Clazakizumab, an Anti-IL-6 Monoclonal Antibody for the Treatment of Rheumatoid Arthritis, Meets Primary Endpoint in Follow-On Phase 2b Clinical Trial

BOTHELL, Wash., May 5, 2015 – Alder BioPharmaceuticals, Inc. (“Alder”) (NASDAQ: ALDR), a clinical-stage biopharmaceutical company developing monoclonal antibody therapeutics for the treatment of migraine, Cushing’s disease and autoimmune and inflammatory diseases, today announced that clazakizumab, previously known as ALD518, met its primary endpoint in a follow-on Phase 2b, dose-ranging clinical trial in adults with moderate to severe rheumatoid arthritis who have experienced an inadequate response to TNF inhibitors. Alder plans to present the full results from the trial at an upcoming scientific meeting.

Key Points:

• Clazakizumab met its primary endpoint, efficacy of clazakizumab versus placebo as assessed by the change in Disease Activity Score in 28 joints using C-reactive protein (DAS28-CRP) from baseline at Week 12. Both the 25mg and 5 mg dosing groups were statistically significantly better than placebo at p<0.001.

• Clazakizumab was well tolerated and there were no differences from placebo in terms of adverse events or laboratory safety data.

• The follow-on Phase 2b, dose-ranging trial was designed to determine safety and efficacy of clazakizumab in 140 patients with moderate to severe rheumatoid arthritis who were anti-TNF inadequate responders.

• Clazakizumab is a humanized, monoclonal antibody, designed to block the pro-inflammatory molecule interleukin-6 (IL-6), which plays a key role in the inflammatory cascade leading to the inflammation, swelling, pain and destruction of large and small joints associated with arthritis.

• Alder plans to present the full results from the trial at an upcoming scientific meeting.

Quote:

Randall C. Schatzman, Ph.D., President and Chief Executive Officer of Alder, said, “These positive safety and efficacy findings in patients with rheumatoid arthritis provide additional support for the promise of clazakizumab as we seek a new partner to continue developing this monoclonal antibody for the treatment of autoimmune and inflammatory diseases.”

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 clazakizumab, ALD403 and ALD1613, our expectations for the initiation of future clinical trials and studies, availability of clinical trial data 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 Annual Report on Form 10-K for the year ended December 31, 2014, which was filed with the Securities and Exchange Commission (SEC) on March 13, 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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