DASATINIB (pH resistant) Film-coated Tablets

- **Indicated for:**
  - 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
- **Posology:** Can be taken two hours after PPI administration

Can be taken by all patients irrespective of pH of stomach

Reliability – physicians can rely on the product's absorption

Supra bioavailable – lower impact to environment

Available strengths: 15.8, 39.5, 55.3, 63.2, 79 and 110.6mg

Gastric pH independence

- The absorption is independent of stomach pH; therapeutic concentrations are achieved in all cases
- Co-administration with PPIs allowed. Required by up to 30% of patients with CML
  - As per Medicare reported data, concomitant use of PPI (e.g. omeprazole) with Dasatinib was 25.9% in the US, i.e. 1/4th of the patients definitely did not absorb the lifesaving drug properly*
- Also suitable for patients suffering from achlorhydria (patients naturally having higher pH in stomach – estimated 10-30% of total population)

*Ref : Sharma M, Holmes HM, Mehta HB, Chen H, Aparasu RR, Shih YT, Giordano SH, Johnson ML. The concomitant use of tyrosine kinase inhibitors and proton pump inhibitors: Prevalence, predictors, and impact on survival and discontinuation of therapy in older adults with cancer. Cancer. 2019 Apr 1;125(7):1155-1162. doi: 10.1002/cncr.31917. Epub 2019 Jan 3

Standard technology

- Resulting in comparable COGS to a generic non value added reference product

Intellectual property

- Priority patent application covering the unique formulation filed

Regulatory pathway

- UK approval 11/2021
- EU DCP procedure finished in 05/2022
- Reference medicinal product: SPRYCEL, from Bristol-Myers Squibb Pharma EEIG, 20, 50, 70, 80, 100, 140 mg, FCT
- Legal basis: Article 10(3) hybrid application for all strengths

Development status

- EU dossier approved
- US FDA scientific advice finalized

Partnership options

- Product is available for out-licensing in selected markets in Europe
- US and RoW available

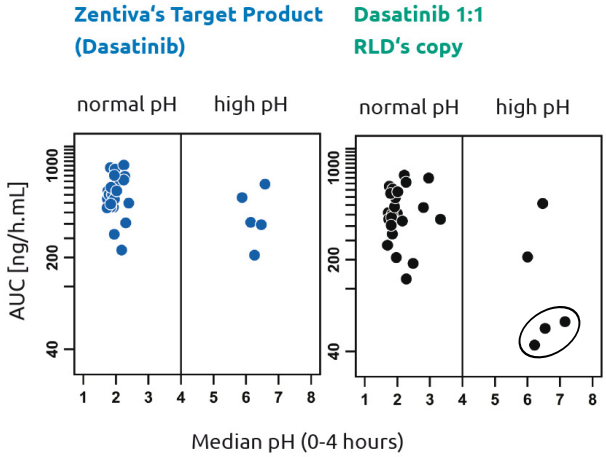

FIG. Randomized, open-label, single-dose, comparative bioavailability study of Dasatinib 140 mg, film-coated tablet versus Sprycel 140 mg, film-coated tablets, in healthy volunteers under fasting conditions

Zentiva Group a.s.
U Kabelovny529/16, 102 00 Prague 10, Czech Republic
Zent2U@zentiva.com
+420 267243231
www.Zent2U.com

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