PRESS RELEASE

HemoGenix® FDA Master File to Measure Blood Stem Cell Potency for Cellular Therapy Products:

Advanced Tests for Umbilical Cord Blood Stem Cell Transplantation to Help Reduce Engraftment Failure

June 26, 2012

Colorado Springs, Colorado – June 26, 2012. HemoGenix® announced today that FDA CBER has given HemoGenix® its first Master File Number for an *in vitro* blood stem cell potency, quality and release assay (HALO®-96 PQR)[1] for cellular therapy products[2] used for stem cell transplantation purposes. HALO®-96 PQR is the first commercially available stem cell potency assay for cellular therapy products. It incorporates the most sensitive readout available to measure changes in the cell's energy source (ATP) as a function of the potential for stem cells to proliferate. Potency and quality of stem cell therapeutic products are required to be measured prior to use to help predict the engraftment of the cells in the patient. At the present time, tests such as cell number, viability and a stem cell marker called CD34 are routinely used. However, none of these tests specifically measure stem cells and none determine the stem cell biological activity required for a potency assay. The only cell functionality test presently used in this field, especially for umbilical cord blood transplantation, is the colony-forming unit (CFU) assay, which is subjective, non-validated and has been used since the early 1970s. HALO®-96 PQR changes this paradigm. It is particularly needed in the umbilical cord blood stem cell transplantation field by providing an application-specific test incorporating all of the compliance characteristics required not only by regulatory agencies[3] and standards organizations, but also the cord blood community[4].

"Stem cell potency is one of the most important parameters necessary for any therapeutic product, especially stem cells. Without it, the dose cannot be defined and the transplantation physician has no indication as to whether the product will engraft in the patient. The number of cord blood units collected and stored and the number of cord blood stem cell transplantations have increased exponentially over the last 12 years. During this time, significant advancements have been made in pre- and post stem cell transplantation procedures. Yet the tests used during the preparation and processing of the cells have remained unchanged and do not even measure the biological functionality of the stem cells being transplanted. Indeed, the standards organizations responsible for applying regulatory guidance to the community have so far failed to allow any new and alternative assays to be used during cord blood processing. HALO®-96 PQR is the first test that actually quantitatively characterizes and defines the stem cells in cord blood, mobilized peripheral blood or bone marrow as high quality and potent "active ingredients" for release prior to transplantation. Presently, approximately 20% engraftment failure is encountered in cord blood transplantation. HALO®-96 PQR could help reduce the risk of engraftment failure by providing valuable and time-sensitive information on the stem cells prior to use. HALO®-96 PQR complies with the guidelines not only with the cord blood community, but also with regulatory agencies thereby providing a benefit to both the stem cell transplantation center and the patient", said Ivan Rich, Founder and CEO of HemoGenix® (www.hemogenix.com).

About HemoGenix, Inc

HemoGenix® is a privately-held Contract Research Service and Assay Development Laboratory based in Colorado Springs, Colorado. Specializing in predictive *in vitro* stem cell toxicity testing, HemoGenix® provides its services to small, medium and many of the largest biopharmaceutical companies. HemoGenix® has developed several assays for stem cell therapy and regenerative medicine applications. These and other

patented and proprietary assays are manufactured and produced in Colorado Springs and sold worldwide. HemoGenix® has been responsible for changing the paradigm and bringing in vitro stem cell hemotoxicity testing into the 21st century. With HALO®-96 PQR the company is now also changing the paradigm to become a leader in stem cell therapy assays. To this end, HemoGenix® is a member of the Alliance for Regenerative Medicine and working with other companies to decrease risk and improve safety for the patient.

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Literature Cited

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3. FDA CBER Guidance for Industry. Potency Tests for Cellular and Gene Therapy Products. (2011).
4. Spellman S, Hurley CK, Brady C et al. (2011) Guidelines for the development and validation of new potency assays for the evaluation of umbilical cord blood. Cytotherapy; 13:848-855.