NILOTINIB (food independence) Tablets

- **Indicated for:**
  - Adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase
  - Adult and paediatric patients with chronic and accelerated phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including Imatinib
- **Posology:** Twice daily with or without food

Safer treatment options – lower risk of overdose and related side effects such as prolongation of the QT interval

Improved compliance – less limiting food restrictions

Supra bioavailable – lower environmental waste

Available strengths: equivalent to 100mg and 200mg of Tasigna

- Due to twice daily dosing, there is a 6-h period during the day where the patients cannot eat. If food is inappropriately consumed, the increased systemic exposure (AUC) and Cmax could contribute to prolongation of the QT interval and have potential fatal consequences in patients
- The Nilotinib NFE tablet formulations have been designed to potentially allow for a dose reduction and to reduce the food effect compared to RLD. Thus the safety risk for the patients can be eliminated in this respect

Intellectual property

- Priority patent application for NFE formulations filed December 2020

Regulatory pathway

- Reference medicinal product: Tasigna 50, 150 and 200mg, hard gelatin capsules from Novartis
- Legal basis: expected Article 10(3) hybrid application for all strengths

Development status

- Pilot bio-equivalency study for proof of concept available from Q4/2022
- Pivotal bio-equivalency study in Q4/2023
- EU dossier available from Q1/2024

Partnership options

- Product is available for out-licensing in selected markets in Europe
- Dossier can be adjusted to markets outside Europe based on request

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