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For Immediate Release:

HIGHLAND THERAPEUTICS ANNOUNCES INITIATION OF PHASE 2 TRIAL FOR HLD100 IN PEDIATRIC ADHD PATIENTS

- **Comparative Trial vs. Vyvanse† Planned for 2017**

Toronto, Canada, August 25, 2016—Highland Therapeutics Inc. today announced that its wholly owned subsidiary, Ironshore Pharmaceuticals & Development, Inc. ("Ironshore"), has initiated enrollment in a Phase 2 study of HLD100, which is currently under development as a new amphetamine-based treatment option for patients with Attention Deficit/Hyperactivity Disorder (ADHD). Utilizing Ironshore's proprietary delayed-release and extended-release technology, DELEXIS®, HLD100 is intended for nighttime dosing and is designed to control ADHD symptoms and improve functioning immediately upon awakening and throughout the day.

The study, HLD100-103, is a "Phase II, Single-center, Open-label, Dose-titration Study Designed to Examine the Safety, Tolerability and Efficacy of Evening Dosed HLD100, a Novel Delayed and Extended Release (DR/ER) Formulation of Dextroamphetamine Sulfate, in Children with Attention Deficit Hyperactivity Disorder" and will enroll 24 pediatric patients, ages 6-12.

"Patients with ADHD, and the physicians who care for them, have a number of different treatment options available to them today," said David Lickrish, Ironshore's President and Chief Executive Officer. "None of those options, however, address the primary shortcoming of otherwise effective stimulant medications: the lack of effective symptom control and impaired functioning during the morning routine.

"If approved by the U.S. Food and Drug Administration (FDA), we intend to launch our lead methylphenidate product (HLD200) to address this unmet medical need, which could finally give patients the start to the day that they deserve while sustaining those advantages into the evening/bedtime period. Our amphetamine-based program (HLD100) could further broaden the choices available to patients and physicians."

The primary objective of the HLD100-103 study is to demonstrate that evening dosing with HLD100 is well tolerated in pediatric patients at steady state. Ironshore has previously conducted multiple single-dose pharmacokinetic (PK) studies with HLD100 in children, adolescents and adults. In addition to the tolerability profile, the investigators in the HLD100-103 study will also make assessments based on the ADHD-RS-IV rating scale and the Before School Functioning Questionnaire (BSFQ) to evaluate overall ADHD symptom control and functional improvements during the morning routine, respectively. Additional efficacy measures are to include the Parent Rating of Evening and Morning Behavior – Revised (PREMB-R) AM and PM subscales, which will assess HLD100's effectiveness during the morning and evening routines, respectively.

According to a survey sponsored by Ironshore, the vast majority of families report challenges with the uncontrolled symptoms of ADHD and the associated functional impairments during the early morning routine, with 29% of these characterizing the level of impairment as 'severe' and another 47% as 'moderate'. This impaired functioning is believed to have a significant impact on the quality of life for the patient and their families. Similarly, the evening routine can also pose significant challenges for ADHD patients and their families. As no currently marketed product improves functioning from the moment the child awakens through to bedtime, there is a need for a more complete, comprehensive, treatment option for ADHD.

Moreover, according to IMS Health, amphetamine-based products have historically been the treatment of choice among adult patients who frequently benefit from a duration of effect that exceeds the 12-hour window offered by existing long-acting formulations.

Dr. Randy Sallee, Chief Medical Officer, said: "Following insightful dialogue with our esteemed physician colleagues, Ironshore has developed a clinical pathway that is specifically designed to show the clinical utility of HLD100 across a range of patient populations, as compared to other treatment options. I believe these data will be of considerable interest to physicians and caregivers who continuously evaluate treatment options for their patients or children, as well as to adult patients looking for more comprehensive control of their ADHD symptoms and functional impairments."

The HLD100-103 study is part of a comprehensive clinical trial plan being developed for HLD100. Based on data from this study, and on continued feedback and dialogue with the FDA, Ironshore anticipates initiating (1) a phase 2b/3 study with Vyvanse as a comparator and (2) the pivotal trial program for HLD100 in 2017.

† Vyvanse is a registered trademark of Shire LLC.

About Highland Therapeutics Inc.

Highland Therapeutics Inc. is a specialty pharmaceutical company that, through its wholly owned subsidiary Ironshore Pharmaceuticals & Development, Inc., is leveraging its proprietary technologies to optimize the delivery of previously approved drug products. The Company's lead products, HLD200 and HLD100, are novel formulations of the psychostimulants (methylphenidate and amphetamine, respectively) used to treat ADHD and are being developed to address a prevalent unmet medical need in the treatment of the disease – the lack of symptom control during the morning routine. The clinically meaningful benefits of Highland's approach are targeted at helping ADHD patients and their families improve the quality of their lives.

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 Highland'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 Highland'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, Highland assumes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.