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Toxicology studies and results for determining safety of a novel therapeutic dual carbon monoxide and oxygen delivery agent

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SANGUINATE™ (pegylated carboxyhemoglobin bovine) is a dual carbon monoxide and oxygen delivery agent that has potential use for indications whose pathophysiology includes an ischemic or hemolytic component. While SANGUINATE is initially under clinical development as an acute therapeutic candidate, it has the potential to be used chronically. Designing toxicology studies must not only deal with the potential safety issues of using bovine hemoglobin but the potential use of this product for both acute and chronic administration. Therefore, toxicology studies were designed both to thoroughly address the potential of vasoreactivity in addition to traditional safety pharmacology studies. To address any toxicity concerns of its use as a single or repeating dose therapeutic, SANGUINATE was tested in multiple species as a single agent, in repeating doses, and as with any new investigational drug, at ascending dose levels to determine its maximum tolerated dose. Twelve toxicology studies were performed in 4 species. Renal toxicity was assessed and no abnormal clinical observations were observed with regards to renal glomerular filtration rate and renal blood flow. There were no adverse effects identified for any dose and therefore, a no observed adverse effects level could not be determined not even at dosage levels of 1200 mg/kg (monkey), 1600 mg/kg (pig) and 2400 mg/kg (rat). The dose limitation of SANGUINATE appears to be caused by plasma expansion of the administered dose, not actually by the activity of the product. This toxicology study design addressed FDA concerns and permitted SANGUINATE to move into clinical trials.

Biography

Hemant Misra received his PhD from Lucknow University in Medicinal and Pharmaceutical Chemistry and has published over 55 articles and a patent. He is VP Clinical Development for Prolong Pharmaceuticals. He has over 30 years of biopharmaceutical development, global clinical study management and corporate development experience. He has managed drug development, CGMP manufacturing, CTM, quality systems and multiple global clinical trials.

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