Olumiant® (baricitinib) – Emergency use authorization expansion

- On July 28, 2021, Eli Lilly announced the emergency use authorization (EUA) approval of Olumiant (baricitinib), for the treatment of suspected or laboratory confirmed coronavirus disease 2019 (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).
    - Previously, Olumiant was indicated for this same indication in combination with Veklury® (remdesivir).
    - EUA use of Olumiant should only be for hospitalized patients.
    - Under the EUA, Olumiant may be used as monotherapy or 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.
- 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.
- Olumiant carries a boxed warning for serious infections, malignancy, and thrombosis.
- The EUA approval is based on data from COV-BARRIER, a randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of Olumiant 4 mg per day + standard of care (SoC) vs. placebo + SoC in 1,525 hospitalized patients with or without oxygen requirements. This trial has not been peer-reviewed and published, but key efficacy findings include:
    - The trial did not meet statistical significance on the primary endpoint, which was defined as a difference in the proportion of participants progressing to the first occurrence of non-invasive ventilation including high flow oxygen or invasive mechanical ventilation including ECMO or death by day 28 (odds ratio: 0.85; 95% CI: 0.67, 1.08; p = 0.1800).
    - Olumiant treatment resulted in a significant reduction (p = 0.0018) in death from any cause by 38% (Olumiant 8.1% vs. placebo 13.1%; hazard ratio [HR]: 0.57; 95% CI: 0.41, 0.78) by day 28.
    - A numerical reduction in mortality was observed for all baseline severity subgroups of Olumiant-treated patients and was most pronounced for patients receiving non-invasive mechanical ventilation at baseline (17.5% vs. 29.4% for Olumiant + SoC vs. SoC; HR: 0.52; 95% CI: 0.33, 0.80; p = 0.0065).
- The recommended dose of Olumiant for EUA use in adults and pediatric patients 9 years of age and older is 4 mg orally once daily for 14 days or until hospital discharge.
- The recommended dose of Olumiant for EUA use in pediatric patients 2 years to less than 9 years of age is 2 mg orally once daily for 14 days or until hospital discharge.