Idera Pharmaceuticals Reports Third Quarter Financial Results and Announces Expansion of Rare Disease Development Portfolio

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-- Enrollment achieved in first two dose cohorts of Phase 1/2 Waldenstrom's trial
-- Myositis program advanced with specification of Phase 2 clinical trial plan in dermatomyositis
-- Rare disease portfolio expanded to include Duchenne muscular dystrophy; collaboration with leading Duchenne patient group announced

CAMBRIDGE, Mass., Nov. 7, 2014 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq:IDRA), a clinical-stage biopharmaceutical company developing nucleic acid therapeutics for rare diseases, today reported financial results and business highlights for the third quarter of 2014. Key business highlights included significant progress with the enrollment of the Company's Phase 1/2 trial of IMO-8400 in Waldenström's macroglobulinema, advancement of a Phase 2 clinical trial plan for IMO-8400 in dermatomyositis, and an expansion of the Company's rare disease portfolio to include a research program in Duchenne muscular dystrophy (DMD).

"With a research program in Duchenne muscular dystrophy and a focused clinical development strategy in dermatomyositis, we have expanded and advanced our rare disease portfolio in diseases where there is strong scientific rationale for Toll-like receptor antagonism and an urgent need for new treatments," said Sudhir Agrawal, D.Phil., Chief Executive Officer of Idera Pharmaceuticals. "In addition, we have enrolled patients in the second dose cohort in our Phase 1/2 trial of IMO-8400 in Waldenström's macroglobulinemia, based on a positive review of safety data from the first dose cohort."

Dr. Agrawal added, "Taken together, these updates represent important steps toward advancing our corporate strategy in genetically defined forms of B-cell lymphoma and rare diseases."

RECENT BUSINESS HIGHLIGHTS

Genetically Defined Forms of B-cell Lymphoma Program

Waldenström's Macroglobulemia

- Idera completed enrollment of the 0.6 mg/kg dose cohort in the Company's Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia. An independent data review committee (DRC) reviewed four-week safety data and recommended that the Company advance the trial to the next dosage level. Enrollment in the 1.2 mg/kg dose cohort was initiated, and the Company has now achieved enrollment of a sufficient number of patients in this cohort to support DRC review of safety data in the fourth quarter. Pending a positive review of safety data, the Company plans to continue dose escalation to the 2.4 mg/kg dose cohort by year end.

MYD88 L265P-Positive Diffuse Large B-cell Lymphoma

- The Company activated multiple clinical sites and expanded screening of patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) harboring the MYD88 L265P oncogenic mutation in its Phase 1/2 clinical trial of IMO-8400 in DLBCL.

- In addition, Idera completed initial development of a prototype companion diagnostic under a collaboration with Abbott Molecular. The Company plans to incorporate the diagnostic into ongoing screening for the MYD88 L265P oncogenic mutation in its Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL.

Upcoming Oncology Data Presentations

- Earlier this week, Idera announced plans to present clinical safety data from the IMO-8400 clinical development program at the American Society of Hematology (ASH) 2014 Annual Meeting in San Francisco from December 6-8. In addition, new preclinical data from studies of IMO-8400 in combination with rituximab in MYD88 L265P-positive B-cell lymphoma models will be presented at ASH 2014.

Rare Autoimmune Disease Program

Duchenne Muscular Dystrophy

- This morning, the Company announced plans to collaborate with Parent Project Muscular Dystrophy (PPMD), a leading patient advocacy organization, to develop a potential non-steroid-based anti-inflammatory treatment using Idera's Toll-like receptor (TLR) antagonism technology. DMD is a rare, fatal muscle disorder affecting approximately 15,000 to 20,000 patients in the U.S. It is characterized by progressive muscle weakness, pulmonary and cardiac dysfunction, and death typically before age 30. Previously published independent research has shown that TLR 7 is up-regulated in DMD patients.[1] In a preclinical model of DMD, knockout of the gene for the MYD88 TLR adaptor protein led to significant improvements in skeletal and cardiac muscle function. In a separate study conducted by researchers from Children's National Health System and Idera, treatment with a TLR antagonist candidate led to a significant reduction of pro-inflammatory cytokines, a significant decrease in creatine kinase, and a significant increase in muscle strength in a preclinical DMD model.[2] Idera plans to collaborate with PPMD to expand preclinical studies and develop a clinical development strategy for a TLR antagonist candidate in DMD.

Dermatomyositis

- Idera advanced plans for a Phase 2 clinical trial of IMO-8400 in dermatomyositis, a rare and severe inflammatory muscle disorder affecting approximately 25,000 patients in the U.S. Dermatomyositis is characterized by muscle weakness, joint pain, skin rash, and difficulty swallowing. Clinical planning has been supported by an ongoing collaboration with The Myositis Association, a leading patient advocacy organization, and an expert advisory committee formed by Idera earlier in 2014. The Company intends to have interactions with regulatory authorities regarding its clinical development strategy in early 2015, with the goal of initiating patient treatment in a Phase 2 clinical trial of IMO-8400 in dermatomyositis.

Pipeline Expansion

Phase 1 Trial of IMO-9200

- The Company initiated patient dosing in a Phase 1 clinical trial of IMO-9200 in healthy volunteers, following acceptance for filing of an Investigational New Drug Application by the U.S. Food and Drug Administration. The Company expects to select a lead autoimmune disease indication for further development of IMO-9200 in the first half of 2015.

- Idera scientists presented new preclinical data that showed IMO-9200 inhibited TLR-mediated immune responses in multiple disease models at the 10th Annual Meeting of the Oligonucleotide Therapeutics Society Annual Meeting in San Diego in October 2014.

Gene Silencing Oligonucleotide Technology Platform

- In addition, the Company advanced preclinical development of its gene silencing oligonucleotide (GSO) technology, a third generation antisense platform. GSOs are specifically designed to avoid the immunotoxicity observed with earlier generation technologies to enable improved therapeutic index. The Company plans to select two GSO drug candidates for further development in 2015.

THIRD QUARTER 2014 FINANCIAL RESULTS

As of September 30, 2014, Idera's cash, cash equivalents and investments totaled $58.3 million compared to $35.6 million as of December 31, 2013.

Net loss applicable to common stockholders for the three months ended September 30, 2014 was $9.6 million, or $0.11 per diluted share, compared to

a net loss applicable to common stockholders of $5.0 million, or $0.11 per diluted share, for the same period in 2013. For the nine month period ended September 30, 2014, the Company's net loss applicable to common stockholders was $27.1 million, or $0.33 per diluted share, compared to a net loss applicable to common stockholders of $14.7 million, or $0.40 per diluted share, for the same period in 2013.

Research and development expenses for the three months ended September 30, 2014 totaled $6.7 million compared to $2.5 million for the same period in 2013. For the nine month period ended September 30, 2014, research and development expenses totaled $19.2 million compared to $6.8 million for the same period in 2013.

General and administrative expenses for the three months ended September 30, 2014 totaled $2.9 million compared to $2.2 million for the same period in 2013. For the nine-month period ended September 30, 2014, general and administrative expenses totaled $7.6 million compared to $5.3 million for the same period in 2013.

WEBCAST AND CONFERENCE CALL

Idera will host a conference call today at 8:00 a.m. EST to discuss third quarter 2014 financial results and corporate highlights. The live webcast, including reference slides, can be accessed under "Investor Events" in the Investors and Media section of the Company's website at www.iderapharma.com. To access the conference call, dial 1-866-202-0886 (domestic) or 1-617-213-8841 (international) and provide the access code 74052148. Following the event, an archive of the webcast will be available in the Investors and Media section of the Company's website for 90 days.

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 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.

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 results 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 when anticipated or at all or warrant submission for regulatory approval; whether such products will receive approval from the U.S. 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 collaborations will be successful; 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 nine months 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.

REFERENCES

[1] Chen Y.-W., et al. Early onset of inflammation and later involvement of TGFβ in Duchenne muscular dystrophy. Neurology. 2005;65;826-834.

[2] Henriques A, et al. Role of Toll-like receptors in the pathogenesis of dystrophin-deficient skeletal and heart muscle. Hum Mol Genet. 2014 May 15;23(10):2604-17.

Idera Pharmaceuticals, Inc.

Condensed Statements of Operations

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(Unaudited)			
Revenues	$30	$7	$71	$43
Operating Expenses				
Research & Development	6,678	2,510	19,248	6,835

General & Administrative	2,873	2,179	7,646	5,305
Total Operating Expenses	9,551	4,689	26,894	12,140
Loss from Operations	(9,521)	(4,682)	(26,823)	(12,097)
Other, net	66	(56)	99	(39)
Net Loss	(9,455)	(4,738)	(26,724)	(12,136)
Loss on Extinguishment of Convertible Preferred Stock and Preferred Stock Dividends	119	278	422	2,587
Net Loss Applicable to Common Stockholders	$(9,574)	$(5,016)	$(27,146)	$(14,723)
Basic and Diluted Net Loss Per Common Share Applicable to Common Stockholders	$(0.11)	$(0.11)	$(0.33)	$(0.40)
Shares Used in Computing Basic and Diluted Net Loss Per Common Share Applicable to Common Stockholders	84,527	45,720	81,200	37,203

Idera Pharmaceuticals, Inc.

Condensed Balance Sheet Data

(In thousands)

	September 30, 2014 (Unaudited)	**December 31, 2013**
Cash, Cash Equivalents & Investments	$58,280	$35,592
Other Assets	$2,352	$1,275
Total Assets	$60,632	$36,867
Total Liabilities	$7,811	$4,415
Total Stockholders' Equity	$52,821	$32,452
Total Liabilities & Stockholders' Equity	$60,632	$36,867

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