



News Release
For Immediate Release

BDSI Announces its Intention to Proceed with Phase III Trials in 2006 on its Second BEMA™ Product Following FDA Meeting

**505(b)(2) regulatory pathway to be available for
BEMA™ Long Acting Analgesic, a treatment for acute pain**

Morrisville, North Carolina, November [28], 2005 – BioDelivery Sciences International, Inc. (NASDAQ:BDSI, BDSIW) announced today that it met on November 15, 2005 with the U.S. Food and Drug Administration to discuss the regulatory pathway and development plan for BEMA™ Long Acting Analgesic (BEMA™ LA), the second analgesic to be formulated with BDSI's BEMA™ delivery system. At the meeting, the FDA gave its preliminary indication that BDSI will be able to utilize the FDA's 505(b)(2) regulations for submission of a New Drug Application for BEMA™ LA. As a result, BDSI announced that it intends to enter clinical development with BEMA™ LA in the first quarter of 2006 and expects to begin Phase III trials in the second half of 2006.

BDSI is initially developing BEMA™ LA for the acute treatment of moderate to severe pain, such as post-operative pain. BEMA™ LA will be a formulation of an analgesic which is already FDA-approved, which is substantially more potent than morphine, but which BDSI believes has a lower risk of opioid related side effects. Notably, this analgesic is considered a Class III narcotic, which means that it has been classified as having less abuse and addiction potential than Class II narcotics such as morphine. BDSI expects BEMA™ LA to compete in the \$24 billion worldwide pain treatment market.

Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI, stated "Receiving this guidance from the FDA is another essential step forward for BDSI's drug development pipeline. BEMA™ LA represents a broadening of our focus on the pain market and is also the third drug formulation for which we have been granted the use of the 505(b)(2) regulatory pathway by FDA. Although final FDA approval of our products and formulations can not be guaranteed, the FDA's receptiveness to our regulatory approval strategy is, we believe, a significant validation of a critical component of our business model."

BDSI's first product, Emezine®, a buccal tablet for treating nausea and vomiting, is presently undergoing 505(b)(2) FDA review, with a decision expected on its approval in the first quarter of 2006. BDSI recently announced that, following positive Phase I clinical results, the company is in the process of ramping up for Phase III trials under the 505(b)(2) process on BEMA™ Fentanyl for the indication of "breakthrough" cancer pain.

In availing itself of the FDA's 505(b)(2) approval process, BDSI is seeking to obtain more timely and efficient approval of new formulations of previously approved therapeutics which incorporate BDSI's licensed drug delivery technologies, such as BEMA™. Because the 505(b)(2) approval process is

designed to address new delivery formulations of drugs previously approved by the FDA, BDSI believes it has the potential to be more efficient and less time consuming than other FDA approval methods.

BDSI's patented BEMA™ drug delivery system is exclusively licensed to BDSI on a worldwide basis. The BEMA™ delivery technology consists of an easy to use, dissolvable, dime-sized polymer disc that is applied to the mucus membrane (i.e. cheek) of the mouth. The disc dissolves over approximately 20-30 minutes, delivering the drug across the mucus membrane for rapid absorption and onset of effect.

BioDelivery Sciences International, Inc. is a specialty biopharmaceutical company that is exploiting its licensed and patented drug delivery technologies to develop and commercialize, either on its own or in partnerships with third parties, clinically-significant new formulations of proven therapeutics targeted at "acute" treatment opportunities such as pain, anxiety, nausea and vomiting and infections. The company's drug delivery technologies include: (i) the patented Bioral® nanocochleate technology, designed for a potentially broad base of applications, and (ii) the patented BEMA™ (transmucosal or mouth) drug delivery technology. The company's headquarters are located in Morrisville, North Carolina and its principal laboratory is located in Newark, New Jersey.

Note: Except for the historical information contained herein, this press release contains, among other things, certain forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties. Such statement may include, without limitation, statements with respect to the Company's plans, objectives, expectations and intentions and other statements identified by words such as "may", "could", "would", "should", "believes", "expects", "anticipates", "estimates", "intends", "plans" 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 additional clinical trials and FDA review of the Company's formulations and products, may differ 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).

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