Celltrion Healthcare announces results from phase III CT-P13 switching trial in patients with Crohn's disease

October 30, 2017

Today at the 25th United European Gastroenterology Week Congress, Celltrion Healthcare presented data from the phase III, randomized controlled, switching trial comparing CT-P13 and reference infliximab. The data showed comparable efficacy and safety between all treatment groups (maintained and switched) in patients with moderate to severe Crohn’s disease (CD) up to one year.

The trial investigated the efficacy and safety of CT-P13 throughout a 54-week treatment period, following a switch from reference infliximab at week 30. 220 patients were randomly assigned to four groups (maintained groups [CT-P13 and reference infliximab] and switched groups [reference infliximab to CT-P13 and CT-P13 to reference infliximab]) in a double-blinded manner. Efficacy, pharmacokinetics (PK) and safety were comparable among all treatment groups up to week 30.The Crohn’s Disease Activity Index – 70 (CDAI-70) response, clinical remission and the Short Inflammatory Bowel Disease questionnaire (SIBDQ) score, a measure of quality of life for people with inflammatory bowel disease, were similar among all groups at each measured time point up to week 54 too.

The safety profiles among all treatment groups, including adverse reactions, serious adverse events, infections, and immunogenicity were similar throughout the one year treatment period.

Professor Stefan Schreiber, Director of the Clinic for Internal Medicine at Kiel Campus of the University Hospital Schleswig-Holstein in Germany, commented on the study, “This is the next randomised controlled trial following the NOR-SWITCH study in patients with inflammatory bowel disease using CT-P13 infliximab that shows positive results. All treatment groups in this study, including reference infliximab maintenance, CT-P13 infliximab maintenance, and switching in both directions (reference to CT-P13 and CT-P13 to reference) groups showed comparable efficacy and safety. As a gastroenterologist, I find these data reassuring and hope they help my fellow physicians make informed treatment decisions to ensure the best outcomes for their patients.”

Improving patient treatment experience of CT-P13

Celltrion Healthcare also presented data from an initial phase I open label study of a subcutaneous (SC) form of CT-P13 in healthy volunteers. The study was designed to evaluate the safety and PK of CT-P13 SC. Results showed PK profiles after a single SC injection were linear by dose levels. Subcutaneous administration of CT-P13 was found to be feasible in terms of bioavailability and safety profile and could provide patients with a more convenient and accessible treatment administration option.[3]

Man Hoon Kim, President and CEO of Celltrion Healthcare, said, “Active switching to biosimilars could have a significant impact on the financial sustainability of healthcare systems by generating budget savings for biologic treatments. This switching study in Crohn’s disease is important in showing clinical evidence of the comparable safety and efficacy when switching to biosimilars. Adding to the wealth of data for CT-P13, Celltrion Healthcare is confident that these results should help physicians to feel even more confident in switching between reference products and biosimilars and is committed to continuously providing more convenient treatment

options, including the subcutaneous form of infliximab to patients.”

Source:

http://www.celltrionhealthcare.com/