



H I G H L A N D
THERAPEUTICS

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For Immediate Release:

HIGHLAND THERAPEUTICS ANNOUNCES INITIATION OF PHASE III TRIAL FOR HLD-200 IN PEDIATRIC ADHD PATIENTS

TORONTO, Canada, April 28, 2014—Highland Therapeutics Inc. (“Highland”), an emerging pharmaceutical company, today announced that its wholly owned subsidiary has begun enrolment in a Phase III study of HLD-200, the Company’s novel formulation of methylphenidate, in pediatric patients with Attention-Deficit Hyperactivity Disorder (“ADHD”).

The study, “A Phase III Clinical Endpoint Evaluation Study (“CEES”) Examining the Safety and Efficacy of HLD-200 in Pediatric Subjects with Attention-Deficit Hyperactivity Disorder”, is expected to be completed in the fourth quarter of 2014. The protocol has been reviewed by the U.S. Food & Drug Administration (“FDA”).

“We are delighted to have achieved yet another important milestone in the development of HLD-200, a product that has the potential to become first-line therapy in the treatment of ADHD,” said David Lickrish, President and CEO of Highland Therapeutics Inc. “The start of our first Phase III trial represents a watershed event in the Company’s history. We believe that HLD-200 could improve the lives of patients and their families, who struggle with the uncontrolled symptoms of ADHD during the morning routine and throughout the day.”

The CEES trial will enroll 54 pediatric patients between the ages of six and twelve. The multicenter study will consist of a six-week open label, treatment-optimization phase followed by a double-blind, placebo-controlled, one-week randomized, parallel-group test period designed to assess the safety and efficacy of HLD-200 treatment in pediatric subjects with ADHD.

The primary objective of the study will be to demonstrate that evening treatment with HLD-200 improves control of ADHD symptoms, compared to placebo, throughout the day in pediatric ADHD subjects, as measured by the Swanson, Kotkin, Agler, M-Flynn and Pelham (“SKAMP”) scale. A key secondary objective will be to demonstrate that evening treatment

with HLD-200 improves control of ADHD symptoms, compared to placebo, during the at-home morning routine in these patients.

According to an independent survey sponsored by Highland, the vast majority of families report challenges with the uncontrolled symptoms of ADHD during the early morning routine, with 55% of these characterizing the level of impairment as 'severe' or 'moderate-to-severe'. This impairment has a significant impact on the quality of life for the patient and their families.

Dr. Albert Agro, Senior Vice President, Clinical Development, said: "The data we have generated to date – from five successful clinical studies in pediatric, adolescent and adult populations – confirm the robustness of Highland's platform technology. We have identified several interesting compounds in a number of disease states that could benefit from the application of this technology, and we intend to advance at least one into our development pipeline in 2014."

Based on the data generated in the CEES study and continued dialogue with the FDA, Highland intends to initiate a pivotal trial with HLD-200 in the fourth quarter of 2014. The Company currently anticipates the submission of a New Drug Application in the first half of 2015.

Methylphenidate is currently sold under the brand name Concerta by Janssen Pharmaceuticals, Inc. (a Johnson & Johnson company) and Ritalin/Ritalin LA by Novartis Pharmaceuticals Corporation.

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, 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 – the lack of symptom control during the morning routine.

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.