Regeneron Announces FDA Acceptance of ARCALYST® (rilonacept) Supplemental Biologics License Application for Review

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TARRYTOWN, N.Y., Nov. 22, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's supplemental Biologics License Application (sBLA) for ARCALYST Injection for Subcutaneous Use for the prevention of gout flares in patients initiating uric acid-lowering therapy. Under the Prescription Drug User Fee Act (PDUFA), the goal for a standard review of an sBLA is ten months from submission, for a target action date of July 30, 2012.

"Based on the positive data from our Phase 3 efficacy studies and the more than 1300 patients in our safety study, we believe that ARCALYST has the potential to become an important new therapy for patients with gout who are initiating uric acid-lowering therapies," stated George D Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "Gout is a serious and sometimes debilitating disease, characterized by elevated levels of uric acid in the blood, which requires treatment with uric acid-lowering therapy to avoid gout flares and its long-term complications. Unfortunately, its management is often impeded by painful gout flares that occur early during treatment with standard-of-care uric acid-lowering therapies. The availability of a treatment that can help avoid gout flares during the initial months of uric acid-lowering therapy has the potential to help patients with this disease."

The sBLA submission for ARCALYST is based on positive efficacy data from PRE-SURGE 1, a North American Phase 3 trial, and PRE-SURGE 2, a similarly designed global Phase 3 trial. Both trials met the primary endpoint of reduction in the mean number of gout flares per patient during the 16-week treatment period in patients initiating uric acid-lowering therapy. ARCALYST was generally well tolerated with the incidence of serious adverse events generally well-balanced across the placebo and ARCALYST groups. Injection site reactions, usually considered mild, were reported more commonly with ARCALYST than with placebo. A third study, RE-SURGE, evaluated the safety of ARCALYST in patients who were at risk for gout flares because they were initiating or taking uric acid-lowering drug treatment. This study showed that ARCALYST was generally well tolerated and the safety profile was consistent with that reported in the PRE-SURGE 1 and PRE-SURGE 2 studies.

About the Phase 3 ARCALYST Program in Gout

In the PRE-SURGE 1 and PRE-SURGE 2 studies, 488 patients were randomized to receive one of the following treatment regimens: ARCALYST 160 milligrams (mg) as an initial subcutaneous loading dose followed by weekly 80mg subcutaneous injections for 16 weeks, or ARCALYST 320mg as an initial subcutaneous loading dose followed by weekly 160mg subcutaneous injections for a total of 16 weeks, or subcutaneous weekly placebo injections for 16 weeks.

The North American PRE-SURGE 1 (**PRE**ventative **S**tudy against **UR**ate lowering drug-induced **G**out **E**xacerbations) study was a double-blind, placebo-controlled study which evaluated the number of gout flares per patient over the first 16 weeks following initiation of allopurinol therapy. Patients who received ARCALYST (rilonacept) at a weekly, self-administered, subcutaneous dose of 160mg had an 80% decrease in mean number of gout flares (p