Idera Pharmaceuticals Presents Data Supporting IMO-8400 as Novel Therapy for Genetically Defined Forms of B-Cell Lymphoma at Annual ASH Meeting

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- Clinical safety data for IMO-8400 support dose escalation in ongoing Phase 1/2 trials

- Preclinical data show promise of early-line combination therapy with IMO-8400 and rituximab

CAMBRIDGE, Mass., Dec. 8, 2014 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq:IDRA), a clinical-stage biopharmaceutical company developing nucleic acid therapeutics for patients with cancer and rare diseases, today announced that data for its lead product candidate IMO-8400 were presented at the 56th Annual Meeting of the American Society of Hematology (ASH) in San Francisco. The data included a presentation on clinical safety results from Phase 1 and Phase 2 clinical trials of IMO-8400. In addition, a second presentation reported preclinical data demonstrating the activity of IMO-8400 in combination with rituximab in B-cell lymphoma models. Overall, these data support continued development of IMO-8400 as a novel therapy for genetically defined forms of B-cell lymphoma.

"Cancer treatment is being transformed by recent advances in genomics, combined with new therapies targeting specific biological processes that drive disease progression. The discovery of the MYD88 L265P oncogenic mutation and its role in over-activating Toll-like receptor signaling in patients with B-cell malignancies has enabled us to advance a targeted Toll-like receptor antagonist into clinical trials," said Lou Brenner, M.D., Senior Vice President and Chief Medical Officer of Idera Pharmaceuticals. "Idera's data presentations at the ASH meeting provide further support for IMO-8400 as a potential treatment for patients with genetically defined forms of B-cell lymphoma."

In multiple independent studies, Toll-like receptor (TLR) signaling has been shown to be over-activated in B-cell lymphomas characterized by the MYD88 L265P oncogenic mutation, thereby enabling tumor cell survival and proliferation. IMO-8400 is a synthetic, oligonucleotide-based antagonist of TLRs 7, 8 and 9. Previously reported preclinical data showed that IMO-8400 inhibited TLR-mediated signaling and tumor cell survival in B-cell lymphoma models. Idera is currently conducting a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia (WM). In addition, the Company has commenced patient screening in a Phase 1/2 trial of IMO-8400 in patients with diffuse large B-cell lymphoma (DLBCL) harboring the MYD88 L265P oncogenic mutation.

Poster Presentation – Abstract #3101 – "IMO-8400, an Antagonist of Toll-like Receptors 7, 8, and 9, in Development for Genetically Defined B-Cell Lymphomas: Safety and Activity in Phase 1 and Phase 2 Clinical Trials"

Results from clinical trials in healthy volunteers and patients with psoriasis showed that IMO-8400 was well tolerated when administered weekly via subcutaneous injection at doses up to 0.6 mg/kg for up to 12 weeks. In these trials, there were no treatment-related serious adverse events, no drug-related discontinuations, and no pattern of systemic adverse events or laboratory changes. The only treatment-related adverse events in more than one patient were injection site reactions, comprised of generally mild erythema with occasional induration, pruritus, tenderness or pain.

Idera is currently conducting a Phase 1/2 dose escalation trial to evaluate the safety, clinical activity and optimized dosing of IMO-8400 in patients with relapsed or refractory WM over 24 weeks. In the first of three escalating dose cohorts, IMO-8400 was well tolerated in patients treated weekly with 0.6 mg/kg for four weeks. An independent Data Review Committee (DRC) evaluated safety data from the first cohort and recommended that patients continue treatment and that the trial escalate to the second dose cohort of 1.2 mg/kg. Based on current enrollment, Idera anticipates DRC review of four-week safety data from the second dose cohort in the fourth quarter. Pending this review, the Company expects to initiate enrollment in the third dose cohort of 2.4 mg/kg by year end. Final 24-week safety and clinical activity data are anticipated in the second half of 2015.

Oral Presentation – Abstract #508 – "Novel Approach to the Potential Treatment of Patients with B-Cell Lymphomas Harboring the MYD88 L265P Mutation: Combination Treatment with TLR Antagonist and Rituximab"

In multiple *in vivo* studies in B-cell lymphoma models, combination therapy with IMO-8400 and rituximab significantly improved measures of disease activity. In a preclinical DLBCL model, combination therapy with IMO-8400 and rituximab significantly reduced tumor volume and significantly decreased production of IL-10, a cytokine that enhances B-cell survival and proliferation, compared to monotherapy with either agent. In a WM model, the combination therapy also significantly reduced tumor volume and significantly decreased production of Immunoglobulin M, a protein overexpressed in WM patients, compared to monotherapy with either agent. In both models, tumor histology demonstrated marked improvements favoring the combination regimen.

"We are excited to present these new and promising data showing the potent activity of combination therapy with IMO-8400 and rituximab in preclinical models of DLBCL and WM," said Timothy Sullivan, Ph.D., Vice President of Development Programs and Alliance Management at Idera Pharmaceuticals. "As we continue to advance our ongoing Phase 1/2 dose escalation trials of IMO-8400 in patients with relapsed or refractory B-cell lymphomas characterized by the MYD88 L265P oncogenic mutation, we believe these preclinical data provide a potential roadmap for future clinical development of IMO-8400 in early-line treatment of DLBCL and WM."

Rituximab is a monoclonal antibody against the protein CD20 and is approved by the U.S. Food and Drug Administration. It is commonly used as first-line therapy in combination with chemotherapy in patients with DLBCL and WM. Rituximab was developed and is marketed by Biogen Idec and Genentech. The preclinical studies presented at the ASH meeting were conducted by scientists from Idera Pharmaceuticals. Both presentations are available on Idera's website at: http://www.iderapharma.com/our-science/key-presentations-and-publications.

About B-cell Lymphomas Characterized by the MYD88 L265P Mutation

In B-cell lymphomas characterized by the MYD88 L265P oncogenic mutation, TLR signaling is over-activated, thereby enabling tumor cell survival and proliferation.

WM is a rare and slow-growing form of B-cell lymphoma with approximately 1,000 to 1,500 new cases diagnosed in the United States each year.[1] The median age at diagnosis is between 60 and 70 years of age. Symptoms include fatigue, night sweats, headaches, visual problems, pain and abnormal

bleeding due to complications such as anemia, retinopathy and peripheral neuropathy.[2] The disease is incurable and there are no approved therapies. About 90 percent of WM patients harbor the MYD88 L265P oncogenic mutation.[3]

DLBCL is the most common form of non-Hodgkin lymphoma (NHL) with approximately 20,000 new cases diagnosed in the United States each year.[4] DLBCL is a fast-growing and potentially lethal lymphoma. Initial symptoms may include rapid swelling in the neck, armpit and groin due to enlarged lymph nodes. Other symptoms include night sweats, unexplained fevers and weight loss.[5] About 10 percent of DLBCL patients harbor the MYD88 L265P oncogenic mutation, and data from an independent study have shown that prognosis in this population is poor, with overall survival markedly impaired compared to patients without the MYD88 L265P mutation.[6,7]

About Toll-Like Receptors (TLRs) and Idera's Proprietary TLR Antagonism Technology Platform

TLRs are receptor proteins that play a central role in the innate immune system. In healthy people, TLRs recognize invading pathogens and endogenous molecules released from damaged or dysfunctional cells, and initiate signaling cascades that trigger an inflammatory response. Through these signaling cascades, TLRs are also involved in activating the adaptive immune system, in which B-cells play a critical role.

Based on the company's proprietary chemistry-based discovery platform, Idera discovered and is developing two synthetic oligonucleotide-based TLR antagonists, IMO-8400 and IMO-9200. These clinical-stage candidates have demonstrated activity in multiple preclinical models of cancer and autoimmune disease.

About Idera Pharmaceuticals

Idera Pharmaceuticals is a clinical-stage biopharmaceutical company developing a novel therapeutic approach for the treatment of genetically defined forms of B-cell lymphoma and rare autoimmune diseases. Idera's proprietary technology involves creating novel nucleic acid therapeutics designed to inhibit over-activation of Toll-like receptors (TLRs). In addition to its TLR programs, Idera is developing gene silencing oligonucleotides (GSOs) that it has created using its proprietary technology to inhibit the production of disease-associated proteins by targeting RNA. To learn more about Idera, visit www.iderapharma.com.

References:

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[3] Treon SP, et al. MYD88 L265P somatic mutation in Waldenström's macroglobulinemia. N Engl J Med. 2012 Aug 30;367(9):826-33.

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[6] Rosenwald A, et al. The use of molecular profiling to predict survival after chemotherapy for diffuse large-B-cell lymphoma. N Engl J Med. 2002 Jun 20;346(25):1937-47.

[7] Fernandez-Rodriguez C, et al. MYD88 (L265P) mutation is an independent prognostic factor for outcome in patients with diffuse large B-cell lymphoma. Leukemia. 2014 Oct;28(10):2104-6.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the Company's strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Idera cannot guarantee that it will actually achieve the plans, intentions or expectations disclosed in its forward-looking statements and you should not place undue reliance on the Company's forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated or implied by its forward-looking statements. Factors that may cause such a difference include: whether results obtained in preclinical studies and clinical trials such as the preclinical and clinical data described in this release will be indicative of the results that will be generated in future clinical trials; whether products based on Idera's technology will advance into or through the clinical trial process on a timely basis or at all, warrant submission for regulatory approval and receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; whether the Company's cash resources are sufficient to fund the Company's proposed programs and the Company's operations for the period anticipated; and such other important factors as are set forth under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014. Although Idera may elect to do so at some point in the future, the Company does not assume any obligation to update any forward-looking statements and it disclaims any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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