BioDelivery Sciences Announces Agreement to Acquire U.S. and Canadian Rights to FDA-approved ELYXYB™ for the Acute Treatment of Migraine

August 4, 2021

The only FDA-approved, ready-to-use oral solution for the acute treatment of migraine with or without aura in adults

First step to building a growth platform in Neurology

Patent protection until 2036

RALEIGH, N.C., Aug. 04, 2021 (GLOBE NEWSWIRE) -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a growing specialty pharmaceutical company dedicated to patients living with serious and complex chronic conditions, announced today that it entered into an agreement on August 3, 2021 with Dr. Reddy's Laboratories Limited to acquire the U.S. and Canadian rights to ELYXYB (celecoxib oral solution), the only FDA-approved ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults.

"ELYXYB represents an excellent strategic fit for BDSI and a very attractive opportunity to diversify our product portfolio by expanding into the dynamic migraine market, deepening our presence in Neurology, a logical adjacency to our pain franchise," stated Jeff Bailey, CEO of BDSI.

"ELYXYB will contribute nicely to the Company's revenue growth and profitability over time. This transaction leverages our commercial expertise and much of our existing infrastructure. We see this acquisition as establishing a great growth platform in Neurology. Further, the deal structure is attractive, allowing us to maintain our strong balance sheet and position us to pursue additional value-enhancing business development opportunities," Bailey concluded.

ELYXYB is an oral solution of celecoxib, formulated using a self-micro emulsifying drug delivery system that improves solubility and bioavailability of the drug leading to better absorption[1]. This allows for the administration of a lower dose of drug to achieve therapeutic effect relative to a conventional oral solid dosage form. In pivotal studies, ELYXYB demonstrated a rapid onset of action which is critically important to patients suffering from acute migraine attacks. The results from pivotal studies established the efficacy of ELYXYB in the treatment of acute migraine. For adult patients who suffer from the debilitating and disruptive effects of migraine, there continues to be a need for reliable and efficacious treatment options. ELYXYB's unit-dose oral solution makes it convenient for patients to take it immediately upon emergence of acute migraine attacks.

With over 13 million migraine patients receiving prescription drug treatment in the U.S. in 2020, the dynamic migraine market continues to grow and evolve, including with new product introductions. BDSI will be conducting an ELYXYB pediatric study which has the potential to address the significant unmet need in the pediatric patient population.

Under the terms of the agreement, ELYXYB will be acquired for an upfront payment of $6 million, plus an additional $9 million on August 3, 2022. BDSI will make tiered quarterly earn-out payments on potential net sales ranging from the high single digits to the low double digits. Additional payments will be made contingent upon the achievement of certain regulatory and sales milestones. The impact of the acquisition is estimated to be cash flow accretive within approximately 24 months of commercial launch, currently planned for Q1 2022. The closing of the transaction is subject to satisfactory completion of customary closing conditions, including the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act).

"We are excited to acquire ELYXYB," said Thomas Smith, MD, Chief Medical Officer at BDSI, and a former thought leader in the migraine space with over 30 years of experience both as a physician and with multiple migraine product developments and launches. The clinical data are quite compelling, including a meaningful speed of onset with Tmax achieved in approximately 60 minutes. Additionally, in the two pivotal studies conducted, the percentage of patients achieving Most Bothersome Symptom (MBS) freedom at two hours post-dose was significantly greater among patients receiving ELYXYB, compared to those receiving placebo. In Study 2, the percentage of patients achieving headache pain freedom two hours post-dose was significantly greater among patients receiving ELYXYB, compared to those receiving placebo. We believe that this profile, coupled with the ready-to-use oral solution, make ELYXYB an attractive option for the acute treatment of migraine in adults."

The Company plans to conduct a BDSI investor day early in the fourth quarter, where further details regarding ELYXYB will be shared.

Please see Important Safety Information about ELYXYB below.

ABOUT BIODELIVERY SCIENCES INTERNATIONAL, INC.

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a commercial-stage specialty pharmaceutical company dedicated to patients living with serious and complex chronic conditions. BDSI has built a portfolio of products that includes utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA®) technology 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 address serious and debilitating conditions, including chronic pain 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 closing of the acquisition of ELYXYB, the contribution of ELYXYB to the Company’s revenue growth and shareholder value, the timing of commercial launch of ELYXYB, the Company’s expansion into neurology, the growth of the migraine market and the significant unmet need in pediatric migraine patients 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 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.

ELYXYB INDICATION AND USAGE

ELYXYB is indicated in adults for the acute treatment of migraine with or without aura.

Limitations of Use: ELYXYB is not indicated for the preventive treatment of migraine.

ELYXYB IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use *[see Warnings and Precautions (5.1)].*
- ELYXYB is contraindicated in the setting of coronary artery bypass graft (CABG) surgery *[see Contraindications (4) and Warnings and Precautions (5.1)].*

Gastrointestinal Bleeding, Ulceration, and Perforation

- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious (GI) events *[see Warnings and Precautions (5.2)].*

ELYXYB is contraindicated in patients with:

- Known hypersensitivity to celecoxib, any components of the drug product, or sulfonamides (4)
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs (4)
- In the setting of CABG surgery (4)

To minimize the potential risk for an adverse cardiovascular (CV) event in NSAID-treated patients, use ELYXYB for the fewest number of days per month as needed, based on individual treatment goals. Physicians and patients should remain alert for the development of such events, throughout the entire treatment course, even in the absence of previous CV symptoms. Patients should be informed about the symptoms of serious CV events and the steps to take if they occur.

Avoid the use of ELYXYB in patients with a recent myocardial infarction (MI) unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If ELYXYB is used in patients with a recent MI, monitor patients for signs of cardiac ischemia.

NSAIDs, including ELYXYB, can cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the esophagus, stomach, small intestine, or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with celecoxib. Only one in five patients who develop a serious upper GI adverse event on NSAID therapy is symptomatic. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occurred in approximately 1% of patients treated for 3 to 6 months, and in about 2% to 4% of patients treated for one year. However, even short-term NSAID therapy is not without risk.

Avoid the use of ELYXYB in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure. If ELYXYB is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

Elevations of ALT or AST (less than three times ULN) may occur in up to 15% of patients treated with NSAIDs, including ELYXYB.

Long-term administration of NSAIDs, including celecoxib, the active ingredient in ELYXYB, has resulted in renal papillary necrosis and other renal injury.

No information is available from controlled clinical studies regarding the use of celecoxib in patients with severe renal impairment. The renal effects of celecoxib may hasten the progression of renal dysfunction in patients with preexisting renal disease.

Overuse of acute migraine drugs (e.g., ergotamine, triptans, opioids, nonsteroidal anti-inflammatory drugs or combination of these drugs for 10 or more days per month), including ELYXYB, may lead to exacerbation of headache (medication overuse headache). Medication overuse headache may present as migraine-like daily headaches or as a marked increase in frequency of migraine attacks. Detoxification of patients, including withdrawal of the overused drugs and treatment of withdrawal symptoms (which often includes a transient worsening of headache) may be necessary.

NSAIDs, including ELYXYB, may increase the risk of bleeding events. Co-morbid conditions such as coagulation disorders or concomitant use of

warfarin, other anticoagulants, antiplatelet drugs (e.g., aspirin), SSRIs, and serotonin norepinephrine reuptake inhibitors (SNRIs) may increase this risk.

Most common adverse reaction (at least 3% and greater than placebo) is dysgeusia.

These are not all the side effects associated with ELYXYB.

Please see Patient Information, Instructions For Use, Medication Guide and Full Prescribing Information for ELYXYB

(https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212157s000lbl.pdf)

[1] Arindam Pal, Srinivas Shenoy, Anirudh Gautam, Sagar Munjal, Jing Niu, Mathangi Gopalakrishnan & Joga Gobburru, Clinical Drug Investigation volume 37, pages 937–946(2017)

Contacts:

Terry Coelho
Executive Vice President & Chief Financial Officer
BDSI_IR@bdsi.com

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

Source: BioDelivery Sciences International