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Safety and biosimilarity of ior®EPOCIM compared to Eprex® based on toxicologic, pharmacodynamic and pharmacokinetic studies in the Sprague-Dawley rat

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This study utilized safety, pharmacodynamic and pharmacokinetic data to compare the biosimilarity of the human recombinant erythropoietin (EPO) products ior® EPOCIM and Eprex® following a 28-day repeated intravenous dose administration in male and female Sprague-Dawley rats with a 14-day recovery period. Safety profiling was based on clinical observations, clinical pathology and pathology findings for control rats dosed with vehicle and rats dosed either with 30, 300 and 600 I.U./kg of ior®EPOCIM or 600 I.U. of Eprex®. Adverse findings for both ior®EPOCIM and Eprex® were similar and were a consequence of thrombotic events (ulcerative skin lesions, swollen hock joints/lameness, stomach ulcers) and decreased body weight gains, all known adverse reactions to this class of drug in rats. With the exception of stomach ulcers, all other adverse findings were fully reversible with a similar time course for both products. Neither drug stimulated the production of anti-drug antibodies. As expected, ior EPOCIM® and Eprex® both increased reticulocyte, red blood cell, hemoglobin, and hematocrit levels in rats to a similar extent. The pharmacokinetics of EPO following dosing with either ior®EPOCIM or Eprex was well behaved, displayed bioequivalence and was consistent with the literature. The results of this study imply that ior®EPOCIM and Eprex® had safety profiles, pharmacodynamic responses and toxicokinetic profiles that were consistent with biosimilarity for both products.

Biography

Gordon T Bolger received his BSc in Biochemistry from McGill University and a PhD degree in Molecular Pharmacology from the State University of New York. He then held key positions at the National Institutes of Health as Assistant Professor at Memorial University of Newfoundland and with Boehringer Ingelheim Research and Development, Canada. He possesses extensive experience in the preclinical drug development area with key expertise in evaluating the pharmacodynamics and pharmacokinetics of candidate drug molecules. He has authored /co-authored 95 publications and 53 scientific communications. Presently, he is a Senior Scientist / Study Director at Nucro-Technics, a pharmaceutical contract research organization.

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