



BioDelivery Sciences Prevails in BELBUCA® ANDA Litigation Maintaining Patent Exclusivity Against Alvogen Until 2032

December 20, 2021

RALEIGH, N.C., Dec. 20, 2021 (GLOBE NEWSWIRE) -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a growing specialty pharmaceutical company dedicated to patients living with serious and complex chronic conditions, today announced that the U.S. District Court of Delaware has issued an opinion in favor of BDSI in the company's patent litigation against Alvogen Group, Inc. and its affiliates, who filed an Abbreviated New Drug Application (ANDA) for BDSI's BELBUCA® product on May 23, 2018. The opinion by the trial judge upholds the validity of claims in BDSI's patents 8,147,866 (the '866 patent), which expires in 2027, and 9,901,539 (the '539 patent), which expires in 2032. Alvogen conceded infringement of these claims. Accordingly, BDSI expects market exclusivity of BELBUCA against Alvogen until 2032.

"We are pleased with the Court's decision and look forward to continuously supplying BELBUCA to chronic pain patients," stated Jeff Bailey, CEO of BDSI. "We would like to thank our shareholders for their support during the lengthy litigation period. With the removal of this legal overhang, we will continue to focus on business development and creating additional shareholder value."

Dechert LLP was the lead counsel representing BDSI.

ABOUT BIODELIVERY SCIENCES INTERNATIONAL, INC.

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a commercial-stage specialty pharmaceutical company dedicated to patients living with chronic conditions. BDSI has built a portfolio of differentiated pain and neurology products and leverages its experienced sales and marketing organization to educate prescribers on their unique features. BDSI's products address serious and debilitating conditions, including chronic pain, acute migraine and opioid-induced constipation.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This press release and any statements of employees, representatives, and partners of BioDelivery Sciences International, Inc. ("BDSI") 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 BDSI'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 BDSI's management and are subject to significant risks and uncertainties, including those detailed in BDSI's filings with the Securities and Exchange Commission. Actual results including, without limitation, the expectations for: continued patent exclusivity through 2027 and 2032 as well as our continued focus on business development, may differ materially from those set forth or implied 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 BDSI's control) including the risk that the current COVID-19 pandemic impacts on our supply chain, commercial partners, patients and their physicians and the healthcare facilities in which they work, and our personnel are greater than we anticipate, as well as those set forth in our 2020 annual report on Form 10-K filed with the US Securities and Exchange Commission and subsequent filings. BDSI 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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Contact:

Bob Yedid
LifeSci Advisors
646-597-6989
Bob@LifeSciAdvisors.com



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