BioDelivery Sciences Announces Five Medical Abstracts Accepted at PAINWeek® 2019 National Conference on Pain Management

August 28, 2019

New Scientific Information Further Highlights Clinical Profiles of BELBUCA® and Symproic®

RALEIGH, N.C., Aug. 28, 2019 (GLOBE NEWSWIRE) -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a rapidly growing specialty pharmaceutical company dedicated to patients living with chronic conditions, today reported the acceptance of five scientific abstracts highlighting data supporting its portfolio of products that address the unmet need of chronic conditions at the upcoming PAINWeek® 2019 National Conference on Pain for Frontline Practitioners taking place September 3-7, 2019 in Las Vegas, NV.

Key Highlights:

- Four abstracts specific to BELBUCA® (buprenorphine buccal film), C-III have been accepted as poster presentations with one of them also to be presented orally.
- Three abstracts include analyses from three Phase 3 studies reviewing constipation, likelihood of developing anxiety and insomnia, and quality-of-life of BELBUCA compared to placebo.
- The fourth abstract reviews the study design of an ongoing Phase 1 trial comparing BELBUCA vs. oxycodone on respiratory depression.
- A fifth abstract reviewing the efficacy of Symproic® (naldemedine) table 0.2 mg vs. placebo in relieving opioid-induced constipation across a wide range of opioid doses has also been accepted as a poster presentation.

"We are very pleased to have these abstracts accepted for presentation at the largest pain conference in the U.S., underscoring our ongoing commitment to further researching BELBUCA and Symproic and educating the medical and scientific community," said Thomas Smith, MD, Chief Medical Officer of BDSI. "This new information adds to the growing awareness of BELBUCA and Symproic as important treatment considerations for patients suffering from chronic pain and opioid induced constipation."

All five posters will be available for public viewing on Thursday, September 5, 2019, from 8:00 a.m. – 8:30 p.m. PDT. Official poster presentations will occur on Thursday evening, September 5, 2019, from 6:30 p.m. – 8:30 p.m. PDT.

Poster Presentations

Poster #53:	*Consistent Efficacy of Buprenorphine Buccal Film in Opioid-Naive and Opioid-Experienced Patients With Moderate to Severe Chronic Low Back Pain*
Authors:	Joseph V. Pergolizzi, Jr., MD, Gary Cutter, PhD
Poster #172:	*Study Design of a Phase I Placebo-Controlled Trial Comparing the Effects of Buprenorphine Buccal Film and Oral Oxycodone Hydrochloride on Respiratory Depression, Tolerability, and Pharmacokinetics*
Authors:	Lynn Webster, MD, Thomas Smith, MD
Poster #76:	*Incidence and Severity of Constipation in Patients Treated for Chronic Pain With Buprenorphine Buccal Film*
Authors:	Martin Hale, MD, Joseph V. Pergolizzi, Jr., MD
Poster #52:	*Buprenorphine Buccal Film Improves Patient Global Impression of Change and Reduces the Prevalence of Anxiety and Insomnia in Patients With Chronic Low Back Pain*
Authors:	Joseph V. Pergolizzi, Jr., MD, Todd Kunkel, PharmD
Poster #77:	*Efficacy and Safety of Naldemedine for Opioid-Induced Constipation in Patients With Chronic Non-cancer Pain: Subgroup Analyses by Opioid Dose*
Authors:	Martin Hale, MD, Mancia Ko, PharmD, MBA

In addition, one abstract, *Buprenorphine Buccal Film Improves Patient Global Impression of Change and Reduces the Prevalence of Anxiety and Insomnia in Patients with Chronic Low Back Pain* was accepted for Oral Presentation and will be presented by Joseph V. Pergolizzi, Jr., MD on Friday, September 6, 2019, from 10:40 a.m. – 12:00 p.m. PDT in the Expert Opinion Live area of the Exhibit Hall.

The full text of the accepted abstracts is currently available by visiting the PAINWeek Conference website.

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 Symproic

Symproic® (naldemedine) is indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Symproic® was made available to patients in the US in October 2017.

Please see Important Safety Information, including Warnings & Precautions, and Adverse Reactions below.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Patients with known or suspected gastrointestinal (GI) obstruction and patients at increased risk of recurrent obstruction, due to the potential for GI perforation.

Patients with a history of a hypersensitivity reaction to Symproic. Reactions have included bronchospasm and rash.

WARNINGS AND PRECAUTIONS

Cases of GI perforation have been reported with use of another peripherally acting opioid antagonist in patients with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the GI tract. Monitor for the development of severe, persistent, or worsening abdominal pain; discontinue if this symptom develops.

Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, increased lacrimation, hot flush/flushing, pyrexia, sneezing, feeling cold, abdominal pain, diarrhea, nausea, and vomiting have occurred in patients treated with Symproic.

Patients having disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal or reduced analgesia. Take into account the overall risk-benefit profile when using Symproic in such patients. Monitor for symptoms of opioid withdrawal in such patients.

DRUG INTERACTIONS

Avoid use with strong CYP3A inducers (e.g., rifampin) because they may reduce the efficacy of Symproic.

Use with moderate (e.g., fluconazole) and strong (e.g., itraconazole) CYP3A inhibitors and P-glycoprotein inhibitors (e.g., cyclosporine) may increase Symproic concentrations. Monitor for potential adverse reactions.

Avoid use of Symproic with another opioid antagonist due to potential for additive effect and increased risk of opioid withdrawal.

USE IN SPECIFIC POPULATIONS

Symproic crosses the placenta and may precipitate opioid withdrawal in a fetus due to the immature fetal blood-brain barrier. Symproic should be used during pregnancy only if the potential benefit justifies the potential risk. Because of the potential for serious adverse reactions, including opioid withdrawal in breastfed infants, a decision should be made to discontinue breastfeeding or discontinue the drug, taking into account the importance of the drug to the mother.

Avoid use in patients with severe hepatic impairment. No dose adjustment of Symproic is required in patients with mild or moderate hepatic impairment.

ADVERSE REACTIONS

The most common adverse reactions with Symproic as compared to placebo in clinical trials were: abdominal pain (8% vs 2%), diarrhea (7% vs 2%), nausea (4% vs 2%), and gastroenteritis (2% vs 1%).

In pooled Studies 1 and 2, the incidence of adverse reactions of opioid withdrawal was 1% (8/542) for Symproic and 1% (3/546) for placebo. In Study 3 (52-week data), the incidence was 3% (20/621) for Symproic and 1% (9/619) for placebo.

To report suspected Adverse Reactions, contact Shionogi at 1-800-849-9707 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying Full Prescribing Information including Medication Guide for Symproic or visit www.symproic.com/pi.

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. For more information, please visit us https://bdsi.com or follow us on Facebook or Twitter BDSI @BioDeliverySI.

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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Source: BioDelivery Sciences International, Inc.