



IRONSHORE

PHARMACEUTICALS & DEVELOPMENT, INC.

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For Immediate Release:

IRONSHORE PHARMACEUTICALS PRESENTS PIVOTAL TRIAL DATA AT AMERICAN PSYCHIATRIC ASSOCIATION MEETING

George Town, Cayman Islands, May 23, 2017—Ironshore Pharmaceuticals & Development, Inc. (“Ironshore”), a wholly owned subsidiary of Highland Therapeutics Inc. and the global leader in the development of novel treatments for Attention-Deficit/Hyperactivity Disorder (“ADHD”), today announced that it will be presenting new Pivotal Trial Data for evening-dosed HLD200 (delayed-release and extended-release methylphenidate) at the American Psychiatric Association (“APA”) meeting, being held in San Diego through May 24, 2017. HLD200 is Ironshore’s investigational drug candidate for the treatment of ADHD; a New Drug Application is currently pending before the U.S. Food and Drug Administration (“FDA”).

“We are delighted to be sharing Pivotal Trial Data for HLD200, which are being presented for the first time. It is a noteworthy finding that HLD200-treated children demonstrated statistically significant improvements, relative to placebo, in ADHD functioning during both the early morning and evening bedtime routines. These findings may correlate to the statistically significant reduction in measures of caregiver strain observed in the study data,” said Dr. Randy Sallee, Chief Medical Officer of Ironshore Pharmaceuticals Inc. “We know a child’s ADHD has an impact on the entire family unit, with parents experiencing much of the burden associated with their child’s inability to complete routine tasks during the morning and evening routine like brushing teeth, getting dressed, staying on schedule, sitting through meals and getting ready for bed. These tasks can be difficult for all young children, but they are exacerbated in patients with ADHD. If approved by the FDA, HLD200 could potentially change the way ADHD is treated given the observed impact on clinical outcomes.”

Details of Ironshore's poster sessions are below:

New Research Posters 2 – Exhibit Hall A, Ground Level

Tuesday, May 23; 10AM – 12PM PDT

Poster #: P7-051

Efficacy of HLD200 on Early Morning and Late Afternoon/Evening Functioning Assessed by Individual Item Ratings on the PREMB-R in Children With ADHD

This post-hoc analysis of data from Ironshore's pivotal study was conducted to further evaluate the efficacy of HLD200 versus placebo in reducing specific at-home functional impairments in children with ADHD by examining individual item ratings on the Parent Rating of Evening and Morning Behavior-Revised ("PREMB-R") AM and PM subscales. After three weeks of treatment, HLD200 significantly improved all PREMB-R AM item scores, and four of the PREMB-R PM item scores, including "settling down and getting ready for bed" and "falling asleep". These findings suggest that HLD200 consistently improves at-home functional impairment in children with ADHD from the early morning and lasting through the evening.

Poster #: P7-055

Consistent Efficacy of HLD200 on Early Morning Functioning in Children With ADHD: Analysis of BSFQ Item Ratings

This post-hoc analysis of data from HLD200's pivotal study was conducted to further evaluate the efficacy of HLD200 versus placebo in reducing specific at-home early morning functioning ("EMF") impairments in children with ADHD by examining individual item ratings on the Before School Functioning Questionnaire ("BSFQ"). In addition to improving overall EMF impairment in children with ADHD, HLD200 demonstrated consistent efficacy by significantly improving 19 out of 20 individual BSFQ item scores versus placebo. These findings suggest that HLD200 improves functioning across commonly reported areas of dysfunction associated with ADHD in children during early morning, before-school activities.

Poster #: P7-044

Effect of HLD200 on Caregiver-Reported ADHD Symptom Improvement in Children With ADHD and Caregiver Strain: Results from a Phase 3 Trial

This poster examines HLD200's efficacy, versus placebo, in children with ADHD based on improvements in caregiver-rated ADHD symptoms, as measured by the Conners' Global Index – Parent ("CGI-P"), and reductions in caregiver strain, as measured by the Caregiver Strain Questionnaire ("CGSQ"), versus placebo. After three weeks of treatment, caregivers reported statistically significant improvements in their child's ADHD symptoms and these improvements coincided with reductions in caregiver strain ($p < 0.001$ on the CGI-P and $p = 0.001$ on the CGSQ).

Poster #: P7-048

Single-Dose Pharmacokinetics of HLD200, a Delayed-Release and Extended-Release Methylphenidate, in Adults and in Adolescents and Children With ADHD

HLD200 was well tolerated and demonstrated low intersubject variability in mean time to achieve ascending plasma concentrations, suggesting that HLD200 is consistent and predictable in the timing of methylphenidate release. After accounting for differences in body weight, the pharmacokinetics of HLD200 were similar between adults, and adolescents and children with ADHD, and their pharmacokinetic profiles appeared to be monophasic and nearly superimposable.

About Ironshore Pharmaceuticals & Development, Inc.

Ironshore Pharmaceuticals & Development, Inc., a wholly owned subsidiary of Highland Therapeutics Inc., is a pharmaceutical company that is leveraging its proprietary technology, DELEXIS®, to optimize the delivery of previously approved drug products.

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 Ironshore'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 Ironshore'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, Ironshore assumes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.