Alder Presents Positive Clinical Data for ALD403 at the 17th Congress of the International Headache Society

-Single IV Dose of ALD403 Demonstrates Efficacy over Six Months for the Preventive Treatment of Migraine-

BOTHELL, Wash., May 15, 2015 – Alder BioPharmaceuticals, Inc. (“Alder”) (NASDAQ: ALDR), a clinical-stage biopharmaceutical company developing monoclonal antibody therapeutics for the treatment of migraine, announced that six-month follow-up data from its Phase 2 proof-of-concept clinical trial of ALD403, its anti-calcitonin gene-related peptide (CGRP) antibody for the prevention of frequent episodic migraine, were presented today by Jeffrey T.L. Smith, M.D., FRCP, Senior Vice President, Translational Medicine at Alder, in an oral presentation at the 17th Congress of the International Headache Society in Valencia, Spain.

Key Points from Oral Session: Migraine Pathophysiology and CGRP as a Therapeutic Target:

- A single intravenous dose of ALD403 1000mg demonstrated prolonged efficacy over six months for the preventive treatment of migraine.
- Over three months, the proportion of patients with a 50%, 75%, and 100% reduction in migraine days for ALD403 and placebo was 61% vs 33% (p < 0.001); 33% vs 9% (p < 0.001); and 16% vs 0% (p < 0.001), respectively.
- Over six months, the proportion of patients with a 50%, 75%, and 100% reduction in migraine days for ALD403 and placebo was 53% vs 28% (p < 0.001); 26% vs 7% (p < 0.002); and 11% vs 0% (p <0.002), respectively.
- ALD403 was well tolerated and there were no differences from placebo in terms of adverse events or laboratory safety data.
- The migraine prevention proof-of-concept trial was conducted in 163 patients with frequent episodic migraine who had on average nine headache days per month. Patients were given a single intravenous dose of 1000mg of ALD403 or placebo. The primary endpoint was the mean change in migraine headache days from baseline to weeks 5-8, and patients were followed for 24 weeks for additional safety and efficacy analyses.

Alder also presented a poster with Phase 1 data for ALD403 titled, “A Single Dose Placebo-Controlled, Randomized, Ascending Dose Study of ALD403, a Humanized Anti-Calcitonin Gene-Related Peptide Monoclonal Antibody Administered IV or SC – Pharmacokinetic and Pharmacodynamic Results.”

ALD403 is Alder’s transformative novel monoclonal antibody that targets CGRP for prevention of migraine. CGRP is a small protein involved in the transmission of and heightened sensitivity to pain experienced in migraine.
Randall C. Schatzman, Ph.D., President and Chief Executive Officer of Alder, said, “We believe that ALD403 has the potential to transform migraine prevention. These data presented today demonstrate the durable efficacy of ALD403 over six months, and we are now focused on identifying the optimal once-quarterly dose of ALD403 for both infusion and self-administration formulations. To this end, we plan to initiate two additional dose-ranging clinical trials in the second half of this year. We believe that providing patients and physicians the choice between these two routes of administration will allow a customized treatment paradigm that best suits each individual patient’s preference and circumstances.”

About Alder BioPharmaceuticals

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 lead clinical candidate, ALD403, inhibits a well-validated molecule shown to trigger migraine attacks, calcitonin gene-related peptide (CGRP), and is currently undergoing Phase 2b clinical testing for the treatment of chronic migraines. Alder plans to initiate additional advanced clinical studies for ALD403 in frequent episodic and chronic migraines in the second half of 2015. Alder’s second program, ALD1613, which targets adrenocorticotropic hormone (ACTH) is undergoing Investigational New Drug (IND)-enabling preclinical studies with the initiation of clinical studies in Cushing’s disease planned for 2016. Finally, 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 the further development of ALD403 and ALD1613, our expectations for the initiation of future clinical trials and studies, availability of clinical trial data, patient enrollment and the potential of ALD403, ALD1613 and clazakizumab 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 March 31, 2015, which was filed with the Securities and Exchange Commission (SEC) on May 7, 2015, 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.

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