



## **Abgenix's ABX-IL8 Antibody Associated With Statistically Significant Improvement In Psoriasis**

- Phase IIa Trial Also Shows Excellent Safety Profile -

FREMONT, Calif. - March 5, 2001 – Abgenix, Inc. (Nasdaq: ABGX) presented the results of its Phase IIa clinical trial of ABX-IL8 for use in the treatment of moderate-to-severe psoriasis at a meeting of the American Academy of Dermatology (AAD) in Washington, D.C. ABX-IL8 is a fully human monoclonal antibody generated with Abgenix's XenoMouse™ technology that blocks the activity of interleukin-8 (IL-8), a chemokine involved in several inflammatory diseases, including psoriasis, rheumatoid arthritis and pulmonary disorders.

The double-blind, placebo-controlled Phase IIa study of ABX-IL8 included 94 moderate-to-severe psoriasis patients at 18 sites in the US. Two doses of ABX-IL8 were assessed, 3mg/kg and 6mg/kg. ABX-IL8 was administered every three weeks for a total of five infusions; the first dose was a 2x loading dose. Patients were evaluated at three-week intervals through Week 18. The primary objective of the phase IIa study was to evaluate the safety of ABX-IL8 at the doses administered, while the Phase IIb study is designed to confirm the efficacy of ABX-IL8.

The following conclusions were presented at the AAD meeting:

- ABX-IL8 administered intravenously at doses ranging up to 6 mg/kg appears to be safe and well tolerated.
- No human anti-human antibody formation was detected up to six weeks following multiple dose administrations of ABX-IL8.
- No infusion-related reactions were seen at any dose at any time point.
- Pharmacokinetics of ABX-IL8 are linear. Serum steady-state was achieved following the second dose.
- ABX-IL8 (3mg/kg) was associated with a statistically significant improvement in plaque psoriasis as assessed by change from baseline Psoriasis Area Severity Index (PASI) scores (see Attachment, Tables 1 and 2), and Physician Global Assessments. The effect of ABX-IL8 at 6mg/kg was not statistically significantly different from that of 3 mg/kg.
- Patients who achieved a 75% improvement in PASI maintained that response through Week 36.
- Retrospective subset analysis indicated that the benefit of ABX-IL8 treatment was greater in patients with more severe (PASI score of 12 or higher) psoriasis (see Attachment, Table 3). This hypothesis will be prospectively evaluated in ongoing studies.

"In this study of patients with moderate-to-severe psoriasis, ABX-IL8 appeared safe and well tolerated and demonstrated statistically significant improvement in disease activity," stated Gerald Krueger, M.D., professor, Department of Dermatology at the University of Utah and chief investigator for the trial. "Based on these results, further study of ABX-IL8 in psoriasis patients is warranted."

"We continue to be pleased by the clinical results achieved with ABX-IL8 in psoriasis, a disease that represents a substantial market opportunity," stated R. Scott Greer, chairman and chief executive officer of Abgenix. "ABX-IL8 appears to offer an attractive safety profile relative to other psoriasis treatments while significantly improving disease response. We look forward to continuing development of ABX-IL8 as a psoriasis treatment and exploring its utility in other inflammatory diseases."

On the basis of the Phase IIa data, Abgenix has initiated a Phase IIb study of ABX-IL8 in psoriasis. This study, which is expected to enroll 228 patients with moderate-to-severe psoriasis, will evaluate two doses of ABX-IL8 and a placebo. Having seen no incremental benefit to the 6mg/kg dose over the 3mg/kg in the Phase IIa trial, Abgenix now plans to evaluate more convenient fixed doses of 100mg and 300mg (approximating 1mg/kg and 3mg/kg as weight-adjusted doses) administered every three weeks in the Phase IIb study.

The Phase IIa study experienced a relatively high withdrawal rate, nearly 25%. Analysis of this population showed that 13% of the patients withdrew from the study for reasons other than lack of efficacy or safety, and possibly due to the inconvenience of the mode of administration, a one-hour intravenous infusion followed by two hours of observation. As there were no infusion-related adverse events, the company intends to shorten the infusion time in the Phase IIb study, and to develop a subcutaneous injection formulation for later stage development.

Abgenix is testing ABX-IL8 in psoriasis because of its potential to intervene at multiple steps in the disease pathology by blocking IL-8. Scientific studies have shown that IL-8 levels can be elevated 150-fold in psoriatic tissue when compared to normal tissue. In addition to contributing to the inflammatory process, IL-8 is also a growth factor for skin cells that are proliferating in psoriatic tissue. Finally, IL-8 is a potent angiogenesis factor and may be contributing to

the formation of new blood vessels that are found in psoriatic lesions.

Researchers believe ABX-IL8 works by lowering the concentration of IL-8 at the site of inflammation and blocking the migration of inflammatory cells (neutrophils and T cells) to the site of inflammation. Thus, ABX-IL8 does not deplete the patient's supply of T-cells, an undesirable side effect of certain other psoriasis therapies.

Psoriasis is a chronic disease characterized by plaques, a thickening and scaling of the skin accompanied by local inflammation. The disease affects approximately four to five million people in the United States and can be debilitating in its most severe form. Approximately 500,000 psoriasis patients suffer from a severe enough form of the disease to require systemic therapy with immunosuppressants and ultraviolet phototherapy. The risk of serious adverse side effects associated with these therapies often requires the patients to alternate between various therapeutic modalities as a precautionary measure.

In addition to psoriasis, Abgenix is concurrently conducting a Phase IIa clinical trial of ABX-IL8 in patients with rheumatoid arthritis.

Abgenix is a biopharmaceutical company focused on the development and commercialization of fully human monoclonal antibody therapies for a variety of diseases. The company's antibody technology platform, which includes XenoMouse™ technology, enables the rapid generation and selection of high affinity, fully human antibody product candidates to essentially any disease target appropriate for antibody therapy. Abgenix leverages its leadership position in human antibody technology by building a large and diversified product portfolio through the establishment of licensing arrangements with multiple pharmaceutical, biotechnology and genomics companies and through the development of its own internal proprietary products. For more information on Abgenix, visit the company's website at [www.abgenix.com](http://www.abgenix.com).

*Statements made in this press release about ABX-IL8, Abgenix's XenoMouse technology, product development activities and collaborative arrangements other than statements of historical fact, are forward looking statements and are subject to a number of uncertainties that could cause actual results to differ materially from the statements made, including risks associated with the success of clinical trials, the progress of research and product development programs, the regulatory approval process, competitive products, future capital requirements and the extent and breadth of Abgenix's patent portfolio. Please see Abgenix's public filings with the Securities and Exchange Commission for information about risks that may affect Abgenix.*

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