



NEWS RELEASE - *for immediate release*

Alexza's AZ-001 Phase IIb Trial Meets Primary Endpoint of 2-Hour Pain Relief in Patients with Migraine Headache

**Initial Analysis Shows Statistically Significant Pain Relief
versus Placebo with All Doses Tested**

Palo Alto, California - March 26, 2007 - Alexza Pharmaceuticals, Inc. (Nasdaq: ALXA) today announced positive top-line results from its 400 patient Phase IIb clinical trial of AZ-001 (*Staccato*[®] prochlorperazine) in patients with migraine headache. All three doses of AZ-001 met the primary endpoint of 2-hour pain-relief, compared to placebo. Alexza also announced today positive initial results from its Phase IIa clinical trial of AZ-004 (*Staccato* loxapine) in schizophrenic patients with acute agitation, where AZ-004 met the primary endpoint of the Phase IIa clinical trial.

"AZ-001 is a product candidate that we believe could fill an important unmet need in the treatment of patients with migraine headaches," said Thomas B. King, President and CEO of Alexza. "AZ-001 combines drug delivery speed comparable to that of an intravenous injection, with the simplicity, convenience and ease of administration of a simple, one-breath inhalation. For the second time in Phase II trials, efficacy has been established for AZ-001, this time with dose-ranging information."

"Prochlorperazine has long been administered intravenously with significant success in treating migraine headaches, usually in a clinic or in an emergency department," said Anthony W. Fox, MD, PhD, President of the EBD Group and advisor to Alexza. "The ability to provide a therapy with an alternative mechanism of action, coupled with rapid pharmacokinetics in an outpatient environment, makes *Staccato* prochlorperazine an exciting drug candidate for many migraine patients."

Clinical Trial Design

The AZ-001 Phase IIb clinical trial was an outpatient, multi-center, randomized, double blind, placebo-controlled study. The study was designed to evaluate the treatment of a single migraine attack in each of 400 migraine patients, with and without aura. In the trial, three doses of AZ-001 (*Staccato* prochlorperazine in 5, 7.5 and 10 mg doses) and placebo (a *Staccato* device containing no drug) were tested, with 100 patients assigned to each treatment group. The primary efficacy endpoint for the trial was headache pain relief at 2-hours post-dose, as defined by the International Headache Society (IHS) using a 4-point headache pain rating scale. Secondary efficacy endpoints for the trial included various additional measurements of pain relief, as well as effects on nausea, vomiting, phonophobia and photophobia. The clinical trial study period was 24 hours post dosing for each patient. All results were considered statistically significant at the $p < 0.05$ level and all analyses were made on an intent-to-treat basis. Side effects were recorded throughout the clinical trial study period and a safety evaluation was made at each patient's closeout visit.



Primary Efficacy Endpoint

AZ-001 met the primary efficacy endpoint of the clinical trial, which was pain relief at 2-hours post-dose using the IHS 4-point scale, for all three doses of the drug compared to placebo. Statistically significant improvements in pain response were observed in 66.0% of patients at the 10 mg dose ($p=0.0013$), 63.7% of patients at the 7.5 mg dose ($p=0.0046$) and 60.2% of patients at the 5 mg dose ($p=0.0076$), compared to 40.8% of patients receiving placebo.

Additional Efficacy Endpoints

Another measure of efficacy was the achievement of a pain-free response at 2 hours, where a patient has a pain score of 0 (or "no") headache pain at the 2-hours post-dose time point. In the trial, AZ-001, showed statistically significant differences from placebo in this measure with 35.0% of patients who received the 10 mg dose achieving pain-free status ($p=0.0019$) and 29.7% of patients who received the 7.5mg dose achieving pain-free status ($p=0.0226$). Patients receiving the 5 mg dose (21.4%) did not achieve a statistically significant pain-free response, compared to placebo. The rate of pain-free response at 2 hours in patients receiving placebo was 15.3%.

The Company believes duration of efficacy is an important consideration in developing migraine therapeutics. A commonly used measure of duration of efficacy is the sustained pain-free response, whereby a patient reports a pain-free score at the 2-hour post-dose time point and remains pain-free for the remainder of the study period (up to 24 hours). The 10 mg and 7.5 mg doses of AZ-001 showed statistically significant differences in sustained pain-free response, compared to placebo. Sustained pain-free outcomes through 24 hours were observed in 30.1% and 23.1% of total patients in the 10 mg and 7.5 mg dose groups, respectively. The placebo dose exhibited a sustained pain-free response in 10.2% of total patients.

AZ-001 exhibited rapid onset of pain relief. The 7.5 mg dose showed statistically significant pain response, compared to placebo, at 15 minutes ($p=0.016$). At 30 minutes, all three doses of AZ-001 showed statistically significant pain response, compared to placebo; 10 mg ($p=0.0056$), 7.5 mg ($p=0.0003$) and 5 mg ($p=0.0056$).

In addition to the various pain response analyses, the Company believes migraine-related symptom management is an important consideration in the overall efficacy of a migraine therapy. Important symptoms to be managed in migraine patients are nausea, vomiting, photophobia (sensitivity to light) and phonophobia (sensitivity to sound). Survival analyses for nausea, photophobia and phonophobia over the 2 hour time period post-dose showed a statistically significant difference, compared to placebo. The total patients with vomiting ($n=20$ in all four dose groups) in the trial were too few to make conclusions about drug effect.

Safety Evaluations

Side effects were recorded throughout the clinical trial study period and a safety evaluation was made at each patient's closeout visit. There were no serious adverse events reported during the trial. The most common drug-related side effects reported across all three active dose groups in the clinical trial were taste (25 - 33%), throat irritation (18 - 30%), cough (16 - 30%), somnolence (6 - 10%), breathlessness (2 - 9%), and dizziness (0 - 9%). These side effects appeared to be dose related, with a lower incidence and severity of the side effects generally seen at the lower doses of AZ-001.



Device Performance

All efficacy and safety analyses were completed on an intent-to-treat basis. *Staccato* devices used in the clinical trial were returned for analysis of device performance. Preliminary analysis of the returned devices and all devices routinely analyzed during quality control and ongoing stability studies related to the clinical trial materials showed a device mechanical failure rate of less than 1%.

About Acute Migraine Headaches

According to the National Headache Foundation, migraines affect 29.5 million Americans. Acute migraine headaches occur often, with more than 50% of migraine sufferers having one to four migraines a month. The Company believes that, based on market research conducted with migraine sufferers, many migraine patients desire to find faster-acting and more predictable therapies for the treatment of their migraine headaches.

About AZ-001 (*Staccato* prochlorperazine)

AZ-001 combines Alexza's proprietary *Staccato* system with prochlorperazine, a drug belonging to the class of compounds known as phenothiazines. Prochlorperazine is currently approved in the United States for the treatment of several indications, including nausea and vomiting. In several published clinical studies, 10 mg of prochlorperazine administered intravenously demonstrated effective relief of migraine pain. The Company believes that AZ-001 could potentially result in a speed of therapeutic onset advantage over oral tablets, and a convenience and comfort advantage over injections.

About Alexza Pharmaceuticals

Alexza Pharmaceuticals is an emerging pharmaceutical company focused on the development and commercialization of novel, proprietary products for the treatment of acute and intermittent conditions. The Company's technology, the *Staccato* system, vaporizes unformulated drug to form a condensation aerosol that allows rapid systemic drug delivery through deep lung inhalation. The drug is quickly absorbed through the lungs into the bloodstream, providing speed of therapeutic onset that is comparable to intravenous administration, but with greater ease, patient comfort and convenience. The Company has four product candidates in clinical development; AZ-001 (*Staccato* prochlorperazine) for the acute treatment of migraine headaches, AZ-002 (*Staccato* alprazolam) for the acute treatment of panic attacks associated with panic disorder, AZ-004 (*Staccato* loxapine) for the treatment of acute agitation in patients with schizophrenia and AZ-003 (*Staccato* fentanyl) for the treatment of patients with acute pain.

Safe Harbor Statement

This press release includes forward-looking statements regarding the development, therapeutic potential and safety of AZ-001. Any statement describing the Company's expectations or beliefs is a forward-looking statement, as defined in the Private Securities Litigation Reform Act of 1995, and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of developing and commercializing drugs. The Company's forward-looking statements also involve assumptions that, if they prove incorrect, would cause its results to differ materially from those expressed or implied by such forward-looking statements. Earlier stage clinical trial results are not



necessarily predictive of later stage clinical trial results. These and other risks concerning the Company's business are described in additional detail in the Company's Form S-1 dated March 8, 2006, and the Company's Reports filed with the Securities and Exchange Commission, including those described in the section titled "Risk Factors" under the headings "We will need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations." and "If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them." Forward-looking statements contained in this announcement are made as of this date, and the Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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