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Phase 3 study: Sarilumab monotherapy meets primary endpoint in active rheumatoid arthritis patients

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Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that a Phase 3 monotherapy study met its primary endpoint demonstrating that sarilumab was superior to adalimumab (marketed by AbbVie as HUMIRA®) in improving signs and symptoms in patients with active rheumatoid arthritis (RA) at Week 24. The study, called SARIL-RA-MONARCH, also met important secondary endpoints including other measures assessing improvements in signs and symptoms of RA and physical function. Sarilumab is an investigational, human IL-6 receptor antibody.

"In this study, sarilumab monotherapy provided stronger efficacy than adalimumab monotherapy. Adalimumab is one of the most commonly used biologic medicines in RA," said Janet van Adelsberg, M.D., Senior Director, Clinical Sciences, Immunology and Inflammation, Regeneron. "This is the first time an IL-6 receptor blocker delivered subcutaneously has demonstrated superiority over adalimumab monotherapy in RA."

The SARIL-RA-MONARCH study enrolled 369 adult patients with active RA who were inadequate responders to, intolerant of, or inappropriate candidates for methotrexate (MTX). Patients were randomized to receive either subcutaneous sarilumab monotherapy (200 mg every 2 weeks) or adalimumab monotherapy (40 mg every 2 weeks); patients who did not respond adequately to adalimumab could increase to weekly dosing.

"Despite the availability of a wide range of treatment options, we believe that new therapies are needed to further address unmet needs of RA patients," said Dr. Simon Cooper, MBBS VP, Global Project Head, Immunology and Inflammation, Sanofi. "These data suggest that sarilumab, if approved, may be an option for patients unable to tolerate or take methotrexate, and we look forward to sharing further details at an upcoming medical congress."

The primary endpoint was change from baseline in DAS28-ESR at 24 weeks, which demonstrated a statistically significant difference in favor of sarilumab (-3.25 for sarilumab compared to -2.22 for adalimumab, p less than 0.0001). The study also met clinically important secondary endpoints including improvements in signs and symptoms of RA as measured by patients achieving a 20 percent improvement in the American College of Rheumatology (ACR) criteria (72 percent for sarilumab vs. 58 percent for adalimumab, p less than 0.01). Additional positive secondary endpoints included ACR50 and ACR70 response, and improvement in physical function, as measured by the Health Assessment Questionnaire – Disability Index (HAQ-DI) as compared to adalimumab (p less than 0.01 for all of these measures). DAS28-ESR is a measure of disease activity in RA, which includes the evaluation of 28 joints in the body for tenderness and swelling, a general health assessment, and ESR, a laboratory measure for inflammation.

The incidence of adverse events (64 percent for both groups), serious adverse events (5 percent for sarilumab vs. 7 percent for adalimumab), infections (29 percent for sarilumab vs. 28 percent for adalimumab), and serious infections (1 percent for both groups) were generally similar between groups. Neutropenia, which was not associated with infections, was more common with sarilumab (14 percent for sarilumab vs. 1 percent for adalimumab), as has been seen in previous studies with IL-6 inhibitors. Injection site erythema (8 percent sarilumab vs. 3 percent adalimumab) was also more common with sarilumab.

Source:
Regeneron Pharmaceuticals, Inc.