Olumiant® (baricitinib) – Emergency use authorization approval

- On November 20, 2020, the FDA announced the emergency use authorization (EUA) of Eli Lilly's Olumiant (baricitinib), in combination with Veklury® (remdesivir), for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients two years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
    - EUA use of Olumiant should only be for hospitalized patients in combination with Veklury.
- Olumiant is FDA approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor antagonist therapies.
    - Olumiant carries a boxed warning for serious infections, malignancy, and thrombosis.
- Veklury is FDA approved for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.
- The EUA approval is based on data from the Adaptive COVID-19 Treatment Trial (ACTT-2), a randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of Olumiant or placebo in combination with Veklury in hospitalized patients with or without oxygen requirements. The study was conducted by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). All patients also received standard of care treatment. This trial has not been peer-reviewed and published, but key efficacy findings include:
    - Patients treated with Olumiant + Veklury had a significant reduction in median time to recovery: 7 days vs. 8 days in patients treated with placebo + Veklury (hazard ratio: 1.15; 95% CI: 1.00, 1.31; p = 0.047).
    - Patients treated with Olumiant + Veklury were more likely to have a better clinical status at day 15 vs. patients treated with placebo + Veklury (odds ratio [OR]: 1.26; 95% CI: 1.01, 1.57; p = 0.044).
    - The proportion of patients who progressed to ventilation (non-invasive or invasive) or died by day 29 was lower in Olumiant + Veklury (23%) vs. placebo + Veklury (28%) (OR: 0.74; 95% CI: 0.56, 0.99; p = 0.039).
    - The proportion of patients who died by day 29 was 4.7% for Olumiant + Veklury vs. 7.1% for placebo + Veklury, (estimated difference in day 29 probability of mortality: -2.6%; 95% CI: -5.8%, 0.5%).
- In the ACTT-2 study, infections and venous thromboembolism occurred in 6% and 4% of patients treated with Olumiant + Veklury, respectively, vs. 10% and 3% of patients treated with placebo + Veklury.
- The recommended dose of Olumiant for EUA use is 4 mg orally once daily for 14 days or until hospital discharge.