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A double blind, phase 1, randomized, parallel-group, single dose, 2 arm, biosimilar study, of a "New Biologic" and "Comparator", intravenously administered to healthy subjects

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New Biologic" is being developed as a biosimilar version of "Comparator". The purpose of this clinical trial is to investigate the pharmacokinetics (PK), safety and tolerability of "New Biologic" and to establish PK similarity to the "Comparator". During the course of the study, PK will be assessed by sampling the levels of drug in plasma and by comparing these levels among the two administration arms of "New Biologic" and licensed "Comparator". Health subjects will receive a single intravenous administration (i.v.) of each drug with the primary objective to compare the area under the concentration-time curve in plasma over the time interval from "0" extrapolated to infinity ($AUC_{0\text{-}inf}$). Safety, tolerability and immunologic response will also be evaluated throughout the study as secondary objectives. $AUC_{0\text{-}inf}$ of "New Biologic" and "Comparator" will be considered the primary PK endpoint. $AUC_{0\text{-}t}$ and C_{max} of "New Biologic" and "Comparator" will be regarded as the secondary PK endpoint. Healthy subjects 18 to 55 years inclusive with a body mass index of 18 and 32 kg/m_2 inclusive and a total body weight >50 kg (110 lbs) will be enrolled. Safety will be assessed throughout the study via monitoring adverse events (AEs), vital signs (supine blood pressure, pulse, respiratory rate, and body temperature), 12 lead electrocardiogram (ECG), clinical laboratory evaluations (hematology, biochemistry, coagulation and urine analysis) echocardiogram and physical examinations. PK samples for the determination of "name" concentrations will be prior to infusion, immediately after the infusion and at 2, 3, 4, 8, 10, 12, 16, 20, 24, 48, 72, 96, 120, 144, 168, 336, 504, 672, 1008, 1344 and 2016 hrs. Immunogenicity samples will be taken to determine the incidence of "anti-name" antibodies and neutralizing antibodies at screening, day 22 and post-study medical.

Biography

Krishna Menon has more than 25 years of experience in drug development with academia and industry. He is a co-founder of Cellceutix and has served as President and Director since inception in June 2007. Prior to Cellceutix, he served at Eli Lilly as Group Leader, Cancer *In Vivo* Research and Clinical Development. At Lilly, he played a key role in lead selection and pre-clinical development of Gemzar and Alimta, two anti-cancer drugs which have generated billions of dollars in yearly revenue. In addition, Lilly honored him with the prestigious President's Recognition Award. Prior to Eli Lilly, he operated his own veterinary oncology and drug development consultancy practice. Earlier in his career, he held research scientist positions at Miles Laboratories and Dana Farber Cancer Research Institute, where he worked under the direction of Dr. Emil Frei, one of the world's leading oncologists and a leader in medical research. He is a trained veterinary surgeon and holds a PhD in Pharmacology from Kerala University. His PhD work focused on anti-folate therapy of various cancers.

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