



Highland Therapeutics Inc.

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For Immediate Release:

HIGHLAND THERAPEUTICS ANNOUNCES POSITIVE INTERIM RESULTS FROM PHASE I/II STUDY OF HLD-200 IN ADHD PATIENTS

TORONTO, Canada, October 3, 2013—Highland Therapeutics Inc. (“Highland”), a specialty pharmaceutical company leveraging its proprietary technologies to optimize the delivery of previously approved drug products, today announced that its wholly owned subsidiary has generated positive interim Phase I/II results from an ongoing study of HLD-200 – a novel formulation of methylphenidate being developed to treat the symptoms associated with Attention-Deficit/Hyperactivity Disorder (ADHD).

The study, “A Phase I/II, Single Center, Single-Treatment, Open-Label, Adaptive Clinical Trial Design Examining the Pharmacokinetic Effects of up to Two Separate HLD-200 Modified Release Formulations of Methylphenidate in Adolescent and Pediatric Subjects with Attention-Deficit Hyperactivity Disorder”, is expected to be completed in the fourth quarter of 2013.

Based on an interim analysis of data from adolescent patients, the study demonstrated that the active pharmaceutical ingredient (API), methylphenidate, was consistently delivered in a manner that allows for dosing of HLD-200 prior to bedtime, with the objective of controlling the symptoms of ADHD immediately upon waking. Further, a comparative analysis of the pharmacokinetic (PK) profiles suggests that HLD-200 could have an extended duration of effect when compared to other once-daily methylphenidate medications. Notably, patients enrolled in the study did not report any significant adverse events, which suggests that HLD-200 could potentially have a better safety profile than other available medications to treat ADHD. 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.

“These results, which are the first we have generated in adolescent patients, confirm that Highland’s drug delivery platform is extremely reliable and delivers the API consistently and reproducibly across patients. Moreover, the drug release does not appear to be affected by the patient’s age or differences in physiology between adolescent patients and healthy adult volunteers,” said David Lickrish, President and CEO of Highland Therapeutics Inc. “We are excited to see that our proprietary

technology has the potential to improve the lives of patients and their families, who struggle with the uncontrolled symptoms of ADHD during the early morning routine. Highland was founded on the belief that we could address this unmet medical need, providing a solution for all families who struggle during this busy and important time of day.”

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. Many physicians advocate that a good start to the day for patients with ADHD could result in positive amplifying effects, whereas the opposite experience often results in negative, cascading effects.

Dr. Bev Inledon, Senior Vice President, Research & Development said: “The market for ADHD treatments has grown substantially over the past 10 years and consumers today have a number of different options to choose from, yet a significant unmet medical need remains. Our goal was to develop a medication that would address this need. Based on the strength of the results achieved to date, we believe that our drug candidates, both HLD-200 (methylphenidate) and HLD-100 (amphetamine), are likely to work exceptionally well in our target markets. Prior to year-end, we intend to request a meeting with the U.S. Food & Drug Administration (FDA) to discuss what steps may be necessary in order to obtain approval for this important, and much-needed, medication.”

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-100 and HLD-200, are novel formulations of the psychostimulants (amphetamine and methylphenidate, 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 early morning routine.

Highland Therapeutics Inc. is a client of MaRS Discovery District’s Life Sciences and Healthcare practice, which provides advisory services and support to help Ontario life sciences companies grow and commercialize their businesses.

For further information, please contact Nelson F. Isabel at (647) 260-7875.

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.