## Olumiant® (baricitinib) – New drug approval

- On June 1, 2018, Eli Lilly and Incyte announced the FDA approval of Olumiant (baricitinib), for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.
    - Use of Olumiant in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.
- RA is a systemic autoimmune disease characterized by inflammation and progressive destruction of joints. Approximately three times as many women as men have the disease. Despite current treatment options, many patients fail to reach their therapeutic goals.
- Olumiant is a JAK inhibitor. JAKs are intracellular enzymes that have been implicated in the pathogenesis of inflammation and certain autoimmune diseases. The blockade of this pathway is believed to disrupt the JAK signaling process.
- The efficacy and safety of Olumiant were based on two placebo-controlled trials in adult patients with RA. Olumiant or placebo was added to existing background DMARD treatment. The primary endpoint was the proportion of patients who achieved at least a 20% improvement in RA signs and symptoms (ACR20) at week 12.
    - At week 12, a greater proportion of Olumiant-treated patients achieved tACR20 vs. placebo (Study 1: 66% in the Olumiant arm vs. 39% in the placebo arm; Study 2: 49% in the Olumiant arm vs. 27% in the placebo arm).
    - In addition, as part of the approval, Eli Lilly and Incyte have agreed to conduct a randomized controlled trial to evaluate the long-term safety of Olumiant in patients with RA.
- Olumiant carries a boxed warning for serious infections, malignancy, and thrombosis.
- Other warnings and precautions of Olumiant include gastrointestinal perforations, laboratory abnormalities, and vaccinations.
- The common adverse reactions (≥ 1%) with Olumiant use were upper respiratory tract infections, nausea, herpes simplex, and herpes zoster.
- The recommended dose of Olumiant is 2 mg orally once daily.
    - Olumiant may be used as monotherapy or in combination with methotrexate or other DMARDs.
    - Prior to initiating Olumiant, patients should be tested for latent tuberculosis (TB), and if positive, treatment of TB should be considered prior to Olumiant use.
- Eli Lilly and Incyte plan to launch Olumiant by the end of the second quarter of 2018. Olumiant will be available as 2 mg tablets.