



FOR IMMEDIATE RELEASE

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NOW AVAILABLE - JORNAY PM™ (METHYLPHENIDATE HCL) CII, THE FIRST AND ONLY ADHD STIMULANT DOSED IN THE EVENING

Novel Drug Delivery Technology Offers Hope to Families Struggling Through Morning Routines

Research Triangle Park, NC, June 11, 2019 — [Ironshore Pharmaceuticals Inc.](http://www.ironshorepharma.com) ("Ironshore"), a wholly owned subsidiary of [Highland Therapeutics Inc.](http://www.highlandtherapeutics.com) and a leader in the commercialization of novel treatments for Attention Deficit Hyperactivity Disorder ("ADHD"), today announced that [JORNAY PM™ \(methylphenidate HCl\) extended-release capsules CII](#) is now available in the United States. JORNAY PM is a CNS stimulant approved by the U.S. Food and Drug Administration ("FDA") for the treatment of ADHD in patients 6 years and older. JORNAY PM is the first and only ADHD stimulant medication that is dosed in the evening and helps improve symptoms from the time the patient wakes up the next morning and continues to control symptoms throughout the day. The evening administration of a stimulant medication is made possible by DELEXIS®, Ironshore's novel drug delivery platform. DELEXIS contains two functional film coatings that act synergistically to achieve a unique pharmacokinetic profile. The first layer delays the initial release of drug for up to 10 hours while the second layer helps to control the rate of release of the active pharmaceutical ingredient throughout the day.

WARNING: ABUSE AND DEPENDENCE

See full prescribing information for complete boxed warning.

- CNS stimulants, including JORNAY PM, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence
- Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy

See additional important safety information below.

JORNAY PM was well tolerated in clinical trials with a safety profile generally consistent with other methylphenidate products. Based on accumulated data from other methylphenidate products, the most common adverse reactions for pediatric patients and adults are: appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased. Additional adverse reactions in pediatric patients 6 to 12 years treated with JORNAY PM: headache, psychomotor hyperactivity, and mood swings. JORNAY PM is the first drug utilizing Ironshore's proprietary drug delivery platform, DELEXIS, and is available in 20 mg, 40 mg, 60 mg, 80 mg, and 100 mg extended-release capsules.

"The launch of our first commercial product for the treatment of ADHD marks an important milestone in the Company's history and demonstrates our commitment to developing innovative, patient-centric treatment options for patients with ADHD," said David Lickrish, Chief Executive Officer of Ironshore Pharmaceuticals & Development Inc. "We are delighted to offer the ADHD community a novel medicine, developed over a 10-year period and supported by nine clinical studies, including two pivotal trials, that works when patients wake up, but does not come at the expense of coverage throughout the day."

Commenting on the availability of JORNAY PM, Dr. Randy Sallee, Ironshore's Chief Medical Officer said, "ADHD can adversely impact a patient's ability to complete their morning routine, prepare for the day, and get out of the house in the morning. As a Board Certified psychiatrist, I believe the therapeutic profile of JORNAY PM, enabled by advanced drug-delivery technology, has the potential to have a profound impact on treatment paradigms in ADHD."

Results from clinical studies demonstrated that children with ADHD treated with JORNAY PM showed improved symptoms in the early morning that lasted throughout the day. The drug also showed significant improvements in standard tests that measure ADHD symptoms at home and school throughout the day, as well as with new assessment tools that measure difficulties in the early morning, late afternoon and evening.

"Patients with ADHD can have very challenging mornings," said Dr. Ann Childress, M.D, President, Center for Psychiatry and Behavioral Medicine, Inc. in Las Vegas and Clinical Trial Investigator. "Several families I work with have developed a number of creative, but often disruptive strategies, like waking up extra early to take medicine in an attempt to improve the early morning routine. I believe that JORNAY PM represents a welcome addition to the

therapeutic options available to physicians that treat ADHD as well as for families who face ADHD-associated difficulties, not only during the morning routine but throughout the day.”

About Ironshore’s Phase III Clinical Studies

The effectiveness of JORNAY PM was established in two separate Pivotal Phase III, multicenter, randomized, double-blind, placebo-controlled studies conducted in a total of 278 pediatric patients aged 6 to 12 years with a diagnosis of ADHD per DSM-5 criteria. In addition to the traditional scales that assess efficacy in ADHD clinical trials such as the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) rating scale and the ADHD Rating Scale (ADHD-RS-IV), Ironshore’s pivotal trials assessed JORNAY PM’s efficacy in the early morning period using the morning subscale of the Parent Rating of Evening and Morning Behavior-Revised scale (PREMB-R AM) and the Before School Functioning Questionnaire (BSFQ).

In Study 1, improvement in ADHD manifestations in a classroom setting was demonstrated by the primary endpoint, an average of all post-dosed SKAMP combined scores measured during a 12-hour period (8:00 AM to 8:00 PM), and improvement in ADHD manifestations in the early morning was demonstrated by the secondary endpoint, PREMB-R AM.

In Study 2, improvement in ADHD manifestations throughout the day was demonstrated by the primary endpoint, ADHD-RS-IV, and improvement in ADHD manifestations before school was demonstrated by the secondary endpoint, the BSFQ, which is intended to assess early morning before school activities from the time the child awakens and some behaviors not specific to early morning.

About ADHD

ADHD is among the most common childhood psychiatric conditions with behavioral symptoms fluctuating throughout the day. It is usually first diagnosed in childhood and often lasts into adulthood. Children with ADHD may have trouble paying attention, controlling impulsive behaviors, or be overly active. Many home-based difficulties for children and adolescents with ADHD occur during the early morning routine (i.e. before the school day begins).

About JORNAY PM

Developed by Ironshore Pharmaceuticals & Development, Inc., JORNAY PM is a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit

Hyperactivity Disorder (ADHD) in people 6 years of age and older. JORNAY PM may help increase attention and decrease impulsiveness and hyperactivity in people 6 years of age and older with ADHD. It is not known if JORNAY PM is safe and effective in children under 6 years of age.

JORNAY PM is dosed once daily in the evening and should be initiated at 8:00 p.m. Timing of administration of JORNAY PM may be adjusted between 6:30 p.m. and 9:30 p.m. to optimize the tolerability and the efficacy the next morning and throughout the day. Please see additional dosing information in the full prescribing information for JORNAY PM at <http://ironshorepharma.com/labeling.pdf>.

IMPORTANT SAFETY INFORMATION

WARNING: ABUSE AND DEPENDENCE

CNS stimulants, including JORNAY PM, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

CONTRAINDICATIONS

- Known hypersensitivity to methylphenidate or other components of JORNAY PM. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate products.
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days because of the risk of hypertensive crisis.

WARNINGS AND PRECAUTIONS

- *Serious Cardiovascular Reactions:* Sudden death, stroke, and myocardial infarction have been reported in adults treated with CNS stimulants at recommended doses. Sudden death has been reported in pediatric patients with structural cardiac abnormalities and other serious heart problems taking CNS stimulants at recommended doses for ADHD. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmias, coronary artery disease, and other serious cardiac problems.
- *Blood Pressure and Heart Rate Increases:* CNS stimulants may cause an increase in blood pressure and heart rate. Monitor all patients for hypertension and tachycardia.

- *Psychiatric Adverse Reactions:* CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychiatric disorder and may induce a manic or mixed episode in patients with bipolar disorder. In patients with no prior history of psychotic illness or mania, CNS stimulants, at recommended doses, may cause psychotic or manic symptoms.
- *Priapism:* Prolonged and painful erections, sometimes requiring intervention, have been reported with methylphenidate products in both pediatric and adult patients. Priapism has also appeared during a period of drug withdrawal. Immediate medical attention should be sought if signs or symptoms of prolonged penile erections or priapism are observed.
- *Peripheral Vasculopathy, including Raynaud's Phenomenon:* CNS stimulants used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Careful observation for digital changes is necessary during treatment with ADHD stimulants.
- *Long-Term Suppression of Growth:* CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Monitor height and weight at appropriate intervals in pediatric patients.

ADVERSE REACTIONS

- Based on accumulated data from other methylphenidate products, the most common (>5% and twice the rate of placebo) adverse reactions for pediatric patients and adults are: appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased.
- Additional adverse reactions ($\geq 5\%$ and twice the rate of placebo) in pediatric patients 6 to 12 years treated with JORNAY PM: headache, psychomotor hyperactivity, and mood swings.

PREGNANCY AND LACTATION

- CNS stimulant medications, such as JORNAY PM, can cause vasoconstriction and thereby decrease placental perfusion.
- The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for JORNAY PM and any potential adverse effects on the breastfed infant from JORNAY PM or from the underlying maternal condition. Monitor breastfeeding infants for adverse reactions, such as agitation, insomnia, anorexia, and reduced weight gain.

Please visit <http://ironshorepharma.com/labeling.pdf> for additional important safety information and the Full Prescribing Information, including Boxed Warning, for JORNAY PM.

About Ironshore Pharmaceuticals Inc.

Ironshore Pharmaceuticals Inc. commercializes innovative, patient-centric treatment options to improve the lives of patients and caregivers. Based in North Carolina, Ironshore Pharmaceuticals Inc. is responsible for the sales, marketing and distribution of pharmaceutical products within the US. Ironshore Pharmaceuticals Inc. is a wholly owned subsidiary of Highland Therapeutics Inc. based in Toronto, Canada.

About Ironshore Pharmaceuticals & Development, Inc.

Ironshore Pharmaceuticals & Development, Inc., based in Grand Cayman, develops novel therapeutics by leveraging its proprietary drug-delivery technology, DELEXIS®. Ironshore Pharmaceuticals & Development, Inc. is a wholly owned subsidiary of Highland Therapeutics Inc. based in Toronto, Canada.

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Forward-Looking Statements

This press release contains forward-looking information, which reflects Ironshore's current expectations regarding future events. Forward-looking information is based on a number of assumptions and is subject to a number of risks and uncertainties, many of which are beyond Ironshore's control that could cause actual results and events to differ materially from those that are disclosed in or implied by such forward-looking information. These forward-looking statements are made as of the date of this press release and, except as expressly required by applicable law, Ironshore assumes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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