Olumiant® (baricitinib) – New indication

- On May 10, 2022, the FDA announced the approval of Eli Lilly's Olumiant (baricitinib), for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
    - This indication was previously approved under emergency use authorization (EUA).
    - The EUA remains in effect for hospitalized pediatric patients 2 to less than 18 years of age requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.
- Olumiant is also approved 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 blockers.
- The approval of Olumiant for the new indication was based on two randomized, double-blind, placebo-controlled clinical trials. COVID-I randomized 1,033 hospitalized adult patients with COVD-19 to Olumiant + Veklury® (remdesivir) or placebo + Veklury. The primary endpoint was time to recovery within 29 days after randomization. COVID-II randomized 1,525 hospitalized adult patients with COVID-19 to Olumiant or placebo. The primary endpoint was the proportion of patients who died or progressed to non-invasive ventilation/high-flow oxygen or invasive mechanical ventilation within the first 28-days of the study.
    - In COVID-I, for the overall population, the median time to recovery (defined as discharged from hospital or hospitalized but not requiring supplemental oxygen or ongoing medical care) was 7 days for Olumiant + Veklury vs. 8 days for placebo + Veklury (Hazard ratio [HR]: 1.16, 95% CI: 1.01, 1.33; p = 0.035).
    - In COVID-II, the estimated proportion of patients who died or progressed to non-invasive ventilation/high-flow oxygen or invasive mechanical ventilation was lower in patients treated with Olumiant (27.8%) vs. placebo (30.5%), but this effect was not statistically significant (Odds ratio: 0.85, 95% CI: 0.67, 1.08; p = 0.180).
- In addition, in the COVID-II exploratory sub-study, in a separate group of patients requiring invasive mechanical ventilation or ECMO at baseline, a pre-specified exploratory analysis showed that the proportion who died by day 28 was 39.2% (20/51) for Olumiant vs. 58.0% (29/50) for placebo (estimated difference in day 28 risk of mortality: -18.8%, 95% CI: -36.3, 0.6; HR 0.54, 95% CI: 0.31, 0.96).
- Olumiant carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.
- The most common adverse reactions (≥ 1%) with Olumiant use in COVID-19 were increases of liver enzymes, thrombocytosis, increases of creatine phosphokinase, neutropenia, deep vein thrombosis, pulmonary embolism, and urinary tract infection.
- The recommended dose of Olumiant for the treatment of COVID-19 is 4 mg once daily orally, with or without food, for 14 days or until hospital discharge, whichever occurs first.

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- Refer to Olumiant’s drug label for dosing for its RA indication.