



**NEWS RELEASE - *for immediate release***

**Alexza Completes Enrollment in AZ-004 Phase IIa Clinical Trial  
in Schizophrenic Patients with Acute Agitation**

**Initial Results Expected to be Reported in Q2 2007**

**Palo Alto, California - January 18, 2006** - Alexza Pharmaceuticals, Inc. (Nasdaq: ALXA) announced today that it has completed patient enrollment in its Phase IIa clinical trial of AZ-004 (Staccato<sup>®</sup> loxapine). AZ-004 is an inhalation product candidate being developed for the acute treatment of agitation in schizophrenic patients.

The Phase IIa clinical trial was a multi-center, randomized, double-blind, placebo-controlled study of 120 patients in an in-patient clinical setting. In the trial, two doses of AZ-004 (5 and 10 mg), and placebo were tested. The primary aim of the clinical trial was to assess the safety and efficacy of a single dose of AZ-004 in acutely treating agitation in schizophrenic patients. Assessments of a patient's agitation state were conducted at serial time points using both standard agitation scales and objective measures of patient's movement over a 4-hour period, with follow-up assessments for the next 20 hours. The change in the PANSS Excited Component (PEC) scale was the primary efficacy measure for the clinical study. Safety evaluations were made throughout the clinical trial period.

"This clinical trial is significant in demonstrating that acutely-agitated schizophrenic patients can self-administer AZ-004 in a clinical setting," said James V. Cassella, PhD, Alexza Senior Vice President of R&D. "We completed enrollment in this proof-of-concept study in less than 4 months, which we believe shows the viability of this treatment option in this patient population. We believe we are on track to provide initial results from this clinical trial during the second quarter of 2007."

**About Schizophrenic Patients with Acute Agitation**

Acute agitation is a complication of many major psychiatric disorders, including schizophrenia, bipolar disorder and dementia, characterized by an unpleasant degree of arousal, tension and irritability, frequently leading to confusion, hyperactivity and hostility. According to the National Institute of Mental Health, schizophrenia afflicts more than three million people in the United States. Agitation is one of the most common and severe symptoms of schizophrenia. Patients may seek treatment in an emergency room, a psychiatric services setting or a private psychiatric hospital, and some do not receive treatment. Treated patients are generally given an intramuscular injection of an atypical antipsychotic drug or a sedative medication. However, intramuscular injections are invasive, can take 30 to 60 minutes to work, are often disconcerting to patients, and can be dangerous to the



medical personnel attempting to give the injection. Alexza believes that many schizophrenic patients can make informed decisions regarding their treatment in an acute agitative state and would prefer a noninvasive treatment. Alexza also believes there is a significant unmet medical need for a faster-acting, noninvasive treatment of acute agitation in schizophrenic patients.

#### About AZ-004 (*Staccato* loxapine)

AZ-004 is the combination of Alexza's proprietary *Staccato* system with loxapine, a drug belonging to the class of compounds known as antipsychotics. In a Phase I dose-escalation clinical trial in healthy subjects, AZ-004 was generally well tolerated at all doses tested and there were no serious adverse events. Across all doses, pharmacokinetic analyses revealed that peak plasma levels were generally reached within the first few minutes after dosing and AZ-004 exhibited good dose proportionality. Alexza believes the non-invasive nature and rapid pharmacokinetic properties resulting from administration via the *Staccato* system make AZ-004, if approved for marketing, a viable product candidate for treating agitation episodes in schizophrenic patients.

#### 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 potential timing of the completion and announcement of results of the AZ-004 Phase IIa clinical trial, potential benefits of AZ-004, future development of the Company's product candidates and safety of the Company's products and technologies. 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. 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 Quarterly and Current Reports filed with the Securities and Exchange Commission, including the risks 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." "Failure or delay in commencing or completing clinical trials for our product candidates could harm our business" 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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