opioid tolerant, adult patients with cancer. The commercial rights are licensed to Meda for all territories worldwide except for Taiwan (licensed to TTY Biopharm) and South Korea(licensed to Kunwha Pharmaceutical Co.).

BEMA Buprenorphine is in Phase 3 clinical trials for the treatment of moderate to severe chronic pain and is licensed on a worldwide basis to Endo Pharmaceuticals. Clonidine Topical Gel for the treatment of painful diabetic neuropathy is currently in Phase 3 development.

An NDA for BUNAVAIL, a BEMA formulation of buprenorphine used in combination with naloxone, is currently under review for the maintenance treatment of opioid dependence and has a PDUFA date of June 7, 2014.

BDSI's headquarters is located in Raleigh, North Carolina. For more information visit www.bdsi.com.

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 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 and those that relate to the Company's ability to leverage the expertise of employees and partners to assist the Company in the execution of its strategy. Actual results (including, without limitation,

the timing for and results of FDA review of BUNAVAIL as well as the outcomes of the Company's commercial plans for BUNAVAIL) 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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