Compass Biomedical Announces FDA Drug Master File Acceptance for PLUS™ Human Platelet Lysate

CLEVELAND, Oct. 6, 2015 /PRNewswire/ -- Compass Biomedical announced that the Food and Drug Administration (FDA), Center for Drug Evaluation and Research has accepted the Type II Drug Master File (DMF) submission for its PLUS™ Human Platelet Lysate. PLUS™, a commercially manufactured human platelet lysate, is a cytokine rich replacement for fetal bovine serum (FBS). With no added heparin required, PLUS™ offers researchers a true xeno-free alternative to FBS. PLUS™ Human Platelet Lysate is available as a Clinical Grade and Research Grade product. Clinical Grade PLUS™ has previously been approved by the FDA for use in at least two investigational new drug (IND) submissions for expansion of mesenchymal stems cells (MSCs). PLUS™ is the only commercially manufactured human platelet lysate (hPL) to have an accepted DMF filing.

A Drug Master File (DMF) is a confidential detailed document submitted to the FDA by a manufacturer that includes the Chemistry, Manufacturing and Controls (CMC) information about their product. An active DMF enables clinical investigators to cross-reference the DMF in their own sponsored IND-application.

"Using the PLUS™ Drug Master File, our customers can save time and money in preparing their FDA submission since they will not need to include all the details required by FDA. This Drug Master File will enable our cell therapy customers to integrate PLUS™ into their clinical trial protocols as a replacement for Fetal Bovine Serum (FBS) more easily. We have seen a rapid adoption of PLUS™ by numerous academic and biotech organizations and expect it to grow further as PLUS™ is used in more clinical trials" said Compass Biomedical CEO, Don Brown.

PLUS™ Human Platelet Lysate
PLUS™ is commercially manufactured human platelet lysate that serves as a cytokine rich replacement for fetal bovine serum (FBS). PLUS™ is prepared from American Association of Blood Banks (AABB)-screened platelet units using state-of-the-art industrial scale manufacturing techniques and provides a safe, serology-tested product with minimal lot-to-lot variation. PLUS™ Human Platelet Lysate offers a true xenogeneic-free culture platform that does not require addition of animal-derived anticoagulants (e.g., heparin). PLUS™ supports the culture of various human cell types, including mesenchymal stem cells (MSCs), dermal fibroblasts, epidermal keratinocytes, and endothelial cells, and has been tested in both traditional culture systems and advanced bioreactor systems.

About Compass Biomedical
Compass Biomedical is a wholly owned subsidiary of Arteriocyte, Inc., a leading biotechnology company, located in Cleveland, Ohio, dedicated to the commercialization of novel technologies and products for translational research. Established in 2012 as part of the Arteriocyte Family, Compass Biomedical currently includes a portfolio of products for stem cell expansion and stem cell therapy and is devoted to providing innovative solutions to scientists and clinicians to bridge the gap between research and clinical applications.