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Sunlenca® (lenacapavir) Impact of Body Weight

This document is in response to your request for information regarding Sunlenca® (lenacapavir [LEN]) and the impact of body weight on its pharmacokinetics.

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Product Labelling[1]

There were no clinically significant differences in the pharmacokinetics of lenacapavir based on body weight (41.4 to 164 kg).

Available Data

Shaik et al[2]

Study Design

Shaik et al performed an analysis of PK data from seven studies to determine the baseline characteristics, including body weight, that could affect LEN exposure (AUC_{tau}, C_{max}, and C_{trough}) in participants with and without HIV-1. This analysis included data from five phase 1 studies, one phase 2 study, and one phase 2/3 study. Samples were collected from participants on Day 1, before and after dosing on Days 8 and 15 (oral initiation period), and at multiple time points from Day 15 to Week 26 (subcutaneous maintenance period).

Results

Of the 7,053 samples included in the population PK dataset, a total of 6,855 LEN concentrations from 384 participants reached the limit of quantification and were used in the analysis. The final LEN model was described by a two-compartment PK model with first-order elimination, first-order absorption (orally administered LEN), and parallel-direct (first-order), transit-compartment absorption (subcutaneously administered LEN). The PK model used the fixed allometric exponents of 0.75 for clearance and 1 for volume of distribution to determine the effect of weight on clearance, intercompartmental clearance, and the volumes of central and peripheral compartments.

There was an inverse correlation between weight and LEN exposure, with changes in exposure parameters (relative to the median value) that ranged from -32.7% for the 95th weight percentile to 24% for the 5th weight percentile (Table 1). Although the impact of weight on LEN exposure was significant, it was not considered clinically meaningful.

Table 1. Effects of Weight on LEN Exposure (Shaik et al)[2]

Weight*	Days 1–15 (Oral Initiation Period)			Day 15–Week 26 (SQ Maintenance Period)		
	AUC_{tau}	C_{max}	C_{trough}	AUC_{Ctau}	C_{max}	C_{trough}
	% Change in Exposure Relative to Median					
109 kg	-32.7	-30.4	-32.4	-28.6	-29	-25.3
55 kg	24	21.6	23.4	20.1	20.5	17.2

SQ=subcutaneous
*Data are reported for the extreme covariate values (5th and 95th percentiles).

References

1. Enclosed, Gilead Sciences Inc. SUNLENCA® (lenacapavir) tablets, for oral use. SUNLENCA® (lenacapavir) injection, for subcutaneous use. U.S. Prescribing Information. Foster City, CA.
2. Shaik N, Bellanti F, Comisar C, et al. Impact of Intrinsic and Extrinsic Factors on the Pharmacokinetics of Long-Acting Lenacapavir for Treatment of HIV [Poster EPB174]. Paper presented at: AIDS 2022; 29 July-2 August, 2022; Montreal, Quebec, Canada.

Abbreviations

AUC_{tau}=area under the curve over dosing interval
C_{max}=maximal concentration
C_{trough}=concentration at the end of the dosing interval
LEN=lenacapavir
PK=pharmacokinetics

Product Label

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www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_pi

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