



June 27, 2017

Alder BioPharmaceuticals Announces Positive Eptinezumab Phase 3 Results for Prevention of Frequent Episodic Migraine

-- Pivotal PROMISE 1 top-line results show eptinezumab met primary and key secondary endpoints --

-- Beginning day 1 after first dose significant reduction in proportion of patients experiencing migraine --

-- Average of 1 in 5 patients had no migraines in any given month over months 1 through 6 --

-- Conference call to be held today, June 27, at 8:00 a.m., ET --

BOTHELL, Wash., June 27, 2017 (GLOBE NEWSWIRE) -- Alder BioPharmaceuticals, Inc., (NASDAQ:ALDR) today announced that eptinezumab, its lead product candidate for migraine prevention, met the primary and key secondary endpoints in PROMISE 1, a Phase 3 pivotal clinical trial evaluating patients with frequent episodic migraine.

PROMISE 1 Highlights

- | PROMISE 1 met the primary endpoint: highly statistically significant reductions in monthly migraine days;
- | Significant Day 1 clinical benefit: $\geq 50\%$ reduction in the proportion of patients experiencing a migraine on Day 1 post-dose;
- | Significant 75% responses at all key time points: $\sim 1/3$ of patients achieved a $\geq 75\%$ reduction in migraine days through 4 and 12 weeks;
- | Average of 1 in 5 patients had 100% response: no migraines in any given month, months 1 through 6; and
- | The safety profile was similar to placebo: consistent with previously reported eptinezumab studies.

"Approximately 13 million people suffer from the pain and debilitation of migraines that occur four or more days a month, yet nine out of 10 individuals don't utilize preventive therapy due to limitations in efficacy, safety and tolerability," said Roger Cady, MD, Alder Vice President of Neurology and Fellow of the American Headache Society. "Patients deserve more from their treatments, and these data show eptinezumab could be a major advance in meeting the significant unmet need for patients to regain control of their lives."

PROMISE 1 Top-Line Results

The primary endpoint, demonstrating statistically significant reductions in monthly migraine days from baseline (average of 8.6 days) over weeks 1 through 12 was 4.3 monthly migraine days for 300mg ($p=0.0001$) and 3.9 days for 100mg ($p=0.0179$) compared to an average 3.2 days for placebo. A 30mg dose level evaluated in the study was not tested as per the statistical analysis plan.

Secondary endpoints evaluating time points through the first quarterly dose include:

- | $\geq 75\%$ reduction in monthly migraine days achieved over weeks 1 through 4 of 31.5% for 300mg and ($p=0.0066$), and 30.8% for 100mg ($p=0.0112$) compared to 20.3% for placebo.
- | $\geq 75\%$ reduction in monthly migraine days achieved over weeks 1 through 12 of 29.7% for 300mg ($p=0.0007$), and 22.2% for 100mg (not statistically significant) compared to 16.2% for placebo.
- | $\geq 50\%$ reduction in monthly migraine days achieved by 56.3% of patients over weeks 1 through 12 for 300mg ($p=0.0001$) and 49.8% for 100mg ($p=0.0085$, unadjusted) compared to 37.4% for placebo.
- | 53.6% reduction in the proportion of patients experiencing migraine on the day following administration at 300mg ($p=0.0087$, unadjusted), and 51.3% at 100mg ($p=0.0167$, unadjusted), compared to 20.7% for placebo

Secondary endpoints demonstrated responses that were improved through the second quarterly dose period, and include:

- | $\geq 75\%$ reduction in monthly migraine days achieved over weeks 13 through 24 of 40.1% for 300mg ($p=0.0006$, unadjusted), and 33.5% for 100mg ($p=0.0434$, unadjusted) compared to 24.8% for placebo.
- | Average of one in five patients receiving 300mg (20.6%) had 100% responses with no migraines in any given month (months 1 through 6).

The observed safety profile in this study to date was similar to placebo. Both the safety profile and the placebo rates were consistent with previously reported eptinezumab studies. Full safety data will be available at the end of the study.

"Alder's goal is to discover and develop best-in-class therapies that have the potential to transform the lives of the millions of underserved patients who are seeking long-term freedom from their migraines," said Alder President and Chief Executive Officer Randy Schatzman, Ph.D. "These positive results, consistent with previously reported eptinezumab studies, support the unique clinical profile of eptinezumab as a potential first-of-its-kind infusion therapy to prevent migraines. Enrollment is on track for PROMISE 2, our second pivotal Phase 3 study that focuses on chronic migraine, and we remain on track to submit our BLA with the U.S. Food and Drug Administration (FDA) in the second half of 2018."

Migraine is a disabling neurological disease.¹ Current preventive treatments for migraine are challenged by safety, efficacy, and tolerability limitations and fail to meet the needs of most patients.^{2,3} Migraine preventive treatments can take weeks to months to achieve meaningful clinical benefit and, subsequently, most patients discontinue within 6 months to 1 year due to lack of efficacy and/or side effects.^{3,4} The eptinezumab development program was designed to redefine physician and patient expectations for migraine prevention. This includes early, meaningful, sustained migraine prevention including the opportunity for patients to experience long periods of migraine freedom.

About PROMISE 1 and 2

PROMISE 1 (**PRE**vention **O**f **M**igraine via **I**ntravenous eptinezumab **S**afety and **E**fficacy 1) is a double-blind, randomized, placebo-controlled Phase 3 study evaluating the efficacy and safety of eptinezumab (300mg, 100mg or 30mg) administered by intravenous infusion once every 12 weeks through week 24. The study continues for an additional 2 doses every 12 weeks with follow up through week 56. The study enrolled 888 patients diagnosed with frequent episodic migraine. The primary endpoint for PROMISE 1 was the mean change in monthly migraine days from baseline (28-day run-in period) for weeks 1 through 12. Key secondary endpoints included the percent of patients who achieved $\geq 75\%$ reduction in monthly migraine days from baseline over weeks 1 through 4 and weeks 1 through 12. Patients enrolled in the study experienced, on average, 8.6 migraines days per month.

Alder expects to complete enrollment in PROMISE 2, which is being conducted in patients with chronic migraine, later this year. Top-line data for that study are expected in the first half of 2018. Together, the results of PROMISE 1, PROMISE 2, and an open-label safety study will support a Biologics License Application (BLA) submission to the FDA for eptinezumab, which Alder plans to file in the second half of 2018.

About Eptinezumab

Eptinezumab is an investigational monoclonal antibody discovered and developed by Alder BioPharmaceuticals for migraine prevention. Eptinezumab is administered quarterly via infusion that allows for 100% of the dose available to selectively and potently inhibit CGRP.⁵ Eptinezumab is currently in multiple global, randomized pivotal, Phase 3 studies to assess its efficacy and safety in migraine prevention.

About Migraine^{1,2,3}

Migraine affects 36 million Americans and is considered the 6th most disabling disease in the world. It is a disabling neurological disease characterized by recurrent episodes of moderate to severe headache accompanied by nausea, vomiting, and sensitivities to light and sound. The occurrence of migraine can be unpredictable with a profound impact on activities of daily living. This disease can last decades, often during what should be the most productive years of patients' lives. Migraine can remit or progress to chronic migraine over time and persist as chronic migraine for years or decades, but it commonly oscillates between periods of frequent episodic and chronic migraine. Current preventive treatments for migraine fail to meet the needs of most patients and there is a significant need for new, effective, and well-tolerated treatment options.

Conference Call and Webcast

Alder will host a conference call and live audio webcast today at 8:00 a.m. ET to discuss PROMISE 1 top-line data. The live call may be accessed by dialing (877) 430-4657 for domestic callers or (484) 756 4339 for international callers, and providing conference ID number 46152061. The webcast and accompanying slides may be accessed from the Events & Presentations page in the Investors section of Alder's website at www.alderbio.com and will be available for replay following the call for 30 days.

About Alder BioPharmaceuticals

Alder BioPharmaceuticals, Inc. is a clinical-stage biopharmaceutical company committed to transforming the treatment paradigm for patients with migraine and other serious neurological or inflammatory conditions. Leveraging its pioneering monoclonal antibody technologies, Alder discovers and develops novel therapeutic antibodies designed to deliver highly differentiated, best-in-class clinical profiles. Alder's lead pivotal-stage product candidate, eptinezumab, is being evaluated for migraine prevention. Eptinezumab is a monoclonal antibody administered quarterly via infusion that allows for 100% of the dose available to selectively and potently inhibit the 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: the continued development and clinical, therapeutic, and commercial potential of eptinezumab; the availability of results from clinical trials; the potential regulatory submission for eptinezumab; the high unmet need for preventative migraine treatments; and Alder's goals and objectives. Words such as "will," "could," "advance," "goal," "potential," "support," "unique," "first-of-its-kind," "on track," "expects," "plans," 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 quarter 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.

References

1. Migraine Research Foundation. Migraine Facts. <http://www.migraineresearchfoundation.org/fact-sheet.html>. Accessed June 17, 2017.
2. Lipton RB, Silberstein SD. Episodic and chronic migraine headache: breaking down barriers to optimal treatment and prevention. *Headache*. 2015; 55(S2):103-122.
3. Bigal ME, Krymchantowski AV, Lipton RB. Barriers to satisfactory migraine outcomes. What have we learned, where do we stand? *Headache*. 2009;49(7):1028—1041.
4. Hepp, Z, Dodick DW, Varon SF, et al. Adherence to oral migraine-preventive medications among patients with chronic migraine. *Cephalalgia* 2015;35(6):477-88.?
5. Baker B, Schaeffler B, Cady R, et al; Rational design of a monoclonal antibody (mAb) inhibiting calcitonin gene-related peptide, ALD403 (eptinezumab), intended for the prevention of migraine. Poster presented at the American Academy of Neurology (AAN) 2017 Annual Meeting.

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