BioDelivery Sciences International to Host ELYXYB™ Investor Day

September 30, 2021

The First and Only FDA-Approved, Ready-to-Use Oral Solution for the Acute Treatment of Migraine with or without Aura in Adults

Virtual Event on October 14, 2021

RALEIGH, N.C., Sept. 30, 2021 (GLOBE NEWSWIRE) -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a growing specialty pharmaceutical company dedicated to patients living with chronic conditions, announced today it will host a virtual ELYXYB™ Investor Day on Thursday, October 14, 2021, at 10:30am ET.

The webinar will feature insights from migraine key opinion leaders including a presentation by Richard B. Lipton, M.D., Edwin S. Lowe Chair in Neurology at Albert Einstein College of Medicine, Director of the Montefiore Headache Center, and internationally noted authority on migraine. Dr. Lipton will discuss the current treatment landscape, the unmet medical needs in treating patients with acute migraine, and the role ELYXYB may play as a treatment option for those patients. ELYXYB is the first and only FDA-approved ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults.

The BDSI management team will also provide an update that will include an overview of the migraine market and details on ELYXYB.

Dr. Lipton and the BDSI management team will be available to answer questions following the formal presentations.

To register for Investor Day, please click here.

ABOUT DR. LIPTON
Richard B. Lipton, M.D., is the Edwin S. Lowe Professor and Vice-Chair of Neurology, Professor of Epidemiology and Population Health, and Professor of Psychiatry and Behavioral Sciences at the Albert Einstein College of Medicine. Dr. Lipton earned his medical degree at the University of Chicago Pritzker School of Medicine. After a medical internship at Northwestern Memorial Hospital, he completed his neurology residency and clinical neurophysiology fellowship at the Albert Einstein College of Medicine. He also completed a fellowship in neuroepidemiology at Columbia University. He is a diplomate of the American Board of Psychiatry and Neurology and a fellow of the American Academy of Neurology. His research focuses on cognitive aging, Alzheimer's disease, and migraine headaches. He is the Principal Investigator of the Einstein Aging Study, an NIH-funded Program Project, and several R01s. His recent studies examine cognitive aging across the lifespan with an emphasis on the effects of pain and stress on brain function. His headache research focuses on the epidemiology of migraines and on clinical trials. His epidemiologic studies have evaluated trigger factors for headache attacks and risk factors for headache progression. Dr. Lipton has published more than 500 original articles, many with trainees. He is a three-time winner of the H.G. Wolff Award for excellence in headache research from the American Headache Society and the Enrico Greppi award from the European Headache Federation. Dr. Lipton is co-Director of the Montefiore Headache Center, an interdisciplinary subspecialty center focused on headache, patient care, research, and education. Dr. Lipton holds leadership positions in several professional societies. He is a Past-President of the American Headache Society (AHS). He serves on the editorial boards of several journals, including Neurology. He has written 11 books. Dr. Lipton enjoys mentoring medical students, residents, Ph.D. students, and fellows.

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)

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 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 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.

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