FDA Approves Juluca® as Simplified Treatment Option for Individuals with HIV

Janssen Therapeutics announced that the U.S. Food and Drug Administration (FDA) has approved Juluca®, the first, complete, single-pill, two-drug regimen for the treatment of HIV-1 infection in certain adults living with the disease who are virologically suppressed.

Juluca is a once-daily, antiretroviral combination of dolutegravir (Tivicay®), an integrase strand transfer inhibitor, and rilpivirine (Edurant®), a non-nucleoside reverse transcriptase inhibitor. With Juluca, individuals with HIV who are virologically suppressed (HIV-1 RNA <50 c/mL) on a stable antiretroviral regimen for at least 6 months and have no history of treatment failure now have a simplified treatment option to consider.

Juluca received FDA approval based on data from the two pivotal Phase 3 SWORD studies, which are identical, randomized, multicenter, open-label, non-inferiority studies designed to assess the safety and efficacy of switching to the two-drug regimen of dolutegravir and rilpivirine compared with remaining on current antiretroviral regimen (CAR). The studies included more than 1,000 patients who previously achieved stable viral suppression for at least 6 months on other antiretroviral regimens and had no history of virologic failure or known resistance to dolutegravir or rilpivirine.

Results demonstrated that Juluca achieved non-inferior viral suppression at 48 weeks compared with a three-drug CAR in both studies. However, the proportion of patients who discontinued treatment due to an adverse event was 4% in those receiving Juluca once daily and less than 1% in those who remained on their CAR. The SWORD trials are ongoing and planned to continue through 148 weeks.


Forteo® for Osteoporosis May Reduce Risk of Vertebral and Clinical Fractures

Eli Lilly and Company announced that treatment with Forteo® for 24 months was associated with significantly fewer vertebral and clinical fractures compared with risedronate, a widely used oral bisphosphonate, in postmenopausal women with severe osteoporosis.

The 2-year randomized, double-blind, double-dummy clinical trial compared subcutaneous daily teriparatide (20 µg; active ingredient in Forteo) with oral weekly risedronate (35 mg) in 1,360 women with at least two moderate or one severe vertebral fractures or fracture and low bone mass.

The reduction in new vertebral fractures with teriparatide was observed as early as 12 months of treatment, and after 24 months of treatment, the teriparatide group compared with the risedronate group experienced a relative risk reduction of 56% (p < 0.001) in new vertebral fractures; a relative risk reduction of 54% (p < 0.001) in new and worsening vertebral fractures; and a relative risk reduction of 52% (p < 0.001) in clinical fractures. No statistically significant difference between groups in the incidence of non-vertebral fractures was observed.

This is the first trial in osteoporosis research that has shown a significant fracture reduction outcome as a primary endpoint in a head-to-head, active-drug comparative study.