



HIGHLAND
THERAPEUTICS

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For Immediate Release:

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

- **The AHEAD study will focus on the Early Morning Routine (EMR)**

TORONTO, Canada, August 24, 2015—Highland Therapeutics Inc. (“Highland”) announced today that its wholly owned subsidiary, Ironshore Pharmaceuticals & Development, Inc. (“Ironshore”), has dosed the first patient in the second of two pivotal studies of HLD-200. HLD-200 is a next-generation formulation of methylphenidate that utilizes Ironshore’s proprietary drug delivery platform, DELEXIS®, to enable nighttime dosing of patients with Attention-Deficit/Hyperactivity Disorder (“ADHD”). Prior studies have shown that it may be possible to improve patient outcomes by dosing patients at night in order to improve functioning and achieve greater control over symptoms associated with ADHD from the time of awakening through to the evening hours the next day.

The study, “A Phase 3, Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel Group Study to Evaluate the Safety and Efficacy of Evening-dosed HLD-200, a Novel Delayed and Extended Release Formulation (DELEXIS) of Methylphenidate Hydrochloride, on Post-waking, Early Morning Function in Children Aged 6 to 12 With Attention Deficit Hyperactivity Disorder (ADHD),” also known as the AHEAD Study, is expected to generate top-line data in early 2016.

“The start of the second pivotal trial is an enormous milestone and a terrific accomplishment for everyone involved in this ground-breaking research. Few studies have attempted to assess behaviours and functioning in ADHD patients during the morning routine,” said David Lickrish, Ironshore’s Chief Executive Officer. “The Before School Functioning Questionnaire, or BSFQ, which was developed by Dr. Tim Wilens and Dr. Paul Hammerness at Massachusetts General Hospital, provides physicians with a new tool for assessing patients during this critical time of

day. We believe that as awareness grows, physicians will start making questions about the morning routine a routine question and adjust their treatment options accordingly.”

The pivotal trial will assess approximately 140 pediatric patients between the ages of six and twelve across 21 sites in the U.S. In conjunction with the other pivotal study that Ironshore recently initiated (where the primary endpoint is the improvement in ADHD symptoms from 8:00am to 8:00pm), the current 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.

“I am thrilled that we are off to such a strong start with the enrollment of patients in this potentially historic trial. We believe HLD-200, if approved, could be the preferred treatment option for physicians and parents who want the most comprehensive coverage throughout the day in a single pill,” said Dr. Randy Sallee, Ironshore’s Chief Medical Officer. “The early morning routine (EMR) and the functional impairments associated with it are important issues that are often underappreciated by physicians, given the current lack of any practical solution. I believe Ironshore is on the cusp of providing such a solution to the millions of families worldwide that struggle with ADHD.”

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.