



Biogen Idec Announces Top-Line Results from Phase II Clinical Trial of Baminercept in Rheumatoid Arthritis

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CAMBRIDGE, Mass.--([BUSINESS WIRE](#))--Biogen Idec (NASDAQ: BIIB) announced today that its Phase II trial of baminercept (BG9924, LT3R-Ig) in rheumatoid arthritis (RA) patients who have had an inadequate response to conventional therapy with a disease-modifying antirheumatic drug (DMARD) did not meet its primary endpoint. The primary endpoint was defined as the proportion of baminercept-treated patients who achieved an ACR50 response, a standard measure of disease improvement in RA, compared to placebo at 14 weeks. The study also did not meet any of the pre-specified secondary endpoints. Biogen Idec will continue to analyze the study results and will submit the data for presentation at an upcoming medical meeting.

Based on these results as well as preliminary data from a Phase II trial of baminercept in RA patients who have had an inadequate response to a tumor necrosis factor (TNF) inhibitor, the company has decided to discontinue the development of the compound in RA.

About the 104RA202 Study

The 104RA202 study was a Phase II randomized, double-blind, placebo-controlled, multicenter, dose-finding trial involved 380 individuals with active RA who had an inadequate response to conventional DMARD therapy. The trial was designed to assess the efficacy of five different regimens of baminercept when administered over 12 weeks in combination with methotrexate within this patient population.

About the 104RA203 Study

The 104RA203 study was a Phase II randomized, double-blind, placebo-controlled, multicenter trial in patients with active RA who had an inadequate response to TNF inhibitors. About 120 patients were expected to be enrolled in the trial, which was designed to assess the efficacy of 200 mg dose of baminercept administered over 12 weeks in combination with methotrexate.

In both studies, the primary endpoint was the proportion of patients who achieved an ACR50 response, defined as a 50% improvement compared to baseline for swollen and tender joint counts and other clinical measures, at week 14. Secondary endpoints included the proportion of patients to achieve scores of ACR20 (a 20% improvement compared to baseline for swollen and tender joint counts and other clinical measures) and ACR70 (a 70% improvement compared to baseline for swollen and tender joint counts and other clinical measures), improvement in DAS scores, and accepted tools to evaluate improvements in Quality of Life.

The safety data to date, including incidence of overall adverse events, serious adverse events and infections, suggest that baminercept was well-tolerated.

About RA

RA is a debilitating autoimmune disease that affects an estimated 1.3 million Americans and hinders daily activities. The damage that occurs in RA is a result of the immune system attacking joint tissue, causing painful chronic inflammation, irreversible destruction of cartilage, tendons and bones, which often results in disability. Common RA symptoms include inflammation of the joints, swelling, fatigue, stiffness and pain. Additionally, since RA is a systemic disease, it can affect other tissues such as the lungs and eyes.

About Biogen Idec

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Founded in 1978, Biogen Idec is a global leader in the discovery, development, manufacturing, and commercialization of innovative therapies. Patients in more than 90 countries benefit from Biogen Idec's significant products that address diseases such as lymphoma, multiple sclerosis, and rheumatoid arthritis. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

Safe Harbor/Forward-Looking Statements

This press release contains "forward-looking statements" regarding Biogen Idec's development of baminercept and therapies for autoimmune diseases that are based on current expectations and assumptions that are subject to risks and uncertainties. Only a small number of research and development programs result in commercialization of a product. In addition, the company may not be able to meet applicable regulatory standards or regulatory authorities may fail to approve the therapies that we develop; and the company may encounter other unexpected hurdles. For further information regarding factors, risks and uncertainties relating to Biogen Idec's drug research and development and other activities, please refer to the filings Biogen Idec has made with the Securities and Exchange Commission, including the "Risk Factors" section of Biogen Idec's Quarterly and Annual Reports, copies of which may be obtained at www.biogenidec.com. Biogen Idec assumes no obligation to update and specifically disclaims any duty to update the information in this press release for any reason, except as required by law, even as new information becomes available or other events occur in the future. All forward-looking statements in this press release are qualified in their entirety by this cautionary statement.

Contact:

Media Contact:
Biogen Idec
Naomi Aoki, 617-914-6524
or
Investor Contact:
Biogen Idec
Eric Hoffman, 617-679-2812