Alder BioPharmaceuticals Initiates Pivotal Clinical Trial of ALD403 for Preventative Treatment of Frequent Episodic Migraine

First of Two Pivotal Trials Planned to Support Biologics License Application for ALD403

BOTHELL, Wash., Oct. 13, 2015 – Alder BioPharmaceuticals, Inc. ("Alder") (NASDAQ: ALDR), a clinical-stage biopharmaceutical company developing monoclonal antibody therapeutics for the treatment of migraine, Cushing's disease, Congenital Adrenal Hyperplasia and autoimmune and inflammatory diseases, today announced the initiation of the first of two planned pivotal clinical trials of ALD403, its transformative monoclonal antibody targeting the calcitonin gene-related peptide (CGRP), for the prevention of frequent episodic migraine. CGRP is a small protein involved in the transmission of and heightened sensitivity to pain experienced in migraine.

Key Points:

- This double-blind, randomized, placebo-controlled, pivotal trial will evaluate the efficacy and safety of three dose levels of an infusion formulation of ALD403, administered quarterly in individuals with frequent episodic migraine.
- The trial will be known as PROMISE 1: PRevention Of Migraine via Intravenous ALD403 Safety and Efficacy 1.
- The trial is expected to enroll approximately 600 patients.
- The primary endpoint of this trial is the change in migraine days between ALD403 and placebo as determined by the difference in responder rates over a 12-week period.
- Top-line data from this trial is expected in the first half of 2017.
- In 2016, Alder also plans to initiate a second pivotal trial in 450 chronic migraine patients to evaluate the efficacy and safety of two dose levels of an infusion formulation of ALD403. This trial will be known as PROMISE 2.
- Together, the results of these two pivotal trials will support a Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA) for the infusion formulation of ALD403, if supported by the data.
- Alder is also advancing the clinical development of a formulation of ALD403 for quarterly self-administration and, following the completion of the current Phase 1 study, plans to initiate a dose-ranging Phase 2b study in frequent episodic migraine patients in 2016.
- Frequent episodic and chronic migraine sufferers represent a substantial market opportunity estimated to be up to $8 to $10 billion per year.
- For more information on the trial, please visit: https://clinicaltrials.gov/ct2/show/NCT02559895

Quote:

Randall C. Schatzman, Ph.D., President and Chief Executive Officer of Alder, said, "Earlier this year, we outlined an accelerated development program for ALD403 based on the data from

previous trials, which demonstrated outstanding efficacy, delivering many patients to migraine-free relief, that is, 100% suppression of migraine occurrence with rapid onset of effect in the first weeks following treatment and responses lasting out to six months. The initiation of this first of two pivotal trials for the quarterly infusion formulation of ALD403 supports our aggressive development strategy for this transformative preventative migraine treatment."

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 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 has initiated a pivotal trial for the treatment of frequent episodic migraine and plans to initiate additional advanced clinical trials for ALD403 in frequent episodic and chronic migraines in 2016. 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 Congenital Adrenal Hyperplasia or 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. Alder is seeking a partner or other strategic alternatives for clazakizumab. 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 June 30, 2015, which was filed with the Securities and Exchange Commission (SEC) on August 5, 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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