



Ironwood Highlights Breadth of Gout Research to be Presented at the 2017 ACR/ARHP Annual Meeting

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Ironwood Pharmaceuticals, Inc.](#) (NASDAQ: IRWD) today announced one oral and twelve poster presentations to be presented at the upcoming ACR/ARHP Annual Meeting in San Diego, California from November 3-8, 2017. The meeting is hosted by the American College of Rheumatology and Association of Rheumatology Health Professionals.

The presentations include a poster entitled, "Less Than Half of Patients Treated with High-Dose Allopurinol Reach Serum Uric Acid Target," which includes data from a quantitative survey of rheumatologists and primary care physicians in the U.S. and E.U. to assess the proportion of patients with gout on allopurinol alone who fail to reach serum uric acid (sUA) target levels. The researchers concluded that less than 50% of patients achieved sUA < 6 mg/dL at any dose of allopurinol, and those on a higher dose of allopurinol were not more likely to reach this target.

"Data to be presented at ACR reinforce the high unmet need in uncontrolled gout, with an estimated two million patients in the U.S. taking allopurinol alone who are not achieving target serum uric acid levels," said Christopher Wright, MD, PhD, senior vice president of global development and chief development officer at Ironwood. "Ironwood is pleased to be able to provide physicians with a new treatment option, DUZALLO® (lesinurad and allopurinol), the first and only medicine available for appropriate patients with gout that treats high uric acid in two ways with one pill. We feel it is an important option for them to consider as they evaluate and treat adult patients with uncontrolled gout."

Other presentations to be given at ACR address the long-term health consequences of gout and the association of uncontrolled gout on diabetes, heart failure and chronic kidney disease.

The titles and scheduled presentation times are as follows:

Unmet Need Among Patients with Gout Taking Allopurinol:

[Less Than Half of Patients Treated with High-Dose Allopurinol Reach Serum Uric Acid Target](#) (abstract #1120, poster), to be presented during the Metabolic and Crystal Arthropathies Poster I on Monday, Nov. 6, 2017, 9:00 a.m. - 11:00 a.m. Eastern Time, by Douglas C.A. Taylor, MBA, Ironwood Pharmaceuticals, Inc., Cambridge, MA, USA.

[Allopurinol Treatment for Gout: How Long to Reach Serum Urate Goal?](#) (abstract #1121, poster), to be presented during the Metabolic and Crystal Arthropathies Poster I on Monday, Nov. 6, 2017, 9:00 a.m. - 11:00 a.m. Eastern Time, by Jean J. Lim, DrPH, Tufts University School of Medicine, Boston, MA; Ironwood Pharmaceuticals, Inc., Cambridge, MA, USA.

[Allopurinol Dose-Titration Patterns Relative to Serum Uric Acid Levels in Gout Patients: US Electronic Health Record Data](#) (abstract #2059, poster), to be presented the Metabolic and Crystal Arthropathies Poster II on Tuesday, Nov. 7, 2017, 9:00 a.m. - 11:00 a.m. Eastern Time, by An Chen Fu, MS, Ironwood Pharmaceuticals, Inc., Cambridge, MA, USA.

Potential Long-Term Health Consequences of Gout:

[Uncontrolled Gout Patients with Higher Heart Failure Hospitalization Rates in US](#) (abstract #1119, poster), to be presented during the Metabolic and Crystal Arthropathies Poster I on Monday, Nov. 6, 2017, 9:00 a.m. - 11:00 a.m. Eastern Time, by Robert Morlock, PhD, YourCareChoice, Ann Arbor, MI, USA.

[Diabetes and Gout: Real-World Evidence Evaluating Patient Characteristics, Treatment Patterns, and Healthcare Utilization](#) (abstract #1118, poster), to be presented during the Metabolic and Crystal Arthropathies Poster I on Monday, Nov. 6, 2017, 9:00 a.m. - 11:00 a.m. Eastern Time, by Douglas C.A. Taylor, MBA, Ironwood Pharmaceuticals, Inc., Cambridge, MA, USA.

[Prevalence of Chronic Kidney Disease and Uncontrolled Serum Uric Acid Levels in US Adult Gout Population: Results from the National Health and Nutrition Examination Survey 2007-2012](#) (abstract #1122, poster), to be presented during the Metabolic and Crystal Arthropathies Poster I on Monday, Nov. 6, 2017, 9:00 a.m. - 11:00 a.m. Eastern Time, by Jean J. Lim, DrPH, Tufts University School of Medicine, Boston, MA; Ironwood Pharmaceuticals, Inc., Cambridge, MA, USA.

Disease State Studies:

[*Determinants of Patient and Physician Disagreement on Presence of a Gout Flare*](#) (abstract #357, poster), to be presented during the Patient Outcomes, Preferences, and Attitudes Poster I on Sunday, Nov. 5, 2017, 9:00 a.m. - 11:00 a.m. Eastern Time, by Aprajita Jagpal, MD, Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham, Birmingham, AL, USA.

[*Patients with Gout Consider Zero Flares over the Previous Six or Twelve Months Necessary for a Remission State*](#) (abstract #350, poster), to be presented during the Patient Outcomes, Preferences, and Attitudes Poster I on Sunday, Nov. 5, 2017, 9:00 a.m. - 11:00 a.m. Eastern Time, by Angelo L. Gaffo, MD, MsPH, Department of Medicine, Division of Immunology and Rheumatology, University of Alabama at Birmingham, Birmingham, AL, USA.

[*Low and Moderate Intensity Exercise Suppresses Inflammatory Responses and Suggests Therapeutic Efficacy in an Acute Mouse Model of Gout*](#) (abstract #60, poster), to be presented during the Biology and Pathology of Bone and Joint Poster I on Sunday, Nov. 5, 2017, 9:00 a.m. - 11:00 a.m. Eastern Time, by Nicholas A. Young, PhD, Department of Internal Medicine, Division of Immunology and Rheumatology, The Ohio State University Wexner Medical Center, Columbus, OH, USA.

[*A Genome-Wide Association Study of Gout in People of European Ancestry*](#) (abstract #1104, poster), to be presented during the Metabolic and Crystal Arthropathies Poster I on Monday, Nov. 6, 2017, 9:00 a.m. - 11:00 a.m. Eastern Time, by Tony R. Merriman, PhD, Department of Biochemistry, University of Otago, New Zealand.

[*Identification of Urate Deposits in Patients with Asymptomatic Hyperuricemia using a Dual-Energy CT Scan*](#) (abstract #2057, poster), to be presented during the Metabolic and Crystal Arthropathies Poster II on Tuesday, Nov. 7, 2017, 9:00 a.m. - 11:00 a.m. Eastern Time, by Penny Wang, Clinical Research Assistant, Division of Rheumatology, Immunology and Allergy, Brigham and Women's Hospital, Boston, MA, USA.

[*Validation of a Definition for Flare in Patients with Established Gout*](#) (abstract #2950, poster), to be presented during the Patient Outcomes, Preferences, and Attitudes III on Wednesday, Nov. 8, 2017, 11:00 a.m. - 12:30 p.m. Eastern Time, by Angelo L. Gaffo, MD, MsPH, Department of Medicine, Division of Immunology and Rheumatology, University of Alabama at Birmingham, Birmingham, AL, USA.

[*Human Cartilage Influences the Crystallization of Monosodium Urate \(MSU\); Understanding the Link between Gout and Osteoarthritis*](#) (abstract #2896, oral presentation), to be presented during the Metabolic and Crystal Arthropathies II: Mechanisms of Crystal Inflammation and Metabolism on Wednesday, Nov. 8, 2017, 9:00 a.m. - 10:30 a.m. Eastern Time, by Nicola Dalbeth, MBChB MD FRACP, University of Auckland, Auckland, New Zealand.

About Hyperuricemia and Gout

Gout, the most common inflammatory arthritis in adults, is a highly symptomatic and painful form of inflammatory arthritis caused by hyperuricemia - high serum uric acid (sUA) levels in the blood. Some patients can lower sUA levels sufficiently by using a xanthine oxidase inhibitor (XOI), such as allopurinol. However, an estimated two million patients currently treated with an XOI in the U.S. suffer from uncontrolled gout, which means they are not achieving target sUA levels of less than 6 mg/dL, as recommended in gout treatment guidelines published by the American College of Rheumatology. Long-term effects can be serious for patients with gout with elevated sUA levels, which is why it is important for patients with gout to reach target sUA levels.

Gout is often hereditary and not a lifestyle disease. While diet and lifestyle changes are important considerations in the management of gout and its comorbidities, they're often not enough to get these patients' sUA levels to target. There are two mechanisms of the disease that can lead to high serum uric acid levels: overproduction and underexcretion of uric acid. It's important for patients to know their serum uric acid levels, and for those patients with levels above 6 mg/dL to talk to their doctor about possible treatment options.

About DUZALLO[®] (lesinurad and allopurinol) Tablets

DUZALLO (lesinurad and allopurinol) is a once-daily oral therapy that contains lesinurad 200 mg plus allopurinol 300 mg; it is also available in a lesinurad 200 mg plus allopurinol 200 mg dosage. DUZALLO is approved by the FDA as a once-daily oral treatment for hyperuricemia associated with gout in patients who have not achieved target serum uric acid (sUA) levels with a medically appropriate daily dose of allopurinol alone. DUZALLO is not recommended for the treatment of asymptomatic hyperuricemia. Allopurinol is an XOI whose action differs from that of uricosuric agents such as lesinurad. Allopurinol reduces the production of uric acid (UA); lesinurad increases renal excretion of UA by selectively inhibiting the action of URAT1, the UA transporter responsible for the majority of renal UA reabsorption. The dual-mechanism combination of DUZALLO can address both inefficient excretion and overproduction of UA, thereby lowering sUA levels. DUZALLO should be taken in the morning with food and water, and patients should be advised to stay well hydrated when taking DUZALLO (about 2 liters of liquid a day).

For more information about DUZALLO, please visit www.duzallo.com.

DUZALLO Important Safety Information

WARNING: RISK OF ACUTE RENAL FAILURE

- | **Acute renal failure has occurred with lesinurad, one of the components of DUZALLO**

Contraindications:

- | Severe renal impairment (estimated creatinine clearance [eCLcr] < 30 mL/min), end-stage renal disease, kidney transplant recipients, or patients on dialysis
- | Tumor lysis syndrome or Lesch-Nyhan syndrome
- | Known hypersensitivity to allopurinol, including previous occurrence of skin rash

Warnings and Precautions:

- | **Renal events:** Adverse reactions related to renal function, including acute renal failure, can occur after initiating DUZALLO. Renal function should be evaluated prior to initiation of DUZALLO and periodically thereafter, as clinically indicated. More frequent renal function monitoring is recommended in patients with eCLcr < 60 mL/min or with serum creatinine elevations 1.5 to 2 times the value when lesinurad treatment was initiated. DUZALLO should not be initiated in patients with an eCLcr < 45 mL/min. Interrupt treatment with DUZALLO if serum creatinine is elevated to > 2 times the pretreatment value or if there are symptoms that may indicate acute uric acid nephropathy, including flank pain, nausea, or vomiting. DUZALLO should not be restarted without another explanation for the serum creatinine abnormalities
- | **Skin rash and hypersensitivity:** Skin rash is a frequently reported adverse event in patients taking allopurinol. In some instances, a skin rash may be followed by more severe hypersensitivity reactions associated with exfoliation, fever, lymphadenopathy, arthralgia, and/or eosinophilia including Stevens-Johnson syndrome and toxic epidermal necrolysis. Associated vasculitis and tissue response may be manifested in various ways including hepatitis, renal impairment, seizures, and on rare occasions, death. Hypersensitivity reactions to allopurinol may be increased in patients with decreased renal function who are receiving thiazide diuretics and DUZALLO concurrently. DUZALLO should be discontinued immediately at the first appearance of skin rash or other signs that may indicate an allergic reaction, and additional medical care should be provided as needed
- | **Hepatotoxicity:** A few cases of reversible clinical hepatotoxicity have been reported in patients taking allopurinol and, in some patients, asymptomatic rises in serum alkaline phosphatase or serum transaminase have been observed. If anorexia, weight loss, or pruritus develops in patients taking DUZALLO, evaluation of liver function should be performed. In patients with preexisting liver disease, periodic liver function tests are recommended
- | **Cardiovascular events:** In clinical trials, major adverse cardiovascular events (defined as cardiovascular deaths, nonfatal myocardial infarctions, and nonfatal strokes) were observed with DUZALLO. A causal relationship has not been established
- | **Bone marrow depression:** Bone marrow depression has been reported in patients receiving allopurinol, most of whom received concomitant drugs with the potential for causing this reaction. This has occurred as early as 6 weeks to as long as 6 years after the initiation of allopurinol therapy. Rarely, a patient may develop varying degrees of bone marrow depression, affecting one or more cell lines, while receiving allopurinol alone. Patients taking allopurinol and mercaptopurine or azathioprine require a reduction in dose to approximately one-third to one-fourth of the usual dose of mercaptopurine or azathioprine
- | **Increase in prothrombin time:** It has been reported that allopurinol prolongs the half-life of dicumarol, a coumarin anticoagulant. The prothrombin time should be reassessed periodically in patients receiving coumarin anticoagulants (dicumarol, warfarin) concomitantly with DUZALLO
- | **Drowsiness:** Occasional occurrence of drowsiness was reported in patients taking allopurinol. Patients should be alerted to the need for caution when engaging in activities where alertness is mandatory

Adverse Reactions:

- | The most common adverse reactions in controlled studies (occurring in 2% or more of patients on lesinurad in combination with allopurinol and at least 1% greater than observed in patients on allopurinol alone) were headache, influenza, blood creatinine increased, and gastroesophageal reflux disease
- | The most common adverse reactions identified during post-approval use of allopurinol are skin rash, nausea, and

diarrhea

Indication and Limitations of Use:

DUZALLO, a combination of lesinurad, a URAT1 inhibitor, and allopurinol, a xanthine oxidase inhibitor, is indicated for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a medically appropriate daily dose of allopurinol alone.

- DUZALLO is not recommended for the treatment of asymptomatic hyperuricemia

Please see full Prescribing Information, including Boxed Warning:

<https://www.irwdpi.com/duzallo/DuzalloPIandMedguide2017.pdf#page=1>

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 commercializing two innovative primary care products: linaclotide, the U.S. branded prescription market leader for adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC), and lesinurad, which is approved for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid (sUA) levels with a medically appropriate daily dose of a xanthine oxidase inhibitor (XOI) alone. We are also advancing a pipeline of internally and externally generated innovative product candidates in areas of significant unmet need, including uncontrolled gastroesophageal reflux disease and vascular and fibrotic diseases. 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 statements about the potential benefits of DUZALLO, prevalence and unmet need, and Ironwood's gout franchise in the U.S. 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 those related to the effectiveness of commercialization efforts by Ironwood; efficacy, safety and tolerability of lesinurad; decisions by regulatory authorities; challenges from and rights of competitors or potential competitors; developments in the intellectual property landscape; and those risks listed under the heading "Risk Factors" and elsewhere in Ironwood's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, 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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