



FOR IMMEDIATE RELEASE

IRONSHORE TO PRESENT NEW DATA AT THE 65TH ANNUAL AACAP MEETING

George Town, Cayman Islands – October 17, 2018 – [Ironshore Pharmaceuticals & Development, Inc.](#) (“Ironshore”), a wholly owned subsidiary of [Highland Therapeutics Inc.](#) and the global leader in the development of novel treatments for Attention Deficit Hyperactivity Disorder (ADHD), today announced that it will present three posters at the 65th Annual Meeting of the American Academy of Child & Adolescent Psychiatry (AACAP), including new data from one of its two pivotal trials supporting the recent Food and Drug Administration (FDA) approval of JORNAY PM™ (methylphenidate) for the treatment of ADHD in patients 6 years and older. The AACAP meeting will take place in Seattle, WA, October 22-27, 2018.

JORNAY PM is the only stimulant medication that is dosed in the evening and has demonstrated improvement in the severity of ADHD symptoms in the early morning and throughout the day. It is expected to be available commercially in the first half of 2019.

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 safety information below.

“We look forward to presenting findings from our pivotal trial of JORNAY PM for the first time at this year’s American Academy of Child & Adolescent Psychiatry meeting,” said Dr. Randy Sallee, Chief Medical Officer of Ironshore Pharmaceuticals, Inc. “In particular, we are pleased to share the primary outcome of the trial which evaluated the efficacy and safety of JORNAY PM in improving at-school impairment of children with ADHD.”

Following is a guide to Ironshore-sponsored data that will be presented during the AACAP annual meeting:

JORNAY PM (methylphenidate HCl) (formerly known as HLD200)

[Efficacy and Safety of Delayed-Release and Extended-Release Methylphenidate \(DR/ER-MPH\) in Children With ADHD: Results From a Pivotal Phase 3 Classroom Trial](#)

Poster 2.23; Wednesday, October 24, 2018; 1:30 pm – 4:00 pm PDT

Dr. Ann Childress to present

[Effect of Delayed-Release and Extended-Release Methylphenidate \(DR/ER-MPH\) on All-Day and Early Morning ADHD-Related Symptoms: Analysis of ADHD-Rating Scale-IV and ADHD-AM-Rating Scale Items From a Phase 3 Trial](#)

Poster 2.31; Wednesday, October 24, 2018; 1:30 pm – 4:00 pm PDT

Andrea Marraffino, PhD to present

ADHD

[Impact of the Placebo Rate on the Relative Risk of Sleep-Related Adverse Events Reported in Studies of Methylphenidate in Youth With ADHD: A Meta-Analysis](#)

Poster 2.36; Wednesday October 24, 2018; 1:30 – 4:00 pm PDT

Stephen V. Faraone, PhD to present

To schedule an interview with an investigator or Ironshore executive, please contact Mrs. Sarah Pierson at sarah@ironshorepharma.com.

In addition, Dr. William Dodson and Dr. Stephen Faraone, leaders in the field of ADHD, will be available to discuss ADHD and the early morning routine at Ironshore's booth (#131).

- **Dr. Bill Dodson** is a board-certified adult psychiatrist who has specialized in adults with ADHD for more than 20 years. Dr. Dodson is a former faculty member at Georgetown University and the University of Colorado Health Sciences Center and is currently in private practice at the Dodson ADHD Center in Greenwood Village, Colorado. He is a frequent lecturer and author on how basic research on ADHD can be applied to everyday clinical practice and a member of ADDitude's ADHD Specialist Panel.
- **Stephen Faraone, PhD** is a Distinguished Professor in the Departments of Psychiatry and Neuroscience & Physiology at SUNY Upstate Medical University and is also the Senior Scientific Advisor to the Research Program Pediatric Psychopharmacology at the Massachusetts General Hospital and a lecturer at Harvard Medical School.

Professor Faraone founded the ADHD Subgroup of the Psychiatric Genomics Consortium (PGC) and was a founding member of the PGC Coordinating Committee. He studies the nature and causes of mental disorders in childhood and has made contributions to research in psychiatric genetics, psychopharmacology, diagnostic issues and methodology.

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

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

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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 see additional safety information in the full prescribing information for JORNAY PM at <http://ironshorepharma.com/labeling.pdf>.

About Ironshore Pharmaceuticals & Development, Inc.

Ironshore Pharmaceuticals & Development, Inc., a wholly owned subsidiary of Highland Therapeutics Inc., is a pharmaceutical company that is leveraging the proprietary drug delivery platform, DELEXIS[®], to optimize the delivery of previously approved drug products.

Highland Therapeutics Inc. is a client of MaRS Discovery District's Health Venture Services group, which provides advisory services, connections to talent, customer and capital networks, and market intelligence to high-impact, Ontario, Canada-based life sciences ventures, helping them commercialize their ideas and build globally competitive companies. For more information, visit Highlandtherapeutics.com

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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.