BioDelivery Sciences to Exhibit Three Scientific Posters Comparing BELBUCA® to Oxycodone at the PAINWeek 2021 Conference

September 7, 2021

RALEIGH, N.C., Sept. 07, 2021 (GLOBE NEWSWIRE) -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a growing specialty pharmaceutical company dedicated to patients living with chronic conditions, will showcase three scientific posters regarding BELBUCA® (buprenorphine buccal film), CIII at the PAINWeek 2021 Conference taking place September 7 – 11, 2021 at The Cosmopolitan of Las Vegas.

The posters include:

- **Risk Stratification of Respiratory Depression With Buprenorphine Buccal Film Versus Oxycodone: Outcomes From a Phase 1 Placebo-Controlled Trial**
  Authors: Lynn Webster, MD; Jacqueline Cater, PhD; Thomas Smith, MD
- **Buprenorphine Buccal Film Versus Oral Oxycodone: Secondary Respiratory, Pharmacokinetic, and Pupillometry Outcomes From a Phase 1 Placebo-Controlled Trial**
  Authors: Lynn Webster, MD; Jacqueline Cater, PhD; Thomas Smith, MD
- **Buprenorphine Buccal Film Versus Oral Oxycodone: Effects on Pupillometry and Respiratory Depression in a Phase 1 Placebo-Controlled Trial**
  Authors: Lynn Webster, MD; Jacqueline Cater, PhD; Thomas Smith, MD

“These posters include important scientific data for healthcare professionals to consider concerning the safety profile of buprenorphine buccal film and oxycodone,” said Thomas Smith, MD, Chief Medical Officer of BDSI. “We are pleased to share these data with healthcare professionals who treat chronic pain patients at this year’s PAINWeek Conference.”

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.

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.

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