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Safety and biosimilarity of ior®LeukoCIM compared to Neupogen® based on toxicity, pharmacodynamic and pharmacokinetic studies in the Sprague-Dawley rat

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This study examined the safety, pharmacodynamic and pharmacokinetic biosimilarity of the human recombinant filgrastim products iorRLeukoCIM and NeupogenR following a 28-day repeated subcutaneous 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 15, 75 and 150 µg/kg of iorRLeukocim or 150 µg/kg of NeupogenR. Adverse clinical findings for both iorRLeukoCIM and NeupogenR were similar and consisted of mild to moderate forelimb alopecia; skin lesions (scab formation on the shaved dorsal region) and mild to severe swelling of the hock-joint (tarsal joint) and hind limb, alone or accompanied with lameness in high dose group animals which was more prominent in males. All adverse findings were fully reversible. As expected, iorLeukoCIMR and NeupogenR both increased white blood cell and neutrophil levels in rats and to a similar extent for high dose iorRLeukoCIM and NeupogenR. The pharmacokinetics of filgrastim following dosing with iorRLeukoCIM was well behaved and comparable for high dose iorRLeukoCIM and NeupogenR. The results of this study imply that iorRLeukoCIM and NeupogenR had safety profiles, pharmacodynamic responses and toxicokinetic profiles that were biosimilar.

Speaker Biography

Nuris Ledon has a PhD in Pharmaceutical Sciences since 2000. She is also an Auxiliary Professor and Senior Researcher at Molecular Immunology Center, La Havana, Cuba with 25 years of experience. She counts with two Master´s degrees, one in Pharmacology and other in Business Administration. She has published more than 50 articles on subjects like Pharmacology and Toxicology of different drugs. She has participated in numerous congress and summits and has tutored several theses.

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