



Ironwood Pharmaceuticals Closes U.S. Transaction with AstraZeneca for Lesinurad

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Ironwood Pharmaceuticals, Inc.](#) (NASDAQ: IRWD) announced today that it has closed the previously-announced transaction with [AstraZeneca](#) for the exclusive U.S. rights to all products containing lesinurad. Lesinurad 200mg tablets were approved as ZURAMPIC[®] by the U.S. Food and Drug Administration (FDA) [in December 2015](#) for use in combination with a xanthine oxidase inhibitor (XOI) for the treatment of hyperuricemia associated with uncontrolled gout. The licensing agreement includes exclusive U.S. rights to the fixed-dose combination of lesinurad and allopurinol. AstraZeneca plans to submit, on Ironwood's behalf, the fixed-dose combination program for FDA regulatory review in the second half of 2016. The agreement also includes certain rights to potentially access RDEA3170 in gout indications in the U.S.

Gout is a serious, progressive and debilitating form of inflammatory arthritis. As many as two million patients in the U.S. on urate-lowering therapy have inadequately controlled hyperuricemia associated with gout, as XOI treatment alone is not sufficient to achieve their serum uric acid (sUA) treatment goals. ZURAMPIC is not recommended for the treatment of asymptomatic hyperuricemia and should not be used as monotherapy.

About ZURAMPIC[®] (lesinurad) 200mg tablets

FDA-approved ZURAMPIC[®] (lesinurad) works selectively to complement xanthine oxidase inhibitors (XOIs) in the treatment of hyperuricemia associated with uncontrolled gout. ZURAMPIC is not recommended for the treatment of asymptomatic hyperuricemia and should not be used as monotherapy. XOIs reduce the production of uric acid; ZURAMPIC increases the excretion of uric acid. Together, the combination of ZURAMPIC and an XOI provides a dual mechanism of action that both decreases production and increases excretion of uric acid, thereby lowering serum uric acid (sUA) levels in patients who have not achieved target serum uric acid levels with XOI treatment alone. ZURAMPIC selectively inhibits the function of transporter proteins urate transporter (URAT1) and organic anion transporter 4 (OAT4), involved in uric acid reabsorption in the kidney. The safety and efficacy of ZURAMPIC was established in three Phase III clinical trials that evaluated a once-daily dose of ZURAMPIC in combination with the XOI allopurinol or febuxostat compared to XOI alone.

Important Safety Information and Limitations of Use

WARNING: RISK OF ACUTE RENAL FAILURE MORE COMMON WHEN USED WITHOUT A XANTHINE OXIDASE INHIBITOR (XOI)

- | **Acute renal failure has occurred with ZURAMPIC and was more common when ZURAMPIC was given alone**
 - | **ZURAMPIC should be used in combination with an XOI**
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Contraindications:

- | Severe renal impairment (eCLcr less than 30 mL/min), end-stage renal disease, kidney transplant recipients, or patients on dialysis
- | Tumor lysis syndrome or Lesch-Nyhan syndrome

Warnings and Precautions:

- | **Renal events:** Adverse reactions related to renal function have occurred after initiating ZURAMPIC. A higher incidence was observed at the 400-mg dose, with the highest incidence occurring with monotherapy use. Monitor renal function at initiation and during therapy with ZURAMPIC, particularly in patients with eCLcr below 60 mL/min, and evaluate for signs and symptoms of acute uric acid nephropathy. ZURAMPIC should not be initiated in patients with an eCLcr less than 45 mL/min
- | **Cardiovascular events:** Major adverse cardiovascular events were observed with ZURAMPIC; a causal relationship

has not been established

Adverse Reactions:

- | Most common adverse reactions with ZURAMPIC (in combination with an XOI and more frequently than on an XOI alone) were headache, influenza, blood creatinine increased, and gastroesophageal reflux disease

Indication and Limitations of Use for ZURAMPIC

ZURAMPIC is a URAT1 inhibitor indicated in combination with an XOI for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with an XOI alone.

- | ZURAMPIC is not recommended for the treatment of asymptomatic hyperuricemia
- | ZURAMPIC should not be used as monotherapy

Please see full Prescribing Information, including Boxed Warning, at: <http://www.azpicentral.com/zurampic/zurampic.pdf>.

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is a commercial biotechnology company focused on creating medicines that make a difference for patients, building value for our fellow shareholders, and empowering our passionate team. We are advancing a pipeline of innovative medicines in areas of significant unmet need, including irritable bowel syndrome with constipation (IBS-C)/chronic idiopathic constipation (CIC), refractory gastroesophageal reflux disease, uncontrolled gout, and vascular and fibrotic diseases. We discovered, developed and are commercializing linaclotide, the U.S. branded prescription market leader in the IBS-C/CIC category, and we are applying our proven R&D and commercial capabilities to advance multiple internally-developed and externally-accessed product opportunities. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. For more information, please visit www.ironwoodpharma.com or www.twitter.com/ironwoodpharma; information that may be important to investors will be routinely posted in both these locations.

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 anticipated timing of regulatory developments for the fixed-dose combination of lesinurad and allopurinol. Applicable risks and uncertainties include, but are not limited to, decisions made by U.S. regulatory authorities, the U.S. Patent and Trademark Office and their foreign counterparts and the efficacy, safety and tolerability of the fixed-dose combination of lesinurad and allopurinol. Applicable risks also include those that are listed under the heading "Risk Factors" and elsewhere in Ironwood's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and in our subsequent SEC filings. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and Ironwood undertakes no obligation to update these forward-looking statements.

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Ironwood Pharmaceuticals, Inc.
Media Relations
Trista Morrison, 617-374-5095
Director, Corporate Communications
tmorrison@ironwoodpharma.com
or
Investor Relations
Mary T. Conway, 617-768-2628
Investor Relations
maconway@ironwoodpharma.com

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