IRONSHORE ANNOUNCES PUBLICATION OF NEW DATA FOR JORNAY PM® IN THE JOURNAL OF CLINICAL PSYCHOPHARMACOLOGY

Research Triangle Park, NC – June 29, 2020 – Ironshore Pharmaceuticals Inc. ("Ironshore"), a wholly owned subsidiary of Highland Therapeutics Inc. and a leader in the commercialization of novel treatments for Attention-Deficit/Hyperactivity Disorder ("ADHD"), today announced the publication of an original paper in the Journal of Clinical Psychopharmacology that describes a model that may facilitate dosage optimization of JORNAY PM® (methylphenidate HCl) extended-release capsules CII. JORNAY PM was approved in August 2018 by the U.S. Food and Drug Administration (FDA) for the treatment of ADHD in patients 6 years and older.

The publication, titled *Model-Based Approach for Establishing the Predicted Clinical Response of a Delayed-Release and Extended-Release Methylphenidate for the Treatment of Attention-Deficit/Hyperactivity Disorder*, is available online at www.psychopharmacology.com and can be accessed by clicking here. It will also appear in the July/August print edition of the Journal of Clinical Psychopharmacology.

Commenting on the publication, Dr. Bev Incledon, EVP, Research & Development for Ironshore Pharmaceuticals & Development, Inc. added, "The PK/PD model described in the paper corroborates what we saw in the clinical trials, where JORNAY PM demonstrated improvement in ADHD symptom control in the early morning, throughout the day and during the evening time period. Importantly, the model predicts increased duration of response with increasing doses, which has important implications for prescribers; the model can help facilitate treatment optimization by predicting anticipated changes in clinical benefit with dose and administration time adjustment." According to the model, the extended duration was disproportionately distributed into the evening, without affecting JORNAY PM's predicted response during the morning and afternoon.

JORNAY PM is the first product to leverage the novel DELEXIS® delayed-release and extended-release drug delivery technology. DELEXIS technology capitalizes upon the slow absorption rate of the colon, which has different absorption qualities relative to the stomach and upper intestine. The DELEXIS technology provides two functional film coatings: 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 from the time the patient awakens the next morning, throughout the day and into the evening.

JORNAY PM is the first and only stimulant medication that is dosed in the evening and has demonstrated improved ADHD symptom control in the early morning, throughout the day and during the evening time period in two pivotal Phase 3 trials.

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.

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 six years of age and older. JORNAY PM may help increase attention and decrease impulsiveness and hyperactivity in people six years of age and older with ADHD. It is not known if JORNAY PM is safe and effective in children under six 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. The recommended starting dose for patients 6 years and older is 20 mg once daily in the evening. Dosage may be titrated weekly in increments of 20 mg per day up to maximum daily dose of 100 mg. The mean optimized dose required to improve symptoms from the time the patient wakes up, throughout the day and into the evening in children 6-12 years old was 67 mg in Study 1 and 68.1 mg in Study 2. The relative bioavailability of JORNAY PM (given once a day) compared to the same daily dose of a methylphenidate immediate-release oral product (given 3 times a day) in adults is approximately 74%. JORNAY PM is primarily absorbed in the colon which may contribute to the reduced bioavailability of the drug. JORNAY PM is not interchangeable on a milligram-per-milligram basis with other methylphenidate formulations.
Please see additional dosing information in the full prescribing information for JORNAY PM at http://ironshorepharma.com/labeling.pdf.

IMPORTANT SAFETY INFORMATION

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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 (≥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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