



H I G H L A N D
THERAPEUTICS

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For Immediate Release:

HIGHLAND THERAPEUTICS ANNOUNCES INITIATION OF PIVOTAL TRIAL OF HLD-200 IN PEDIATRIC ADHD PATIENTS

- **Primary endpoint: Improvement in ADHD symptoms, vs. placebo, from 8AM to 8PM**

TORONTO, Canada, July 29, 2015—Highland Therapeutics Inc. (“Highland”), a pharmaceutical company, today announced that its wholly owned subsidiary, Ironshore Pharmaceuticals & Development, Inc. (“Ironshore”), has initiated enrolment in a pivotal study to assess the safety and efficacy of HLD-200 – a next-generation formulation of methylphenidate – in children with Attention-Deficit/Hyperactivity Disorder (“ADHD”).

The study, “A Phase 3, Multicenter, Open-label Treatment-optimized, Double-blind, Randomized, Placebo-controlled, Forced-withdrawal, Parallel Group Study to Evaluate the Safety and Efficacy of Evening Dosed HLD200, a Novel Delayed and Extended Release Formulation (DELEXIS) of Methylphenidate Hydrochloride, in Children Aged 6-12 with Attention Deficit Hyperactivity Disorder (ADHD) in a Laboratory Classroom Setting” is expected to generate top-line data by year-end.

“The initiation of this pivotal study, the first of two we anticipate completing over the next six months, is a historic moment for the Company and the result of many years of dedication and passion from the remarkable team we have assembled,” said David Lickrish, Ironshore’s Chief Executive Officer. “We have long believed that our products could change the way ADHD is treated given HLD-200’s potential for (1) control over symptoms during the Early Morning Routine (EMR), (2) a consistent clinical effect throughout the day and (3) an extended duration of effect into the important evening homework period, representing a win-win-win for patients.”

The pivotal trial will enroll approximately 150 pediatric patients between the ages of six and twelve across seven sites in the U.S. The study will utilize an open-label, treatment-optimization Phase, followed by a double-blind, placebo-controlled, 1-week, parallel-group study design to assess safety and tolerability as well as the time-course of treatment effect of evening-dosed

HLD-200 in pediatric subjects diagnosed with ADHD. The study has been designed to build upon the successful results of the exploratory Phase 3 trial, known as CEES (Clinical Endpoint Evaluation Study), which was completed in 2014.

The primary objective of the study is to assess whether prior-evening treatment with HLD-200 improves control of ADHD symptoms, compared with placebo, from 8:00am to 8:00pm in pediatric subjects with ADHD.

Commenting on the pivotal study, Dr. Randy Sallee, Ironshore's Chief Medical Officer said, "Impaired functioning during the morning routine as a result of uncontrolled ADHD symptoms is an important unmet medical need for which no practical solution exists today. The initiation of this study brings us one step closer to reaching one of Ironshore's founding objectives – to provide such a solution. Should we also demonstrate an extended duration of effect, we believe HLD-200 could represent a first-line therapy in ADHD, potentially covering the 'bookends' of the patient's day – from early morning to evening homework time. The results of this study, in conjunction with those of a second pivotal study we expect to initiate shortly, if successful, would provide Ironshore with a robust clinical package to submit as part of a New Drug Application in mid-2016."

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 technology, DELEXIS®, to optimize the delivery of previously approved drug products. The Company's lead product candidates, HLD-200 and HLD-100, 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 – inadequate symptom control during the morning routine. Intended for nighttime dosing, DELEXIS® is designed to provide a consistent delay in the initial release of the active drug, followed by a period of extended release; with the objective of providing control of ADHD symptoms immediately upon waking and throughout the day.

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.

For further information, please visit the Company's website at www.highlandtherapeutics.com, or contact:

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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.