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Entyvio® oppnår høyere klinisk remisjon enn Humira®

Entyvio® (vedolizumab) oppnår høyere klinisk remisjon enn Humira® (adalimumab) i den første direkte sammenlignende studien mellom to biologiske legemidler til behandling av ulcerøs kolitt.

Vedolizumab bedre enn adalimumab på klinisk remisjon og slimhinnetilheling etter 52 uker hos pasienter med moderat til alvorlig aktiv ulcerøs kolitt.

«Studien viser med stor tydelighet at vedolizumab har en bedre effekt enn adalimumab hos pasienter med moderat til alvorlig ulcerøs kolitt som har feilet eller vist intoleranse på konvensjonell behandling og/eller biologisk behandling med anti-TNF (annet enn adalimumab). Effektmål var klinisk remisjon og tilheling av slimhinnen», oppsummerer professor Jørgen Jahnsen ved Akershus Universitetssykehus. «Studier som sammenligner biologiske legemidler er viktige og har vært savnet blant klinikere. Resultater fra slike studier vil bidra til å gi et bedre grunnlag for valg av behandling.»

«Denne første direkte sammenlignende studien som er gjort mellom to biologiske legemidler innenfor inflammatorisk tarmsykdom viser potensialet som ligger i Entyvio ved å evaluere både effekt og sikkerhet for Entyvio versus Humira i behandling av ulcerøs kolitt» sier landssjef i Takeda Norge, Duarte Marchand. «Resultatene fra denne studien, som viser at Entyvio er signifikant bedre enn Humira på klinisk remisjon og slimhinnetilheling, bekrefter det vi allerede har sett i virkelighetsdata over lang tid, og dette motiverer oss til å fortsette vår innsats for at mennesker som lever med IBD skal ha et bedre liv».

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For fullstendig pressemelding på engelsk, se under.

Osaka, JAPAN, March 9, 2019 – Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) ("Takeda") today announced results from the Phase 3b head-to-head VARSITY study which demonstrated that the gut-selective biologic vedolizumab (Entyvio®) was superior to the anti-tumor necrosis factor-alpha (anti-TNF☒) biologic adalimumab (Humira®) in achieving clinical remission* in patients with moderately to severely active ulcerative colitis at week 52. Data showed that 31.3% (n=120/383) of patients receiving vedolizumab intravenous (IV) achieved the primary endpoint of clinical remission compared to 22.5% (n=87/386) of patients treated with adalimumab subcutaneous (SC) at week 52, with the difference being statistically significant (p=0.0061). These results were announced as an oral presentation (OP34) on Saturday March 9, 2019 from 09:40-09:50, at the 14th Congress of the European Crohn's and Colitis Organisation (ECCO) in Copenhagen, Denmark.[1]

Furthermore, treatment with vedolizumab was associated with significantly higher rates of mucosal healing** at week 52, with 39.7% of patients receiving vedolizumab achieving mucosal healing compared to 27.7% treated with adalimumab (p=0.0005). A non-statistically significant difference in favor of adalimumab was seen in the percentage of patients using oral corticosteroids at baseline who discontinued corticosteroids and were in clinical remission*** at week 52. While the study was not powered to compare the safety of the two biologics, patients treated with vedolizumab (62.7%) had a lower rate of overall adverse events over 52 weeks than patients treated with adalimumab (69.2%), with a lower rate of infections reported in patients treated with vedolizumab (33.5%) as compared to adalimumab (43.5%). The rate of serious adverse events was also lower in vedolizumab-treated patients than adalimumab (11.0% vs. 13.7% respectively).[1]

"The VARSITY study addresses critical questions concerning the selection of biologic therapy in ulcerative colitis," said Dr. Bruce E. Sands, primary investigator of the VARSITY study and Chief of the Dr. Henry D. Janowitz

Division of Gastroenterology at Mount Sinai Hospital and the Icahn School of Medicine at Mount Sinai in New York. “The goal of treatment in ulcerative colitis is to achieve clinical remission and mucosal healing, and these results clearly highlight the benefits seen with vedolizumab versus adalimumab on these important outcomes. The results also showed lower rates of overall and serious adverse events including infections in patients treated with vedolizumab than adalimumab.”

“As the first clinical study to directly compare the efficacy and safety of two commonly used biologic therapies in patients with ulcerative colitis, VARSITY provides invaluable knowledge to help inform physicians’ treatment decisions when initiating biologic therapy,” said Jeff Bornstein, M.D., Executive Medical Director, Takeda. “This is also the first time we have seen a direct comparison between two medicines with distinct modes of action in ulcerative colitis, the gut-selective anti-alpha4beta7 integrin vedolizumab and the anti-TNF⊠ adalimumab. This is an exciting time in the landscape of ulcerative colitis treatment, as head-to-head clinical data has not previously been available to guide treatment decisions around biologic therapies.”

VARSITY is a phase 3b, randomized, double-blind, double-dummy, multi-center, active-controlled study to evaluate the efficacy and safety of vedolizumab IV compared to adalimumab SC at week 52 in patients with moderately to severely active ulcerative colitis. The study randomized 769 patients (vedolizumab n=383 or adalimumab n=386), all of whom had inadequate response with, loss of response to, or intolerance to corticosteroids, immunomodulators, or one TNF⊠-antagonist other than adalimumab prior to being enrolled. Patients were randomized into one of two treatment groups, vedolizumab IV and placebo SC or adalimumab SC and placebo IV. Patients in the vedolizumab group were administered vedolizumab IV 300 mg at weeks 0, 2, 6 and every 8 weeks thereafter until week 46, along with placebo SC at week 0 and every 2 weeks until week 50. The adalimumab group were administered adalimumab SC 160 mg at week 0, 80 mg at week 2 and 40 mg every 2 weeks until week 50, along with placebo IV at weeks 0, 2, 6 and every 8 weeks thereafter until week 46. Dose escalation was not permitted in either treatment arm during the study.[1,2]

* Primary endpoint: Clinical remission is defined as a complete Mayo score of ⩽2 points and no individual subscore ⊠1 point.[2]

** Secondary endpoint: Mucosal healing is defined as Mayo endoscopic subscore of ⩽1 point. Mayo score: instrument designed to measure disease activity of ulcerative colitis. [2]

*** Secondary endpoint: Corticosteroid-free clinical remission is defined as patients using oral corticosteroids at baseline (week 0) who have discontinued oral corticosteroids and are in clinical remission at week 52.[2]

References

1. Schreiber S, Peyrin-Biroulet L, Loftus EV Jr, et al. VARSITY: A double-blind, double-dummy, randomised, controlled trial of vedolizumab versus adalimumab in patients with active ulcerative colitis. Presented at the 14th Congress of the Crohn's and Colitis Organisation (ECCO), Copenhagen, Denmark. Oral presentation #OP34 (Saturday March 9, 2019, 09:40-09:50).

2. An efficacy and safety study of vedolizumab intravenous (IV) compared to adalimumab subcutaneous (SC) in participants with ulcerative colitis. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT02497469. Last updated: February 18, 2019. Last Accessed: February 2019.

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Takeda (TSE: 4502) er et forskningsbasert, globalt selskap med hovedvekt på legemidler. Selskapet er til stede i mer enn 70 markeder og satser blant annet innen spesialområder som kreft, mage/tarm og vaksiner.

Som det største farmasøytiske selskapet i Japan, og et av de ledende globale selskapene i industrien, arbeider Takeda, gjennom medisinsk innovasjon, for bedre helse for pasienter over hele verden.

I Norge har Takeda cirka 270 medarbeidere og et eget produksjonsanlegg i Asker utenfor Oslo. Målt i volum er Takeda landets største leverandør av legemidler. Takeda har et bredt spekter av reseptbelagte medisiner til sykehus, spesialister og allmennpraktiserende leger. Takedas reseptfrie

medisiner og kosttilskudd selges i apotek.

Takeda kjøpte i 2011 Nycomed, som har vært en ledende aktør i norsk legemiddelindustri og en viktig del av nordmenns hverdag i over 140 år. Selskapet har skapt, utviklet og produsert flere av landets mest kjente legemidler. Den arven skal Takeda bygge videre på og jobbe for bedre helse og et friskere Norge.

Mer informasjon om Takeda på www.takeda.com

Mer informasjon om Takeda Norge på www.takeda.no

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