On 15 September 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Livtencity, intended for the treatment of cytomegalovirus (CMV) infection and/or disease that is refractory to one or more prior therapies. The applicant for this medicinal product is Takeda Pharmaceuticals International AG Ireland Branch.

Livtencity will be available as a 200 mg film-coated tablet. The active substance of Livtencity is maribavir, an antiviral for systemic use (ATC code: J05AX10). Maribavir inhibits antiviral activity by competitive inhibition of the human cytomegalovirus (HCMV) protein kinase UL97 at the adenosine triphosphate (ATP) binding site to abolish phosphotransferase, thereby interfering with viral DNA replication, encapsidation, and nuclear egress.

The main benefit of Livtencity is its ability to achieve CMV viremia clearance at week 8 without a need for alternative anti-CMV therapy or rescue treatment in a higher proportion of patients compared to the investigator-assigned anti-CMV therapy, as shown in a phase 3, randomised, open-label, active-controlled superiority study in adult transplant recipients with refractory CMV infection. The most common side effects are dysgeusia and abdominal complaints.

The full indication is:

Livtencity is indicated for the treatment of cytomegalovirus (CMV) infection and/or disease that are refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet in adult patients who have undergone a haematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT).

Livtencity should be initiated by a physician experienced in the management of patients who have undergone solid organ transplant or haematopoietic stem cell transplant.

Detailed recommendations for the use of this product will be described in the summary of product
characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.