European Commission Approves RINVOQ® (upadacitinib) for the Treatment of Adults With Moderate to Severe Ulcerative Colitis

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Clinical Response & Mucosal Healing‡§

In the placebo-controlled ulcerative colitis induction and maintenance clinical trials, the overall safety findings were generally consistent with the known safety profile of upadacitinib; no new important safety risks were observed.[1] The rates of overall adverse events (AE), serious AEs, and AEs resulting in treatment discontinuation were lower with upadacitinib compared to placebo.[1] The most commonly reported adverse reactions (≥5 percent of patients) with RINVOQ 45 mg, 30 mg or 15 mg were upper respiratory tract infection, blood CPK increased, acne, neutropaenia, and rash.[1] In the overall clinical program, major cardiovascular events, thrombotic events, malignancy excluding non-melanoma skin cancer, and gastrointestinal perforation were reported infrequently (all <1.0 cases per 100 patient-years in patients who received at least one RINVOQ dose).[1]

About the U-ACHIEVE Induction, U-ACCOMPLISH and U-ACHIEVE Maintenance Studies[2,6,15,16]

The three Phase 3 studies are multicenter, randomized, double-blind, placebo-controlled studies to evaluate the efficacy and safety of RINVOQ 45 mg once daily as induction therapy, and RINVOQ 15 mg and 30 mg once daily as maintenance therapy in subjects with moderate to severe ulcerative colitis. The results of these studies were published in *The Lancet* in May 2022. More information can be found on http://www.clinicaltrials.gov (NCT03006068, NCT03653026, NCT02819635).

Immunosuppressive medicinal products

Upadacitinib should be used with caution in patients with diverticular disease and especially in patients chronically treated with concomitant medications associated with an increased risk of diverticulitis.

Cardiovascular risk

Venous thromboembolisms

See RINVOQ full summary of product characteristics (SmPC) atwww.ema.europa.eu.

With a robust clinical trial program, AbbVie is committed to cutting-edge research to drive exciting developments in inflammatory bowel diseases (IBD), like ulcerative colitis and Crohn's disease. By innovating, learning and adapting, AbbVie aspires to eliminate the burden of IBD and make a positive long-term impact on the lives of people with IBD. For more information on AbbVie in gastroenterology, visit https://www.abbvie.com/our-science/therapeutic-focus-areas/immunology/immunology-focus-areas/gastroenterology.html.

About AbbVie

AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health and gastroenterology, in addition to products and services across our Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.com. Follow @abbvie on Twitter, Facebook, LinkedIn or Instagram.

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* This approval is without prejudice to the final conclusions of the ongoing referral procedure under Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data.

† Clinical remission (per Adapted Mayo Score) is defined as stool frequency subscore (SFS) ≤1 and not greater than baseline, rectal bleeding subscore (RBS) of 0 and endoscopic subscore ≤1 without friability.

‡ Clinical response (per Adapted Mayo Score) is defined as a decrease from baseline in the Adapted Mayo score ≥2 points and ≥30 percent from baseline, plus a decrease in RBS ≥1 or an absolute RBS ≤1.

§ Mucosal healing is defined as endoscopic subscore ≤1 without friability.

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https://aall.investorroom.com/news?item=155