



Ironwood Pharmaceuticals Initiates Phase I Clinical Study of sGC Stimulator IW-1973

- Seventh clinical study ongoing in Ironwood pipeline this year -

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Ironwood Pharmaceuticals, Inc.](http://www.ironwoodpharma.com) (NASDAQ: IRWD) announced today that dosing has begun in a Phase I clinical study of IW-1973, the first clinical compound in a broad, pharmacologically-differentiated library of soluble guanylate cyclase (sGC) stimulators discovered by Ironwood. Data are expected in the second half of 2015. Ironwood expects to advance a second sGC stimulator, IW-1701, into a Phase I clinical study later this year.

"We look forward to exploring the potential of sGC stimulators across multiple, select therapeutic opportunities within a broad potential range that may span cardiovascular diseases, fibrosis, muscular dystrophy, glaucoma, dementia and diabetic complications," said Mark Currie, Ph.D., chief scientific officer and president of research and development at Ironwood. "It is rare in drug discovery to have the opportunity to modulate one of the fundamental regulators in the human body, and we are fortunate to have the pharmacologic expertise to advance what we believe can be strongly differentiated molecules in this space."

The randomized, double-blind, placebo-controlled Phase I clinical study is designed to assess the safety, pharmacokinetic profile and pharmacodynamic effects of IW-1973 in healthy volunteers.

The IW-1973 Phase I study is the seventh clinical study ongoing in Ironwood's research and development pipeline this year. Other clinical studies conducted by Ironwood include an ongoing Phase IIa clinical study of IW-9179 in diabetic gastroparesis and a recently completed Phase IIa clinical study of IW-3718 for refractory gastroesophageal reflux disease. Clinical studies ongoing with partners include Phase III trials with linaclotide for adults with irritable bowel syndrome with constipation for China and for Japan, as well as a Phase III trial with a 72 mcg dose of linaclotide in adult patients with chronic idiopathic constipation and a Phase II clinical study of linaclotide for adults with opioid-induced constipation, both in the U.S.

About IW-1973

IW-1973 is an investigational soluble guanylate cyclase (sGC) stimulator discovered by Ironwood. SGC is an enzyme found inside cells throughout the body; it modulates levels of the second messenger cyclic guanosine monophosphate (cGMP), a signaling molecule that regulates many physiological changes and may be relevant for the treatment of a broad range of diseases including cardiovascular diseases such as pulmonary arterial hypertension and congestive heart failure as well as fibrosis, muscular dystrophy, glaucoma, dementia and diabetic complications. Data from preclinical studies of IW-1973 suggest a pharmacokinetic profile consistent with once daily dosing and showed a gradual lowering of blood pressure without profound hypotension or tachycardia in animal models. Ironwood established its expertise with guanylate cyclase C (GC-C), another modulator of cGMP, through the discovery and development of linaclotide; the company then leveraged that GC-C expertise to discover and patent a broad library of chemically distinct sGC stimulators. Ironwood is currently utilizing medicinal chemistry, formulation and pharmacology to drive toward optimizing these molecules for pursuit of various indications and dosing schedules.

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is focused on creating medicines that make a difference for patients, building value to earn the continued support of our fellow shareholders, and empowering our team to passionately pursue excellence. We discovered, developed and are commercializing linaclotide, which is approved in the United States and a number of other countries. Our pipeline priorities include exploring further opportunities for linaclotide, as well as leveraging our therapeutic expertise in gastrointestinal disorders and our pharmacologic expertise in guanylate cyclases to address patient needs across the upper and lower gastrointestinal tract. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. Connect with us at www.ironwoodpharma.com or on Twitter at [www.twitter.com/ironwoodpharma](https://twitter.com/ironwoodpharma); information that may be important to investors will be routinely posted in both these locations.

Any trademarks referred to in this press release are the property of their respective owners. All rights reserved.

This press release contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including, but not limited to, statements about the clinical program for IW-1973; the design of the Phase I

study and the data to be generated; the completion of the Phase I clinical study and the date on which the data from the study are expected to be available; the study's impact on future development plans; the design and potential impact of IW-1973; the therapeutic opportunities for sGC stimulators; the design, breadth, scope and potential of our library of sGC stimulators, their pharmacological differentiation, and our development plans and activities with respect thereto, including the therapeutic opportunities and dosing schedules we intend to pursue; the results of our preclinical studies of IW-1973 and our other sGC stimulators and the impact thereof; the breadth and strength of the intellectual property for IW-1973 and our other sGC stimulators; and the timing of the expected Phase I clinical study for IW-1701. Each forward - looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include, but are not limited to, the risk that we are unable to complete the Phase I clinical study for IW-1973 on the same timeline as we currently anticipate or are otherwise unable to effectively execute on our clinical program for IW-1973; the risk that the data from such clinical study are not available when we currently anticipate them or do not demonstrate the results we expect, including with respect to safety, pharmacokinetic profile or pharmacodynamic effects; the risk that the clinical study needs to be discontinued for any reason, including safety, tolerability, enrollment, manufacturing or economic reasons; the risk that the data from non-clinical studies do not support the data from our clinical study; the risk that we are not able to initiate the Phase I clinical study for IW-1701 on the same timeline as we currently anticipate; the risk that the therapeutic opportunities for sGC stimulators and the potential for our library of sGC stimulators is not as we expect; those related to decisions made by regulatory authorities; those related to decisions made by the U.S. Patent and Trademark Office and its foreign counterparts, intellectual property rights of competitors or potential competitors, and the risk that we may never get sufficient patent protection for IW-1973 and our other sGC stimulators; and those risks related to competition and future business decisions made by us and our competitors or potential competitors. Applicable risks also include those that are listed under the heading "Risk Factors" and elsewhere in Ironwood's Annual Report on Form 10-K for the year ended December 31, 2014, in addition to the risk factors that are listed from time to time in Ironwood's Annual Reports on Form 10 - K, Quarterly Reports on Form 10 - Q and any other subsequent SEC filings. We undertake no obligation to update these forward-looking statements to reflect events or circumstances occurring after this press release. Except as otherwise noted, these forward-looking statements speak only as of the date of this press release. All forward - looking statements are qualified in their entirety by this cautionary statement.

Ironwood Pharmaceuticals, Inc.

Media Relations

Trista Morrison, 617-374-5095

Director, Corporate Communications

tmorrison@ironwoodpharma.com

or

Investor Relations

Meredith Kaya, 617-374-5082

Director, Investor Relations

mkaya@ironwoodpharma.com

Source: Ironwood Pharmaceuticals, Inc.

News Provided by Acquire Media