BioDelivery Sciences Expands Upon Report from Pain Management Task Force

June 24, 2019

Company's Activities Support Buprenorphine Recommendations Including:

- *Primary Use of Buprenorphine in Chronic Pain when Clinically Indicated*
- *Having Payers Provide Coverage and Reimbursement for Buprenorphine for Chronic Pain*

RALEIGH, N.C., June 24, 2019 (GLOBE NEWSWIRE) -- BioDelivery Sciences International, Inc. (Nasdaq: BDSI), the manufacturer of BELBUCA® (buprenorphine buccal film), CIII, shared today how its scientific investments for BELBUCA throughout 2019, including clinical trials, publications, and medical education initiatives align with the recommendations regarding buprenorphine from the recently released Pain Management Best Practices Inter-Agency Task Force's ("Task Force") final report which proposes best practices for managing chronic and acute pain. The Task Force consisted of representatives from relevant HHS agencies, the VA, DOD, and the White House Office of National Drug Control Policy (ONDCP). Non-federal representatives included individuals representing diverse disciplines and views, including experts in areas related to pain management, pain advocacy, addiction, recovery, substance use disorders, mental health, minority health and more. Members also included patients, representatives from veteran service organizations, the addiction treatment community and groups with expertise in overdose reversal, including first responders, medical boards and hospitals.

In addition to recommending including buprenorphine in third-party payer and hospital formularies and encouraging primary use of buprenorphine rather than use only after failure of standard mu agonist opioids such as hydrocodone or fentanyl, the Task Force's report goes further to discuss buprenorphine's reduced potential for respiratory depression, its benefit as an antagonist at the kappa receptor, and reviews DEA scheduling of opioids and the reduced potential for abuse of a C-III agent versus a C-II opioid.

"Consistent with the Task Force recommendations, BDSI is investing in furthering the understanding of buprenorphine by working to ensure appropriate access, engaging the medical community on increasing knowledge of primary use of buprenorphine in chronic pain when clinically appropriate, and advancing our efforts with data generation and dissemination," stated Thomas Smith, MD, Chief Medical Officer of BDSI. "In fact, our current scientific platform with our clinical study on respiratory depression, the upcoming journal publications reviewing many aspects of buprenorphine ranging from efficacy through pharmacology, and numerous educational initiatives to help improve patient care in chronic pain all align with the Task Force's recommendations."

The prevalence of chronic daily pain is significant, affecting an estimated 50 million adults in the United States. Of those individuals, approximately forty percent suffer from high-impact chronic pain, which frequently limits life or work activities. In an effort to address challenges in patient care, the Task Force report outlines best practices for managing acute and chronic pain and focuses on the importance of providing patient-centered pain management care to ensure better clinical outcomes for improving the quality of life and functionality for patients.

The Pain Management Best Practices Inter-Agency Task Force's report is available for viewing online at https://www.hhs.gov/ash/advisory-committees/pain/index.html.

Please see Important Safety Information about BELBUCA below. **For full Prescribing Information, including Boxed Warning, visit** www.belbuca.com.

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 and those in development address serious and debilitating conditions such as chronic pain, breakthrough cancer pain, opioid dependence and opioid induced constipation.

IMPORTANT SAFETY INFORMATION ABOUT BELBUCA®

BELBUCA® (buprenorphine buccal film), CIII is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with long-acting opioid formulations, reserve BELBUCA® for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

BELBUCA® is not indicated as an as-needed (prn) analgesic.

WARNING: ADDICTION, ABUSE, AND MISUSE; RISK EVALUATION AND MITIGATION STRATEGY (REMS); LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES AND OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse
BELBUCA® exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk prior to prescribing BELBUCA®, and monitor patients regularly for these behaviors and conditions.

Risk Evaluation and Mitigation Strategy (REMS)
To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the FDA has required a REMS for these products. Under the requirements of the REMS, drug companies with approved opioid analgesic products must make REMS-compliant education programs available to healthcare providers. Healthcare providers are strongly encouraged to

- **complete a REMS-compliant education program,**
- **counsel patients and/or their caregivers, with every prescription, on safe use, serious risks, storage, and disposal of these products,**
- **emphasize to patients and their caregivers the importance of reading the Medication Guide every time it is provided by their pharmacist, and**
- **consider other tools to improve patient, household, and community safety.**

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of BELBUCA®. Monitor for respiratory depression, especially during initiation of BELBUCA® or following a dose increase.

Accidental Exposure
Accidental exposure to even one dose of BELBUCA®, especially by children, can result in a fatal overdose of buprenorphine.

Neonatal Opioid Withdrawal Syndrome
Prolonged use of BELBUCA® during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Risks from Concomitant Use with Benzodiazepines or Other CNS Depressants
Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.

BELBUCA® is contraindicated in patients with significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; known or suspected gastrointestinal obstruction, including paralytic ileus; and hypersensitivity (e.g., anaphylaxis) to buprenorphine.

BELBUCA® contains buprenorphine, a Schedule III controlled substance. As an opioid, BELBUCA® exposes users to the risks of addiction, abuse, and misuse. Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed BELBUCA® and in those who obtain the drug illicitly. Addiction can occur at recommended doses and if the drug is misused or abused.

Potential serious adverse events caused by opioids include addiction, abuse, and misuse; life-threatening respiratory depression; neonatal opioid withdrawal syndrome; risks due to interactions with benzodiazepines or other central nervous system depressants; risk of life-threatening respiratory depression in patients with chronic pulmonary disease or in elderly, cachectic, or debilitated patients; adrenal insufficiency; QTc prolongation; severe hypotension; risks of use in patients with increased intracranial pressure, brain tumors, head injury, or impaired consciousness; hepatotoxicity; risk of overdose in patients with moderate or severe hepatic impairment; anaphylactic/allergic reactions; risk of use in patients with gastrointestinal conditions; increased risk of seizures in patients with seizure disorders; risks of use in cancer patients with oral mucositis; risks of driving and operating machinery.

The most common adverse reactions (≥5%) reported by patients treated with BELBUCA® in the clinical trials were nausea, constipation, headache, vomiting, fatigue, dizziness, somnolence, diarrhea, dry mouth, and upper respiratory tract infection.

For full Prescribing Information, including Boxed Warning, visit www.belbuca.com.

To report SUSPECTED ADVERSE REACTIONS, contact BioDelivery Sciences International, Inc. at 1-800-469-0261 or FDA at 1-800-FDA-1088 or www.fda.gov/safety/medwatch

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This press release and any statements of employees, representatives, and partners of 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 the 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 the BDSI's management and are subject to significant risks and uncertainties, including those detailed in the BDSI's filings with the Securities and Exchange Commission. Actual results 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 the BDSI's control) including those set forth in our 2018 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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