LIVTENCITY

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
IB/0010	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	25/03/2024	n/a		
II/0008	Update of section 5.2 of the SmPC in order to update pharmacokinetic information based on the updated	21/03/2024		SmPC	

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

	Population PK analysis data. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/11024 /202305	Periodic Safety Update EU Single assessment - maribavir	11/01/2024	n/a		PRAC Recommendation - maintenance
II/0004	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	12/10/2023	n/a		The variation refers to the submission of the results of the Study SHP620-302, listed as a category 3 study in the RMP. This Phase III trial is a multicenter, randomized, double-blind, double-dummy, active-controlled study of maribavir compared to valganciclovir for the treatment of asymptomatic Cytomegalovirus (CMV) infection in HSCT recipients. This study was conducted in post-HSCT recipients with a first episode of asymptomatic post-transplant CMV infection. Overall, the CHMP agrees that the results have no impact on the approved indication, as well as on the SmPC. However, it is requested by the Committee that TEAEs such as neutropenia, thrombocytopenia and anaemia in maribavir-treated patients should be closely monitored during the post-marketing period and that these cases, including the assessment of causality, should be discussed in the upcoming PSURs. The same applies to further evaluate if there could be a correlation between fluctuations in immunosuppressant drug levels and increased

					occurrence of adverse events when maribavir is used in the approved indication. Finally, the CHMP also required that cases of renal impairment after treatment with maribavir as well as cases with immunosuppressant drug level increased and acute GVHD should be continued to be closely monitored and to be discussed in the upcoming PSURs. The RMP version 2.0 was considered acceptable by the CHMP.
IA/0006	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	13/07/2023	n/a		
IB/0005	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	04/07/2023	05/01/2024	SmPC	
II/0002/G	This was an application for a group of variations. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	20/04/2023	n/a		
IAIN/0003	A.1 - Administrative change - Change in the name and/or address of the MAH	13/02/2023	05/01/2024	SmPC, Labelling and PL	
IB/0001	B.II.e.5.a.2 - Change in pack size of the finished	16/01/2023	05/01/2024	SmPC,	

	product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes			Labelling and PL	