Phase 3 Study Results On Adults With Active Ulcerative Colitis

/PRNewswire/ -- New study findings presented today show that subcutaneous induction regimens of the anti-tumor necrosis factor (TNF)-alpha therapy SIMPONI@ (golimumab) induced clinical response in a majority of patients with moderately to severely active ulcerative colitis (UC) who had previously failed or were intolerant to conventional agents. Investigators presented data from the Janssen Research & Development, LLC, (Janssen)-sponsored Phase 3 study at Digestive Disease Week@ (DDW@) during a late breaker session and reported that more than 50 percent of patients in each of two SIMPONI dosing groups achieved clinical response at week 6, the primary endpoint of the study, which was significantly more than those in clinical response after receiving placebo. Treatment with SIMPONI also resulted in significant induction of clinical remission and mucosal healing and improvement in health-related quality of life measures at week 6 compared with placebo.

"Therapeutic options for patients living with moderate to severe forms of ulcerative colitis who have failed or become intolerant to conventional treatments are quite limited today, which is particularly challenging in managing a disease that primarily affects a younger, active patient population," said the study's lead investigator, William Sandborn, MD, professor and chief of the Division of Gastroenterology at the University of California, San Diego (UCSD) School of Medicine, and director of the UCSD Inflammatory Bowel Disease Center. "These data are promising because treatment with two subcutaneous administrations of SIMPONI induced clinical response at week 6, and also improved patient outcomes in other important measures of disease activity-clinical remission, mucosal healing and quality of life. We look forward to presenting data from the SIMPONI maintenance therapy portion of the trial in the future."

In the Program of Ulcerative Colitis Research Studies Utilizing an Investigational Treatment (PURSUIT) trial, a significantly higher proportion of patients receiving induction treatment with subcutaneous administrations of SIMPONI 200 mg at week 0 and SIMPONI 100 mg at week 2 or SIMPONI 400 mg at week 0 and SIMPONI 200 mg at week 2 met the primary endpoint of clinical response at week 6 compared with the placebo [51.8 percent, 55.0 percent and 29.7 percent of patients achieving clinical response, respectively ($P < 0.0001$)]. Clinical response at week 6 was defined as a decrease in the Mayo score of at least 30 percent and 3 points compared to baseline score, with either a decrease from baseline in the rectal bleeding subscore of at least 1 or a rectal bleeding subscore of 0 or 1. The Mayo score is a 12-point clinical assessment and colonoscopy-based measure of disease activity, which assesses improvement in symptoms based on rectal bleeding, endoscopic findings, stool frequency and a physician's global assessment.

Consistently significant results among the SIMPONI 200 mg/100 mg and SIMPONI

400 mg/200 mg groups were reported across all major secondary endpoints at week 6 compared with the placebo group, including clinical remission, defined as a Mayo score of 2 points or less [18.7 percent, 17.8 percent and 6.3 percent, (P < 0.0001)]; mucosal healing, defined as a Mayo endoscopy score of 0 or 1 [43.2 percent, 45.3 percent and 28.5 percent, (P = 0.0005)]; and a mean change from baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) score [(27.4 percent, 27.0 percent and 14.6 percent, (P < 0.0001)]. The IBDQ is a 32-question survey that measures health-related quality of life in adult patients with IBD.

Through week 6, a similar proportion of patients in the combined SIMPONI groups (39.1 percent) and placebo group (38.2 percent) reported an adverse event (AE). Rates of serious AEs were 3.0 percent and 6.1 percent in the combined SIMPONI groups and placebo group, respectively. Injection site reactions were uncommon and comparable across SIMPONI groups. Malignancy rates were 0.0 percent, 0.3 percent and 0.3 percent in the SIMPONI 200 mg/100 mg, SIMPONI 400 mg/200 mg and placebo groups, respectively. One death resulting from postoperative complications following repeated surgeries for an ischiorectal abscess and a single case of demyelination were reported in the SIMPONI 400 mg/200 mg group. The safety of SIMPONI induction in the treatment of UC was consistent with the safety profile of SIMPONI in labeled rheumatologic indications.

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