



H I G H L A N D
THERAPEUTICS

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For Immediate Release:

HIGHLAND THERAPEUTICS ANNOUNCES NOTICE OF PATENT ALLOWANCE; PROVIDES UPDATE ON AMPHETAMINE DEVELOPMENT PLANS

TORONTO, Canada, March 10, 2015—Highland Therapeutics Inc. (“Highland”), a pharmaceutical company, today announced that the U.S. Patent and Trademark Office (“USPTO”) has issued a Notice of Allowance for a patent (# 13/429,292) covering HLD-100, the Company’s novel formulation of dextroamphetamine. HLD-100 is intended to be taken once-daily in the evening in order to control the symptoms of ADHD immediately upon awakening and throughout the day. When issued, the patent will expire 2032.

“This Notice of Allowance is another important milestone in the development of our emerging ADHD franchise,” said David Lickrish, Highland’s President and CEO. “We selected methylphenidate (HLD-200) as our lead program given that over 80% of long-acting methylphenidate prescriptions are for pediatric and adolescent patients, where the need for improved functioning during the morning routine is most acute. However, an estimated 12 million amphetamine prescriptions are also written annually for these patient populations. Developing a portfolio of ADHD products is the best way to accommodate the two-thirds of patients that show a preferential response to one class of stimulant or another; thereby maximizing our potential contribution to ADHD-patient care and choice.”

HLD-100 Clinical Development Update

With HLD-200 (Highland’s lead methylphenidate program) scheduled to complete its pivotal trials and clinical development program later this year, management is in a position to commit additional resources to HLD-100 to broaden the Company’s product offerings in ADHD. HLD-100 has already completed pharmacokinetic trials in pediatric, adolescent and adult populations, tracking the same development path as HLD-200. During these trials, HLD-100 exhibited similar hallmark pharmacokinetic attributes as HLD-200, including a low 8.8% coefficient of variation

(CV) with respect to the time to maximum concentration (Tmax). A low CV is considered desirable, given the potential to deliver a more consistent and predictable clinical response.

The next step in the development process is to advance HLD-100 into a Phase 2B study, to assess HLD-100's ability to provide clinically meaningful control of ADHD symptoms, from the moment the patient awakens and throughout the day. Highland intends to initiate this study in the second half of 2015.

David Lickrish added, "As our products continue to meet their investigational milestones, we intend to sponsor additional studies to show a benefit for the millions of adults who also struggle with uncontrolled symptoms during the morning routine."

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.