



HIGHLAND  
THERAPEUTICS

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## **HIGHLAND THERAPEUTICS ANNOUNCES NEW CHIEF COMMERCIAL OFFICER AND APPOINTMENT OF CHIEF SCIENTIFIC OFFICER**

***Danny Villeneuve Joins as EVP, Chief Commercial Officer and Dr. Bev Incledon is Promoted to Chief Scientific Officer***

Toronto, Canada – September 17, 2020 – Highland Therapeutics Inc. (“Highland”) today announced two executive appointments at its wholly owned subsidiaries. Mr. Danny Villeneuve has assumed the role of Executive Vice President and Chief Commercial Officer and Dr. Bev Incledon has been promoted to the role of Executive Vice President and Chief Scientific Officer at Ironshore Pharmaceuticals Inc. and Ironshore Pharmaceuticals & Development, Inc., respectively. Both appointments are effective immediately.

“I am delighted to welcome Danny to the Ironshore family of companies and congratulate both him and Bev on the appointments,” said David Lickrish, Highland’s Chairman & Chief Executive Officer. “Danny brings a wealth of experience to Ironshore, gained from a 25-year career in the pharmaceutical industry, including 13 years directly in ADHD. His leadership skills and deep expertise in all facets of commercial operations, including sales, marketing and market access will be terrific assets to leverage as we seek to improve outcomes for patients with ADHD.”

Commenting on the promotion of Dr. Incledon, Mr. Lickrish stated, “Bev has been with the Company since its early days and was instrumental in designing the DELEXIS® technology, developing and managing clinical programs and building out both the R&D capabilities and Medical Affairs functions. Moreover, Dr. Incledon has identified a pipeline of new opportunities where DELEXIS may impart unique clinical advantages. I have no doubt Dr. Incledon will continue to excel in his role as Chief Scientific Officer.”

Commenting on his appointment, Mr. Villeneuve said, “I am excited to be joining Ironshore in the capacity of Chief Commercial Officer to help bring JORNAY PM to a broader audience of

patients and prescribers. Having worked with the Ironshore team in the past as a consultant, I already know this is a patient-centric organization committed to improving the lives of ADHD patients and their families, something that aligns with my own values.”

JORNAY PM is the first and only stimulant medication that is dosed in the evening, demonstrating improvement in the severity of ADHD symptoms in the early morning and 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 safety information below*

Commenting on his promotion, Dr. Incledon said, “I am immensely proud of the work we have accomplished at Ironshore – from the development of DELEXIS to the FDA approval of JORNAY PM, we have accomplished a lot of “firsts” as we continuously focus on innovation. DELEXIS, given its targeted delivery of both small and large molecules to the lower GI tract, is a particularly powerful platform which may have the potential to dramatically improve clinical outcomes in a variety of therapeutic settings including mucosal vaccine development, immunology, GI indications, diabetes, chronopharmacology and CNS applications where highly consistent, extended drug exposure may be advantageous.”

Dr. Incledon has over 28 years of pharmaceutical industry experience encompassing all facets of drug development, from drug discovery to manufacturing. Dr. Incledon was a Post-Doctoral Fellow at Cornell University, conducting his research in mathematical modeling of oxidative refolding of ribonuclease and the determination of refolding pathways in the presence of protein disulfide isomerase. He obtained his PhD degree in Biophysics and Bachelor of Science (Honors) in Applied Biochemistry with a Minor in Biomedical Technology from the University of Guelph.

**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**

### **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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