



**IRONSHORE**

PHARMACEUTICALS & DEVELOPMENT, INC.

## **IRONSHORE PHARMACEUTICALS ANNOUNCES PDUFA DATE OF AUGUST 8, 2018 FOR HLD200**

George Town, Grand Cayman, July 12, 2018 – Ironshore Pharmaceuticals & Development, Inc. (“Ironshore”), a wholly owned subsidiary of Highland Therapeutics Inc., today announced that the U.S. Food and Drug Administration (FDA) has accepted the resubmission of the New Drug Application (NDA) for HLD200, Ironshore’s lead compound currently under review as a new treatment for Attention Deficit Hyperactivity Disorder (ADHD) and set a Prescription Drug User Fee Act (PDUFA) date of August 8, 2018.

HLD200 is a delayed-release and extended-release formulation of methylphenidate which was developed to be dosed at night to target an onset of effect in the morning. HLD200 was developed over a 10-year period and the NDA contains data from nine trials including two pivotal Phase-3 studies. In both studies, HLD200 achieved statistically significant improvements in symptoms associated with ADHD on each of the endpoints evaluated.

HLD200 is the first product that leverages Ironshore’s DELEXIS® technology platform which could have a meaningful impact on health outcomes in a variety of therapeutic areas including, among others, central nervous system disorders and inflammatory bowel disease.

While the NDA resubmission for HLD200 has been accepted for review by the FDA, such acceptance does not mean that HLD200 will be approved by the FDA for the treatment of ADHD.

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

Ironshore Pharmaceuticals & Development, Inc., a wholly owned subsidiary of Highland Therapeutics Inc., is a pharmaceutical company that is leveraging its technology, 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 & capital networks, and market intelligence to high-impact, Ontario-based life sciences ventures, helping them commercialize their ideas and build globally competitive companies.

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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.