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Alder BioPharmaceuticals Presents Positive Phase 2b Study Data for Eptinezumab at 69th Annual American Academy of Neurology Meeting

- Eptinezumab emerging clinical profile suggests migraine preventative benefit achieved as soon as 24 to 48 hours after a single infusion -

BOTHELL, Wash., April 28, 2017 (GLOBE NEWSWIRE) -- Alder BioPharmaceuticals, Inc. (NASDAQ:ALDR), a clinical-stage biopharmaceutical company developing monoclonal antibody therapeutics, today announced the presentation of positive data from its Phase 2b clinical trial evaluating eptinezumab (formerly ALD403) for the prevention of migraine.

Key findings from the study showed that chronic migraine patients treated with a single infusion of eptinezumab (ALD403) experienced a significant reduction in migraine days as measured by 75% responder rates, with maximum efficacy in 1 to 4 weeks that was maintained through 12-weeks. Post hoc analysis of the trial data also suggested that a single administration led to a clinically meaningful reduction in the percentage of patients experiencing migraine within 24 to 48 hours post infusion. These data and additional study results are the topic of a podium presentation titled "Randomized, Double-Blind, Placebo-Controlled Trial of ALD403 (Eptinezumab), an Anti-CGRP Peptide Antibody, in the Prevention of Chronic Migraine" presented at the 69th Annual American Academy of Neurology (AAN) meeting in Boston.

"Eptinezumab has demonstrated its potential as a preventative treatment for migraine in clinical trials to date. The data from these trials, and the fact that it's the only anti-CGRP monoclonal antibody being developed for administration via infusion, suggest that, if approved, eptinezumab may be an important therapeutic option for patients needing fast onset to migraine prevention that is sustained for 12 weeks for the treatment of their migraines," said Jeffrey Smith, M.D., FRCP, a founder of Alder and managing director of Alder's Irish subsidiary, Alder BioPharmaceuticals Limited.

Randall C. Schatzman, Ph.D., president and chief executive officer of Alder, added, "These new data further demonstrate the differentiated delivery and clinical profile of eptinezumab for migraine prevention. We are on track to report top-line results from our first Phase 3 pivotal trial of eptinezumab later this quarter. Our focus is on moving through the clinical development program toward a BLA filing next year so that eptinezumab, if approved, can meet patient needs as a potentially transformative migraine prevention therapy."

The study was a parallel group, double-blind, randomized, placebo controlled, dose-ranging Phase 2b trial to evaluate the efficacy, safety and pharmacokinetics of eptinezumab (ALD403) administered intravenously in patients with chronic migraine. The study enrolled 616 patients across 90 sites, stratified into four experimental dose groups: 10 mg ALD403, 30mg ALD403, 100 mg ALD403, 300 mg ALD403, and a placebo group. The primary endpoint was the reduction in migraine days as measured by the 75% responder rates from baseline to week 12, and secondary endpoints included the evaluation of safety and pharmacokinetics.

Key Points:

A single administration of eptinezumab (ALD403):

- Significantly reduced migraine days in patients with chronic migraine as measured by 75% responder rates
- Produced a reduction in the number of patients experiencing migraine within 24 to 48 hours post infusion*
- Resulted in 1/3 of patients achieving a 75% reduction in their migraine days in Weeks 1-4 that was maintained through Week 12
- Significantly reduced the percentage of migraine attacks that patients reported as severe
- Demonstrated a tolerability and safety profile similar to placebo, with no serious adverse events deemed treatment related or infusion reactions observed

*post hoc analysis

About Alder BioPharmaceuticals
Alder BioPharmaceuticals, Inc., is a clinical-stage biopharmaceutical company that discovers, develops and seeks to commercialize genetically engineered therapeutic antibodies with the potential to meaningfully transform current treatment paradigms. Alder's lead pivotal-stage product candidate, eptinezumab, is being evaluated for migraine prevention.

Eptinezumab is a monoclonal antibody that inhibits calcitonin gene-related peptide (CGRP), a protein that is active in mediating the initiation of migraine. Alder is additionally evaluating ALD1910, a preclinical product candidate also in development as a migraine prevention therapy. ALD1910 is a monoclonal antibody that inhibits pituitary adenylate cyclase-activating polypeptide-38 (PACAP-38), another protein that is active in mediating the initiation of migraine. Clazakizumab, Alder's third program, is a monoclonal antibody candidate that inhibits interleukin-6 and is licensed to Vitaeris, Inc. For more information, please visit http://www.alderbio.com.

Forward Looking Statements

This press release contains forward-looking statements, including, without limitation, statements relating to: Alder's belief that eptinezumab is a unique and potentially transformative migraine prevention therapy; the continued development and clinical, therapeutic and commercial potential of eptinezumab (formerly ALD403); the availability of results from clinical trials; the potential regulatory approval of eptinezumab; the emerging differentiated delivery and clinical profile of eptinezumab; and the high unmet need for preventative migraine treatments. Words such as "emerging," "potential," "suggest," "may," "option," "on track," "focus," "toward," "can," "meet," or other similar expressions, identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. The forward-looking statements in this press release are based upon Alder's current plans, assumptions, beliefs, expectations, estimates and projections, and involve substantial risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements due to these risks and uncertainties as well as other factors, which include, without limitation: risks related to the potential failure of eptinezumab to demonstrate safety and efficacy in clinical testing; Alder's ability to conduct clinical trials and studies of eptinezumab sufficient to achieve a positive completion; the availability of data at the expected times; the clinical, therapeutic and commercial value of eptinezumab; risks and uncertainties related to regulatory application, review and approval processes and Alder's compliance with applicable legal and regulatory requirements; risks and uncertainties relating to the manufacture of eptinezumab; Alder's ability to obtain and protect intellectual property rights, and operate without infringing on the intellectual property rights of others; the uncertain timing and level of expenses associated with the development of eptinezumab; the sufficiency of Alder's capital and other resources; market competition; changes in economic and business conditions; and other factors discussed under the caption "Risk Factors" in Alder's Quarterly Report on Form 10-Q for the year ended March 31, 2017, which was filed with the Securities and Exchange Commission (SEC) on April 27, 2017, and is available on the SEC's website at www.sec.gov. Additional information will also be set forth in Alder's other reports and filings it will make with the SEC from time to time. The forward-looking statements made in this press release speak only as of the date of this press release. Alder expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Alder's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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