

Japan approves first post-transplant anti- cytomegalovirus infection treatment

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Cytomegalovirus is one of the most common and serious post-transplant infections



Takeda Pharma has announced that LIVTENCITY (maribavir) has been approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) for post-transplant cytomegalovirus (CMV) infection/disease that is refractory to existing anti-CMV therapies. LIVTENCITY is the first and only post-transplant anti-CMV treatment approved in Japan that targets and inhibits pUL97 kinase and its natural substrates.

The approval is primarily based on the results of the Phase 3 SOLSTICE trial, which evaluated the safety and efficacy of LIVTENCITY versus alternative antiviral treatments for patients with CMV infection/disease refractory to prior therapies who underwent hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT), and the Japanese Phase 3 open-label study in patients with CMV infection, including those with refractory CMV infection who underwent HSCT or SOT.

LIVTENCITY (maribavir), an orally administered (tablet) anti-CMV compound, is the first and only antiviral agent that targets and inhibits the CMV-specific UL97 protein kinase and thus its natural substrates. As of June 2024, LIVTENCITY is approved in more than 30 countries for post-transplant CMV refractory to prior therapies, including such major markets as Japan, the United States, Canada, Australia, the European Union and China.