IMMUSOFT

PROGRAMMING YOUR CELLS TO CURE DISEASE

IMMUSOFT COMPLETES PRE-IND HEARING WITH FDA

Biotech seeking approval for clinical trial to treat MPS I

SEATTLE, Wash. (July 24, 2015) – Immusoft Corporation today completed a pre-IND (Investigational New Drug) hearing with the U.S. Food and Drug Administration for the company's proposed MPS I clinical trial.

MPS I is a rare but fatal lysosomal storage disease, which Immusoft seeks to treat using its Immune System Programming (ISP™) platform. ISP™ is a cell-based technology that enables sustained delivery of gene-encoded medicines.

The FDA's feedback is the critical next step to ensure that Immusoft's remaining preclinical studies produce the data needed to receive approval for a human clinical trial.

"Today's meeting with the FDA was a very important step," said Matthew Scholz, Immusoft's founder and CEO. "We are grateful for their careful consideration of our proposal for clinical testing of an ISP™ cell product to treat MPS I," he said.

"The feedback we received today," Scholz said, "will ensure our approach is in accord with the FDA's requirements for human clinical trials, and that we'll have the chance to explore the promise of our technology to treat this devastating disease."

The ISP™ system produces batches of autologous plasmablasts that secrete high levels of therapeutic proteins into the bloodstream. ISP™ plasmablasts infused back into a patient's body are expected to survive in the bone marrow for many years. Immusoft has perfected the ability to generate ISP™ plasmablasts ex vivo and can adapt the system to secrete virtually any biologic.

As part of the pre-IND process, Immusoft has had the counsel of Joyce Frey-Vasconcells, the former Deputy Director of the FDA's Office of Cellular Tissue and Gene Therapies, and Paul Orchard, M.D., a well-regarded pediatric hematologist.

About Immusoft

Immusoft Corporation's mission is to innovate breakthroughs in biotechnology and deliver targeted medicines by programming a patient's own cells to cure disease. Its Immune System Programming (ISP™) technology instructs a patient's cells to produce gene-encoded medicines (biologics). Founded in 2009, Immusoft is based in Seattle, Wash.

Phone: 206 397 0028
info@immusoft.com
454 N 34th St, Seattle, WA 98103