Neumedicines

ABSTRACT #1 - Global Conference on Radiation Topics

HemaMax™ Development as a Frontline, Single Dose Radiation Medical Countermeasure

HemaMax™ (recombinant human interleukin-12; rHuIL-12) is being developed as a post-exposure (+24hr) medical countermeasure (MCM) against the hematopoietic syndrome of acute radiation syndrome (HSARS). One single dose of HemaMax subcutaneously administered 24 hours after lethal total body irradiation (TBI) exposure increases survival in non-human primates (rhesus monkeys; NHP) in the absence of any additional supportive care. These properties support conceptual operations (ConOps) in which HemaMax as MCM can be administered to persons in a mass casualty event who have been exposed or potentially exposed to ionizing radiation. This use of HemaMax is expected to decrease the number of casualties, even if no supportive care were to be available for protracted periods of time

Efficacy of a single dose of HemaMax administered after 24 hours without supportive care was established in NHP after lethal whole body irradiation (WBI) (LD50/30) with single subcutaneous doses of 100 ng/kg and 250 ng/kg in initial HSARS survival efficacy experiments (PLoS ONE 7(2): e30434). Neumedicines subsequently conducted a larger, blinded, survival study in NHP under good laboratory practice (GLP).

Neumedicines GLP blinded NHP study established that one single subcutaneous dose of HemaMax administered 24 hours after lethal radiation exposure of 7 Gy WBI (LD90/60) significantly increased survival in NHP compared to control (n=18) ($p<0.05$ Logrank). Statistically significant efficacious doses ranged from 500 ng/kg down to 50 ng/kg. This latter dose corresponds to an approximate unit dose in humans of 1.2 ug.

The same HemaMax GMP drug product used in NHP studies was administered to healthy volunteers in two Phase I safety trials in healthy volunteers. In the First-in-Human (FIH) single ascending dose study in 32 subjects, HemaMax was found to be safe and well tolerated at 2, 5, 10 and 12 ug doses. A follow-up phase 1b safety study is ongoing in 60 subjects to further confirm the safety and tolerability.

Neumedicines plans to continue development of HemaMax under the Animal Rule with the goal of garnering BLA approval of HemaMax to prevent or reduce the mortality and morbidity associated with the Hematopoietic Syndrome of Acute Radiation Syndrome.

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