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Relative bioavailability of Rolapitant tablets compared with Rolapitant capsules and the effect of food on Rolapitant pharmacokinetics in healthy subjects

Rolapitant (VARUBI®/VARUBY®), a selective and long-acting neurokinin-1 receptor antagonist, is approved in oral tablet formulation for the prevention of delayed chemotherapy-induced nausea and vomiting in adults in the US and EU. These studies assessed the relative bioavailability of Rolapitant tablet formulations compared with Rolapitant capsules used in phase-3 studies and the effect of food on Rolapitant tablet pharmacokinetics (PK) in healthy subjects. An open-label, single-dose, parallel-group study was conducted in 84 healthy subjects to evaluate the relative bioavailability of two test formulations of Rolapitant (high shear tablets and fluid bed tablets; each 2×90 mg) versus the reference capsules (4×45 mg). A second open-label, single-dose, parallel-group study was conducted in 80 healthy subjects to assess the effect of a high-fat meal on Rolapitant PK (2×90 mg the intended commercial formulation of high shear tablets). Bioavailability was similar for the test tablets versus capsules. For tablets versus the capsules, the 90% confidence intervals (CI) for the geometric mean C_{max} and AUC ratios were contained within the equivalence limits of 0.80 to 1.25. For the food effect assessment, the 90% CIs for the geometric mean AUC ratios (fed/fasted) were within 0.8 to 1.25. These data suggested that the bioavailability of Rolapitant following administration as 2×90 mg high shear tablets and 2×90 mg fluid bed tablets was comparable to that following administration of 4×45 mg of the reference capsules. In addition, Rolapitant can be taken without regard to meals.

Biography

Xiaodong Wang is the Senior Director at TESARO Inc., an oncology-focused biopharmaceutical company in Waltham, USA. He currently leads a group in Clinical Pharmacology and Drug Disposition supporting the development and regulatory submission of several drug candidates in the late phase of the TESARO pipeline. Prior to TESARO, he had worked at several other biopharmaceutical companies, leading efforts to characterize the clinical pharmacology and pharmacometrics of small and large molecules at Bristol-Myers Squibb as well as in Genentech. He has received his PhD from the Department of Pharmaceutical Sciences, State University of New York, USA.

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