



## HIGHLAND THERAPEUTICS ANNOUNCES APPOINTMENT OF STEPHANIE C. READ TO BOARD OF DIRECTORS

Toronto, Canada – December 9, 2020 – Highland Therapeutics Inc. (“Highland”) today announced the appointment of Stephanie C. Read to its Board of Directors, effective November 13, 2020. Ms. Read brings to the Company a wealth of experience and expertise gained from over twenty years of tenure in the pharmaceuticals industry, including in the ADHD market.

“It is my pleasure to welcome Ms. Read, an accomplished executive, to the Highland Board of Directors,” said David Lickrish, Highland’s Chairman & Chief Executive Officer. “Ms. Read’s leadership skills encompass a wide range of functional areas, including corporate strategy, business development and product development through successful commercial launch, and she has proven expertise in strategies to unlock the potential of novel assets with unique delivery systems. In addition, her deal-making experience and global network will serve us well as we look to expand the availability of JORNAY PM® internationally, as well as to pursue in-licensing opportunities to leverage our specialty sales force, which is focused on supporting pediatricians and psychiatrists. Ms. Read has already made substantial contributions and I very much look forward to working with her, as Highland continues its evolution as a fully integrated pharmaceutical company.”

Commenting on her appointment, Ms. Read said, “I am very pleased to join the Highland Board of Directors. In my short tenure, I have been impressed with the Company’s patient-focused approach to medicines development and rapidly evolving strategies to expand patient access as a key component of the recent JORNAY PM launch. The DELEXIS® drug-delivery system has exciting potential across multiple disease states that could benefit from once-daily, sustained-release delivery to the colon in a non-pH-dependent manner. I believe Highland is well positioned to achieve its objectives and I am eager to contribute to its success.”

Ms. Read currently serves as Vice President, Strategy and Development for CSL Limited, a global pharmaceutical company that generated operating revenues in excess of US\$9 billion in the 2019/2020 fiscal year. Prior to joining CSL in 2015, she was Executive Director, Corporate Strategy and Ventures at AstraZeneca/MedImmune. Earlier in her career, she served as

Associate Director, Global Medical Affairs for Shire Pharmaceuticals. Ms. Read holds a M.Sc. in Biotechnology from Johns Hopkins University and a B.Sc. from Virginia Tech.

**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*

**About DELEXIS**

Developed by Ironshore Pharmaceuticals & Development, Inc., DELEXIS is a novel oral, once-daily, drug delivery technology. DELEXIS has delayed-release properties that limit the release of the medication overnight and extended-release properties that control the release of the medication throughout the following day. To learn more about DELEXIS, please visit

<https://www.ironshorepharma.com/delexis.html>.

**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 Highland Therapeutics Inc.**

Through its wholly owned subsidiary, Ironshore Pharmaceuticals & Development, Inc., Highland developed JORNAY PM, 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. JORNAY is distributed in the U.S. by Ironshore Pharmaceuticals Inc.

**About Ironshore Pharmaceuticals & Development, Inc.**

Ironshore Pharmaceuticals & Development, Inc., based in Grand Cayman, developed JORNAY PM 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.

**About Ironshore Pharmaceuticals Inc.**

Ironshore Pharmaceuticals Inc. commercializes innovative, patient- and caregiver-focused treatment options to improve lives. 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.

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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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