INN: Dasatinib

VALUE ADDED DASATINIB

L1H Protein kinase inhibitor antineoplastic - **Tablet**

SUPRABIOAVAILABLE

STRENGTH DIFFERENT FROM RLD*

DASATINIB

Is a prescription medicine used to treat adult patients with:

- Newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in the chronic phase.
- Chronic, accelerated or blast phase CML with resistance or intolerance to prior therapy including imatinib.
- Ph+ acute lymphoblastic leukemia (ALL) and lymphoid blast CML with resistance or intolerance to prior therapy.

Dasatinib is a prescription medicine used to treat paediatric patients with:

- Newly diagnosed Ph+ CML in chronic phase (Ph+CML-CP) or Ph+ CML-CP resistant or intolerant to prior therapy including imatinib.
- Newly diagnosed Ph+ ALL in combination with chemotherapy.

CURRENT LIMITATIONS

At the moment, Dasatinib should not be taken with H2 antagonists or proton pump inhibitors (e.g. famotidine and Omeprazole). This is because Omeprazole at steady state will reduce the AUC of Dasatinib by 43%, and the C_{max} of Dasatinib by 42%.

H2 antagonists and proton pump inhibitors (PPI) must not be taken together.

pH dependence on absorption.

Safety - Leukemia patients suffering from achlorhydria or taking antacid / PPI might not receive the full effective dose of Dasatinib.

* RLD - Reference Listed Drug; AUC - Area Under the Curve

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ZENTIVA

Zentiva's Value added Dasatinib is in tablet form for the same indications as other Dasatinib products on the market.

ADVANTAGES

Can be taken by patients with high stomach pH level (achlorhydria) and with or without PPI (Omeprazole).

Suprabioavailable and hence has a lower dose.

Due to suprabioavailability there is more absorption of this drug in the gastrointestinal tract with less drug content waste. Less waste also benefits the environment.

A patent application to protect the novel and inventive aspects of this formulation has been filed and is currently pending.

POTENTIAL BENEFITS

The prescriber or patient does not need to worry about consumption of Omeprazole (PPI) when taking Zentiva's Dasatinib, which has been proven to deliver clinically effective dose with or without PPI (Omeprazole).

Based on results from pilot PK study, patients with achlorhydria are expected to benefit more from Zentiva's Dasatinib than from 1:1 Dasatinib copy of RLD due to less reduction effect on AUC.

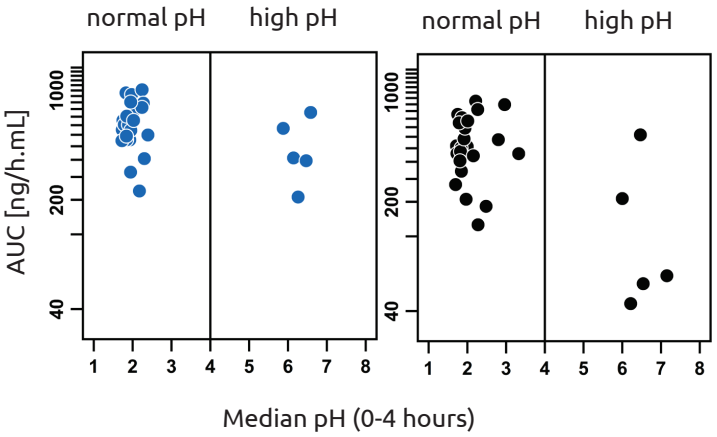
EPIDEMIOLOGY: DID YOU KNOW?

- Total of 4.2:100 000/year in the Western world
- Incident of 100 000 new patients worldwide every year.
- The prevalence of CML is steadily rising due to increase in life expectancy.
- In most cases, lifelong treatment is needed.

The number of people treated with Dasatinib in Europe was 14 000, and in US was more than 10 000.

CLINICAL STUDY

Zentiva's Target Product (Dasatinib) | **Dasatinib 1:1 RLD's copy**



A pilot study on Zentiva's Target Product (Dasatinib) showed similar AUC of Dasatinib, irrespective of test subjects' stomach pH while Dasatinib 1:1 RLD's copy showed some test subjects have lower AUC with higher stomach pH. The study was conducted on healthy volunteers.

Confirmative pivotal study results are available upon CDA signature.

AVAILABILITY

EU dossier availability:
Filed (Q3 2020)

US dossier availability:
Target Filing: Q1 2022

Product available for out licensing in selected EU countries and partnership outside Europe.

https://www.ema.europa.eu/en/documents/product-information/sprycel-epar-product-information_en.pdf
https://www.medicines.org.uk/emc/product/7742/smpc

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