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Genentech, USA

E-BABE- Understanding of pirfenidone pharmacokinetics in bioequivalence study using PBPK approach

Pirfenidone is the first treatment approved to treat Idiopathic Pulmonary Fibrosis (IPF). Film-coated tablets were developed to offer an alternative to the marketed capsule formulation, and the bioequivalence (BE) study of pirfenidone after single-dose of tablet and capsules under fasted and fed states were assessed. A physiologically-based pharmacokinetic (PBPK) model was developed to describe pharmacokinetic (PK) for pirfenidone under fasted and fed conditions. The mechanistic absorption model simulation captured the observed BE study data and explained the phenomenon of Cmax slightly exceeding the BE criteria based on the hypothesis of slower disintegration with capsule under fed condition. The PBPK simulation result further supports the conclusion that the small difference in Cmax between the tablet and the capsules observed in the fed state is not expected to have clinically meaningful impact on the benefit-risk profile of pirfenidone.

Biography

Dr. Yuan Chen is a Principal Scientist in the Department of Drug Metabolism and Pharmacokinetics at Genentech. Yuan has nearly 20 years of experience in the drug metabolism and pharmacokinetics discipline working at Roche and Genentech. She has been DMPK project lead for many drug discovery and development projects, and contributed to many clinical candidate nomination and filing of IND to the regulatory authorities. Yuan's current research focus is on physiologically-based pharmacokinetic (PBPK) modeling for the prediction of human PK, absorption, and CYP-and transporter-mediated drug-drug interactions. She leads PBPK effort at Genentech and has been active member on IQ PBPK expert working groups.

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