In a Move by the U.S. Department of Health and Human Services - Patient Limit on Access to Opioid Dependence Treatments to be Expanded

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RALEIGH, N.C., Sept. 18, 2015 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) stated that the U.S. Department of Health and Human Services Secretary, Sylvia M. Burwell, announced important new steps to increase access to treatments for opioid dependence and prevention of opioid overdose. A component of the planned changes includes a move to expand access to medication assisted treatment (MAT) by revising the regulations that limit the prescribing of buprenorphine to treat opioid dependence.

A recent report from HHS indicated that 2.5 million people in the U.S. currently need treatment for opioid dependence; however, fewer than 1 million are receiving it. Under current regulations, physicians certified can prescribe buprenorphine treatment for opioid dependence for up to 30 patients initially and then after one year can request authorization to prescribe up to a maximum of 100 patients. As a result, access to care is limited and physicians are often forced to turn away patients seeking care.

"This is a major step forward in providing access to treatment for patients and their families who are dealing with opioid addiction," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BioDelivery Sciences. "We are very encouraged by the steps taken by the Department of Health and Human Services, including efforts to address what has been an ongoing barrier to treatment access. BioDelivery Sciences is fully committed to supporting efforts aimed at addressing the opioid epidemic in the U.S."

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.

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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 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 results of the Company's commercialization efforts for BUNAVAIL and the Company's clinical trials for, and FDA review of, the Company's products in development) 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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