Livtencity™ (maribavir) – New orphan drug approval

- On November 23, 2021, Takeda announced the FDA approval of Livtencity (maribavir), for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.

- CMV is a beta herpesvirus that commonly infects humans. CMV typically resides latent and asymptomatic in the body but may reactivate during periods of immunosuppression. In transplant recipients, reactivation of CMV can lead to serious consequences including loss of the transplanted organ and, in extreme cases, can be fatal.

    — Out of the estimated 200,000 adult transplants per year globally, CMV is one of the most common viral infections experienced by transplant recipients, with an estimated incidence rate between 16% to 56% in solid organ transplant (SOT) recipients and 30% to 70% in hematopoietic stem cell transplant (HSCT) recipients.

- Livtencity is the first antiviral agent that targets and inhibits the pUL97 protein kinase and its natural substrates.

- The efficacy of Livtencity was established in a randomized, open-label, active-controlled study in 352 HSCT or SOT recipients with CMV infections. Patients were randomized to Livtencity or investigator assigned treatment (IAT) (ganciclovir, valganciclovir, foscarnet, or cidofovir) for up to 8 weeks. After completion of the treatment period, patients entered a 12-week follow-up phase. The primary endpoint was confirmed CMV DNA level < lower limit of quantification (ie, < 137 IU/mL) at the end of week 8.

    — At week 8, 56% of patients treated with Livtencity met the primary endpoint vs. 24% with IAT (adjusted difference of 33, 95% CI: 23, 43; p < 0.001).

- Warnings and precautions for Livtencity include risk of reduced antiviral activity when coadministered with ganciclovir and valganciclovir; virologic failure during treatment and relapse post-treatment; and risk of adverse reactions or loss of virologic response due to drug interactions.

- The most common adverse reactions (all grades, > 10%) with Livtencity use were taste disturbance, nausea, diarrhea, vomiting, and fatigue.

- The recommended dosage of Livtencity is 400 mg (two 200 mg tablets) taken orally twice daily with or without food.

  Takeda plans to launch Livtencity in the coming days. Livtencity will be available as a 200 mg tablet.