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AbbVie receives FDA approval for RINVOQ

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RINVOQ (upadacitinib) met all primary and ranked secondary endpoints across a variety of patients with moderately to severely active rheumatoid arthritis

AbbVie, a research-based global biopharmaceutical company, has announced that the U.S. Food and Drug Administration (FDA) has approved RINVOQ™ (upadacitinib), a 15 mg, once-daily oral Janus kinase (JAK) inhibitor, for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate (MTX-IR).[1] RINVOQ is expected to be available in the U.S. in late August 2019.

The FDA approval of RINVOQ is supported by data from the SELECT program, one of the largest registrational Phase 3 programs in RA with approximately 4,400 patients evaluated across all treatment arms in five studies.[2-6] The studies include assessments of efficacy, safety and tolerability across a variety of RA patients, including those who failed or were intolerant to biologic disease-modifying anti-rheumatic drugs and who were naïve or inadequate responders to methotrexate. RINVOQ is not indicated for methotrexate-naïve patients.

"Despite the availability of multiple treatment options with varying mechanisms of action, many patients still do not achieve clinical remission or low disease activity—the primary treatment goals for rheumatoid arthritis," said Roy M. Fleischmann, M.D., primary investigator for SELECT-COMPARE and clinical professor at the University of Texas Southwestern Medical Center at Dallas. "With this FDA approval, RINVOQ has the potential to help additional people living with RA achieve remission who have not yet reached this goal."

Across the SELECT Phase 3 studies, RINVOQ met all primary and ranked secondary endpoints. The primary endpoints include:

- In SELECT-EARLY, 52 percent of MTX-naïve patients treated with RINVOQ 15 mg achieved ACR50 vs 28 percent treated with MTX at week 12[1]
- In SELECT-MONOTHERAPY, 68 percent of MTX-IR patients treated with RINVOQ 15 mg achieved ACR20 vs 41 percent treated with continued MTX at week 14[1]

- In SELECT-COMPARE, 71 percent of MTX-IR patients treated with RINVOQ 15 mg plus MTX achieved ACR20 vs 36 percent treated with placebo plus MTX at week 12[1]
- In SELECT-NEXT, 64 percent of csDMARD-IR patients treated with RINVOQ 15 mg plus csDMARDs achieved ACR20 vs 36 percent treated with placebo plus csDMARDs at week 12[1]
- In SELECT-BEYOND, 65 percent of biologic-IR patients treated with RINVOQ 15 mg plus csDMARDs achieved ACR20 vs 28 percent treated with placebo plus csDMARDs at week 12[1]

"The discovery and development of RINVOQ is indicative of AbbVie's long-standing commitment to advancing the science for people living with immune-mediated conditions," said Michael Severino, M.D., vice chairman and president, AbbVie. "Today's FDA approval marks an important milestone in our pursuit to deliver innovative medicines that advance care for people living with rheumatoid arthritis."