S-AMLODIPINE (Levoamlodipine) Tablets

- **Indicated for** This medication is indicated for the treatment of hypertension, chronic stable angina pectoris, and vasospastic angina. These indications are the same as for Amlodipine racemate; however, they are achieved with lower side effects (specifically, reduced risk of oedema) and a lower dose (using only the active enantiomer).

Available strengths: 2.5mg, 5mg (equivalent to 5mg and 10mg of Amlodipine racemate)

Same Efficacy as Racemate with Reduced Oedema Occurrence:

- Oedema side effects are observed in approximately 10% of patients taking a 10 mg dose.*
- Oedema is considered the primary reason for treatment discontinuation or a switch to less preferred treatments.
- Published clinical data demonstrate a significantly lower incidence of oedema for S-Amlodipine compared to the racemate (this finding will also be confirmed by Zentiva's clinical study).
- Additionally, there is the possibility to use the active enantiomer in combination therapies.

Reference markets

- Amlodipine continues to be one of the main therapies for hypertension, with sales of 6.6 billion tablets (MAT Q2 2023) and a growing market share according to IQVIA data.

* Ref – Norvasc Leaflet - https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/019787s047lbl.pdf
MAT – Moving Annual Total

Comparable Efficacy to Amlodipine with Reduced Oedema Incidence

Oedema is considered the primary reason for treatment discontinuation

Favorable Key Opinion Leader (KOL) reviews

Regulatory pathway

- Legal basis: Article 10(3) hybrid application

Development status

- We are currently in the formulation stage.
- Our clinical strategy involves conducting PK studies comparing the new formulation with the racemate.
- Additionally, a safety study comparing the new formulation with racemate amlodipine, specifically focusing on oedema endpoints, will be conducted following scientific advice in October 2022.
- The EU dossier is expected to be completed by Q4/2024.

Partnership options

- The product is available for out-licensing in selected markets in Europe or for co-development on an exclusive or semi-exclusive basis
- The dossier can be customized for markets outside Europe based on specific requests

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