



## **BioDelivery Sciences Announces the Approval of BUNAVAIL® for Induction of Buprenorphine Treatment for Opioid Dependence**

May 2, 2017

RALEIGH, N.C., May 2, 2017 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that the U.S. Food and Drug Administration (FDA) has approved a Supplemental New Drug Application (sNDA) for BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) revising the indication to include the use of BUNAVAIL for the initiation of buprenorphine treatment for opioid dependence.

The approval broadens the indication for BUNAVAIL to include induction, or the initial process undertaken when a patient is transitioned from the abused opioid responsible for their addiction to the dose of BUNAVAIL which is intended to provide relief from cravings and withdrawal. Induction is the first step to assist a patient in discontinuing or markedly reducing their use of other opioids. Previously, the indication for BUNAVAIL only covered the maintenance treatment phase of opioid dependence treatment.

The expansion of the indication for BUNAVAIL is expected to help maintain the competitiveness of BUNAVAIL in the market and allows BDSI and its sales representatives to communicate the benefits of BUNAVAIL in treating opioid dependence from induction through the longer maintenance phase of treatment. This has become particularly important as recent Federal law and administrative rule changes have provided the opportunity for more new patients to enter buprenorphine treatment for opioid dependence.

### **About BUNAVAIL**

#### **INDICATION**

BUNAVAIL® (buprenorphine and naloxone) Buccal Film (CIII) is indicated for the treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.

Prescription use of this product is limited under the Drug Addiction Treatment Act (DATA).

#### **IMPORTANT SAFETY INFORMATION**

Keep BUNAVAIL (buprenorphine and naloxone) Buccal Film (CIII) out of the sight and reach of children. Ingestion of BUNAVAIL by a child may cause severe breathing problems and death. If a child takes BUNAVAIL, get emergency help right away.

Do not take BUNAVAIL if you are allergic to buprenorphine or naloxone, as serious negative effects including anaphylactic shock, have been reported.

Do not take BUNAVAIL before the effects of other opioids (e.g., heroin, methadone, oxycodone, morphine) have lessened as you may experience withdrawal symptoms.

BUNAVAIL is not appropriate as an analgesic. There have been reported deaths of opioid naïve individuals who received a buprenorphine dose smaller than the lowest available BUNAVAIL strength.

Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how BUNAVAIL affects you.

BUNAVAIL contains buprenorphine, an opioid that can cause physical dependence. Your doctor can tell you more about the difference between physical dependence and drug addiction. Do not stop taking BUNAVAIL without talking to your doctor. You could become sick with uncomfortable withdrawal symptoms because your body has become used to this medicine.

Do not switch from BUNAVAIL to other medicines that contain buprenorphine without talking with your doctor. The amount of buprenorphine in a dose of BUNAVAIL is not the same as the amount of buprenorphine in other medicines. Your doctor will prescribe a dose of BUNAVAIL that may be different than other buprenorphine-containing medicines you may have been taking.

BUNAVAIL can cause serious life-threatening breathing problems, overdose and death, particularly when taken by the intravenous (IV) route in combination with benzodiazepines, sedatives, tranquilizers or alcohol. You should not drink alcohol while taking BUNAVAIL, as this can lead to loss of consciousness or even death.

Consider dose reduction of CNS depressants, BUNAVAIL buccal film, or both in situations of concomitant prescription.

Like other opioids (e.g., heroin, methadone, oxycodone, morphine), BUNAVAIL may produce orthostatic hypotension ('dizzy spells') in ambulatory individuals.

Common side effects of BUNAVAIL include headache, drug withdrawal syndrome, lethargy (lack of energy), sweating, constipation, decrease in sleep (insomnia), fatigue and sleepiness.

Cases of adrenal insufficiency, a potentially-life threatening condition, have been reported with opioid use, more often following greater than one month of treatment.

Monitor liver function tests prior to initiation and during treatment and evaluate suspected hepatic events.

Because BUNAVAIL contains naloxone, injecting BUNAVAIL may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

BUNAVAIL can be abused in a manner similar to other opioids, legal or illicit. Keep BUNAVAIL in a safe place. Do not give your BUNAVAIL to other people, it can cause them harm or even death. Selling or giving away this medicine is against the law.

BUNAVAIL is not recommended in patients with severe hepatic impairment. BUNAVAIL may be used with caution for maintenance treatment in patients with moderate hepatic impairment.

Before taking BUNAVAIL, tell your doctor if you are pregnant or plan to become pregnant. If you become pregnant while taking BUNAVAIL, tell your doctor immediately as there may be significant risks to you and your baby; your baby may have symptoms of withdrawal at birth.

Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy, whether that use is medically-authorized or illicit.

Before taking BUNAVAIL, talk to your doctor if you are breast-feeding or plan to breast-feed your baby. BUNAVAIL can pass into your breast milk and may harm your baby. Monitor your baby for increased sleepiness and breathing problems. Your doctor should tell you about the best way to feed your baby if you are taking BUNAVAIL.

This is not a complete list of potential adverse events associated with BUNAVAIL Buccal Film. Please see full Prescribing Information for a complete list.

To report negative side effects associated with taking BUNAVAIL Buccal Film, please call 1-800-469-0261. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**For more information, please see full [Prescribing Information](#) and [Medication Guide](#) for BUNAVAIL Buccal Film (CIII)**

### **About BioDelivery Sciences International**

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a specialty pharmaceutical company with a focus in the areas of pain management and addiction medicine. BDSI is utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA<sup>®</sup>) technology and other drug delivery technologies 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 development strategy focuses on the utilization of the FDA's 505(b)(2) approval process. This regulatory pathway creates the potential for more timely and efficient approval of new formulations of previously approved therapeutics.

BDSI's area of focus is the development and commercialization of products in the areas of pain management and addiction. These are areas where BDSI believes its drug delivery technologies and products can best be applied to address critical unmet medical needs. BDSI's marketed products and those in development address serious and debilitating conditions such as breakthrough cancer pain, chronic pain, painful diabetic neuropathy and opioid dependence. BDSI's headquarters is in Raleigh, North Carolina.

For more information, please visit or follow us:

Internet: [www.bdsi.com](http://www.bdsi.com)  
Facebook: [Facebook.com/BioDeliverySI](https://www.facebook.com/BioDeliverySI)  
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**BUNAVAIL<sup>®</sup> (buprenorphine and naloxone) buccal film (CIII) and BELBUCA<sup>®</sup> (buprenorphine) buccal film (CIII) are marketed in the U.S. by BioDelivery Sciences. ONSOLIS<sup>®</sup> (fentanyl buccal soluble film) (CII) is licensed in the U.S. to Collegium Pharmaceutical pursuant to the U.S. licensing and development agreement between BDSI and Collegium. For full prescribing information and important safety information on BDSI products, including BOXED WARNINGS for ONSOLIS, please visit [www.bdsi.com](http://www.bdsi.com) where the Company promptly posts press releases, SEC filings and other important information or contact the Company at (800) 469-0261. For full prescribing and safety information on BELBUCA, please visit [www.belbuca.com](http://www.belbuca.com) and for full prescribing and safety information on BUNAVAIL, please visit [www.bunavail.com](http://www.bunavail.com).**

### **Cautionary Note on Forward-Looking Statements**

This press release any statements of employees, representatives and partners of BioDelivery Sciences International, Inc. (the "Company") 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 Company'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 Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the results of the Company's commercialization and strategic initiatives) may differ significantly from those set forth 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 Company's control). The Company 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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