Alder BioPharmaceuticals Initiates Phase 2b Clinical Trial of ALD403 for Preventative Treatment of Chronic Migraine

ALD403 Targets Well-Validated Biology through Inhibition of Calcitonin Gene-Related Peptide (CGRP)

BOTHELL, Wash., November 3, 2014 – Alder BioPharmaceuticals, Inc. (NASDAQ: ALDR), a clinical-stage biopharmaceutical company developing monoclonal antibody therapeutics for the treatment of migraine, autoimmune and inflammatory diseases, today announced the initiation of a Phase 2b clinical trial of ALD403, its antibody therapeutic candidate targeting the calcitonin gene-related peptide (CGRP), for the preventative treatment of chronic migraine. It is believed that the involvement of this small protein, CGRP, is critically important in the transmission of and heightened sensitivity to pain experienced in migraine.

Key points:

- The Phase 2b double blind, randomized, placebo-controlled dose-ranging trial will evaluate an intravenous (IV) formulation of ALD403 in individuals with chronic migraine and is expected to enroll approximately 600 patients at more than 60 sites worldwide.
- The primary endpoint of this Phase 2b trial is the change in migraine days between ALD403 and placebo as judged by the difference in the responder rates at week 12.
- Patient screening was initiated in October 2014 and primary endpoint data from this trial is expected in the second half of 2015. The dose and efficacy data from this trial will be used to inform the Phase 3 trial, which is expected to initiate in second half of 2016, if supported by the Phase 2b data.
- Chronic migraine sufferers are defined as individuals who experience fifteen or more migraine days per month. This population, together with frequent episodic migraine sufferers, or those suffering five to fourteen migraine days per month, has been estimated to be a potential $7.5 billion market opportunity for a preventative therapeutic.

Quote:

Randall C. Schatzman, Ph.D., Chief Executive Officer, Alder BioPharmaceuticals, said, “There is a significant unmet need for a convenient therapy that can prevent a migraine before it starts, and we look forward to reporting preliminary data from this trial in the second half of 2015. We have designed an aggressive development plan for ALD403 because we believe there is a significant benefit and commercial opportunity for not only an IV formulation but also a subcutaneous one as well. Therefore, we plan to initiate a second Phase 2b trial of our subcutaneous formulation for the treatment of frequent episodic migraine sufferers in the first half of 2015, which will be run in parallel with the Phase 2b chronic migraine study.”

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 ALD403 inhibits a well-validated molecule shown to trigger migraine attacks, calcitonin gene-related peptide (CGRP), and is now undergoing clinical testing. Alder advanced ALD403 into a Phase 2b trial for the treatment of chronic migraines and plans to initiate a Phase 2b trial for 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, data availability from ongoing clinical trials, market opportunity for therapeutics 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 document 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, 2014, which was filed with the Securities and Exchange Commission (SEC) on August 5, 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.

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