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Alder BioPharmaceuticals Reports Fourth Quarter and Year-End 2014 Financial and Operating Results

- Provides Anticipated 2015 Pipeline Advancement Milestones -

BOTHELL, Wash., March 4, 2015 (GLOBE NEWSWIRE) -- Alder BioPharmaceuticals, Inc. ("Alder") (Nasdaq:ALDR), a clinical-stage biopharmaceutical company developing monoclonal antibody therapeutics for the treatment of migraine, autoimmune and inflammatory diseases, today provided recent corporate highlights and reported its financial results for the fourth quarter and full year ended December 31, 2014.

"2014 was a very exciting year for Alder as we became a public company in May and advanced our lead clinical candidate, ALD403, into a Phase 2b trial for the preventative treatment of chronic migraine," said Randall C. Schatzman, Ph.D., President and Chief Executive Officer of Alder. "After completing a follow-on financing in January this year, we are in a position to expedite development of ALD403 and to advance earlier programs in our pipeline. We plan to initiate a second Phase 2b trial for ALD403 for the treatment of frequent episodic migraine sufferers in the first half of the year and to report primary endpoint data from our ongoing Phase 2b trial in chronic migraine sufferers in the second half of the year. In addition, following the announcement of positive Phase 2b data for Clazakizumab in patients with active psoriatic arthritis last year, we are actively seeking a partner to continue the development of this promising treatment for patients suffering from rheumatoid arthritis. Lastly, we announced the advancement of a new clinical candidate, ALD1613, into IND-enabling studies, and we plan to initiate a Phase 1 trial in Cushing's disease in 2016."

2014 and Recent Pipeline and Corporate Highlights

ALD403 advanced into a Phase 2b trial following positive Phase 2 proof-of-concept data published in *Lancet Neurology* and presented at both the 56th Annual Scientific Meeting of the American Headache Society and the American Academy of Neurology Meeting in 2014.

- | In October 2014, Alder initiated a 600-patient Phase 2b dose-ranging trial of an intravenous (IV) formulation of ALD403 (an anti-calcitonin gene-related peptide (CGRP)) for the preventative treatment of chronic migraine sufferers. The primary endpoint of the trial is the change in migraine days between ALD403 and placebo as judged by the difference in the responder rates at week 12.
- | In October 2014, Alder announced that data from the Phase 2 proof-of-concept clinical trial of ALD403 was published in the October 6, 2014, issue of *Lancet Neurology*. The data show that the trial met its primary endpoint, significantly reducing mean migraine days per month versus placebo during weeks five to eight. The data also demonstrate that a single infusion of ALD403 resulted in a 100% decrease in migraine days per month for 26-41% of patients depending on the month observed. The trial was conducted in 163 patients with five to 14 migraine days per month randomized to receive a single intravenous infusion of either 1000 mg of ALD403 or placebo. Clinical response to ALD403 was observed within the first month following a single administration and was durable over the entire three-month course of the study. ALD403 was well-tolerated, and there was no difference in adverse events or laboratory safety data from placebo. These data were also presented in a late-breaker poster presentation at the 56th Annual Scientific Meeting of the American Headache Society in Los Angeles in June 2014 and at the American Academy of Neurology Meeting in Philadelphia in April 2014.

Clazakizumab, previously known as ALD518, met primary endpoint in a Phase 2b clinical trial in adults with active psoriatic arthritis (PsA).

- | In November 2014, Alder presented positive data from a randomized, double-blind, placebo-controlled, dose-ranging multicenter Phase 2b clinical trial evaluating the safety and efficacy of Clazakizumab in adults with active PsA at the American College of Rheumatology Annual Meeting in Boston. The data show that Clazakizumab met the primary endpoint of the study, ACR20 response rate at week 16 versus placebo. At week 16, ACR20 response rates were 29.3, 46.3, 52.4 and 39 % for placebo and 25, 100 and 200 mg Clazakizumab, respectively. While there was no clear dose response, ACR 20/50/70 response rates were higher than placebo for all Clazakizumab treatment arms at week 24. Clazakizumab was well-tolerated, and there were no differences from placebo in terms of adverse events or laboratory safety data.

- Effective December 29, 2014, Alder regained the worldwide rights to Clazakizumab from Bristol-Myers Squibb (BMS) following BMS' decision to end further development following an internal portfolio prioritization. Alder is actively seeking a new partner to continue the development plans for Clazakizumab in autoimmune and inflammatory diseases based on the positive Phase 2b rheumatoid arthritis (RA) and PsA clinical trial results reported to date. BMS remains responsible for the cost of ongoing clinical trials through June 2015.

Corporate Updates

- In January 2015, Alder completed a follow-on offering with net proceeds of approximately \$190.7 million. The offering had an aggregate of 6,900,000 shares at a public offering price of \$29.50 per share, before underwriting discounts and commissions and offering expenses.

Anticipated Upcoming Milestones

- Initiate a second ALD403 Phase 2b trial in migraine prevention:** Alder plans to initiate a second Phase 2b dose-ranging trial for ALD403 in the first half of 2015. This Phase 2b trial will study ALD403 for the treatment of high frequency migraine sufferers with a primary endpoint of change in migraine days between ALD403 and placebo as judged by the difference in the responder rates at week 12.
- Announce top-line Phase 2b, dose-ranging clinical trial data for Clazakizumab:** Alder plans to report top-line data from a 140 patient follow-on Phase 2b, dose-ranging clinical trial designed to determine the safety and efficacy of Clazakizumab in RA patients who are anti-TNF inadequate responders in the first half of 2015.
- Announce primary endpoint data for ALD403 Phase 2b trial in chronic migraine:** Alder plans to announce primary endpoint data from its Phase 2b dose-ranging trial of an IV formulation for the preventative treatment of chronic migraine sufferers in the second half of 2015.
- Initiate Phase 1 trial for ALD1613:** Alder plans to advance ALD1613 through Investigational New Drug (IND) enabling toxicology studies in 2015 and commence a Phase 1 trial in 2016 for the treatment of Cushing's disease, an orphan disease driven by long-term exposure to cortisol as a result of increased expression of Adrenocorticotrophic hormone (ACTH) produced by a pituitary tumor.

Fourth Quarter and Year-End 2014 Financial Results

For the quarter ended December 31, 2014, Alder reported total revenues of \$6.4 million compared to \$4.8 million for the same period in 2013. For the full year 2014, Alder reported total revenues of \$54.7 million compared to \$18.8 million for 2013. Increased revenues for both periods were due to the acceleration of recognition of previously deferred revenue as a result of the early termination of the license agreement with BMS for Clazakizumab.

Research and development expenses for the quarter ended December 31, 2014, totaled \$10.0 million, compared to \$6.3 million for the same period in 2013. The higher costs in the 2014 period were primarily due to clinical trials for the prevention of migraines. For the full year 2014, research and development expenses totaled \$33.4 million, compared to \$31.9 million for 2013. The increase for the 2014 period was due to drug supply and clinical trial costs for the prevention of migraine.

General and administrative expenses for the quarter ended December 31, 2014, totaled \$3.4 million, compared to \$2.4 million for the same period in 2013. For the full year 2014, general and administrative expenses totaled \$12.5 million, compared to \$7.7 million for the same period in 2013. Increased general and administrative expenses for both periods were due to an increase in additional costs to operate as a public company.

Net loss for the quarter ended December 31, 2014, totaled \$6.9 million, or \$0.22 per share on a fully-diluted basis, compared to a net loss of \$3.9 million, or \$3.94 per share, for the same period in 2013. For the full year 2014, net income totaled \$8.9 million, or \$0.30 per share on a fully-diluted basis, compared to a net loss of \$20.6 million, or \$21.14 per share, for 2013.

As of December 31, 2014, Alder had \$55.9 million in cash and cash equivalents and short-term investments, compared to \$23.2 million as of December 31, 2013.

Conference Call and Webcast

Alder will host a conference call today at 5:00 p.m. EST to discuss these financial results and recent corporate highlights. The live call may be accessed by dialing (877) 430-4657 for domestic callers or (484) 756-4339 for international callers, and providing conference ID number 81724486. A live webcast of the conference call will be available online from the investors section of Alder's website at www.alderbio.com and will be available for replay following the call for 30 days.

About Alder BioPharmaceuticals, Inc.

Alder BioPharmaceuticals, Inc., is a clinical-stage biopharmaceutical company that discovers, develops and seeks to commercialize therapeutic antibodies with the potential to meaningfully transform current treatment paradigms. Alder's ALD403 inhibits a well-validated molecule shown to trigger migraine attacks, calcitonin gene-related peptide (CGRP), and is now undergoing Phase 2 clinical testing. ALD403 is currently in an ongoing Phase 2b trial for the treatment of chronic migraines, and Alder plans to initiate a Phase 2b trial for the treatment of frequent episodic migraines in the first half of 2015. Alder's second program, Clazakizumab, previously known as ALD518, is designed to block the pro-inflammatory cytokine IL-6 and has completed a Phase 2b clinical trial. For more information, please visit <http://www.alderbio.com>.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding our expectations for the initiation of future clinical trials and studies, availability of clinical trial data, patient enrollment and the potential of ALD403 to address the unmet medical needs of patients. All forward-looking statements included in this press release are based on our management's beliefs and assumptions and on information currently available to our management, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this press release may turn out to be wrong and actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. In evaluating these statements, you should specifically consider various factors, including the risks outlined under the caption "Risk Factors" set forth in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, which was filed with the Securities and Exchange Commission (SEC) on November 3, 2014, and is available on the SEC's website at www.sec.gov. Additional information will also be set forth in our other reports and filings we will make with the SEC from time to time. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Condensed Consolidated Balance Sheets

(Unaudited)

(Amounts in thousands)

	December 31, 2014	December 31, 2013
Cash, cash equivalents, and short-term investments	\$ 55,872	\$ 23,227
Prepaid expenses and other assets	8,487	3,512
Total assets	\$ 64,359	\$ 26,739
Deferred revenue	\$ --	\$ 54,324
Other liabilities	5,202	4,403
Convertible preferred stock	--	111,374
Total stockholders' equity (deficit)	59,157	(143,362)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 64,359	\$ 26,739

Condensed Consolidated Statements of Operations

(Unaudited)

(Amounts in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2014	2013	2014	2013
Revenues				
Collaboration and license agreements	\$ 6,436	\$ 4,824	\$ 54,705	\$ 18,796
Operating expenses				
Research and development	9,995	6,334	33,439	31,883

General and administrative	3,408	2,353	12,462	7,674
Total operating expenses	13,403	8,687	45,901	39,557
Income (loss) from operations	(6,967)	(3,863)	8,804	(20,761)
Other income (expense), net	25	(12)	104	148
Net income (loss)	\$ (6,942)	\$ (3,875)	\$ 8,908	\$ (20,613)
Net income (loss) per share - basic	\$ (0.22)	\$ (3.94)	\$ 0.43	\$ (21.14)
Net income (loss) per share - diluted	\$ (0.22)	\$ (3.94)	\$ 0.30	\$ (21.14)
Weighted average number of common shares used in net income (loss) per share - basic	30,893,040	982,680	20,506,565	975,158
Weighted average number of common shares used in net income (loss) per share - diluted	30,893,040	982,680	29,427,287	975,158

CONTACT: Media Contact:

David Schull

Russo Partners, LLC

(212) 845-4271

david.schull@russopartnersllc.com

Investor Relations Contact:

Sarah McCabe

Stern Investor Relations, Inc.

(212) 362-1200

sarah@sternir.com