

Partnership Aims to Enhance Safety of Human Serum from Viruses Such as the Virus that Causes COVID-19

BOCA RATON, FL – January 20, 2021 – Akron Biotechnology, LLC (Akron Biotech), today announced it has signed an exclusive global agreement to manufacture virally inactivated Human AB Serum for the cell therapy market using Octaplas[®], Octapharma's pooled, solvent-detergent treated human plasma. Akron Biotech is a leading manufacturer of cGMP-compliant ancillary materials for cell and gene therapy development and commercialization. Switzerland-based Octapharma is one of the largest human protein manufacturers in the world, developing and producing human proteins from human plasma and human cell lines.

Human AB Serum converted from plasma is a critical media supplement used in cell therapy manufacturing. These challenging times once again demonstrated the paramount role of patient safety. Therefore, starting with a virally inactivated, licensed pharmaceutical grade plasma product such as Octaplas[®] can help to support research and development requirements with a view to eventual commercialization.

Under the agreement, Akron Biotech will produce Human AB Serum converted from Octaplas[®], which is Octapharma's pooled, solvent/detergent treated human plasma product. The Octaplas[®] viral inactivation and production process includes multiple independent, complementary, and validated steps to eliminate or reduce non-enveloped and enveloped viruses such as the novel viral agent SARS-CoV-2, the virus causing COVID-19. The products will be co-labeled and available in the US, EU, and Asia.

Guidance documents published by regulatory agencies around the world make clear that the highest quality raw and ancillary materials available should be employed in the manufacture of cell therapies, and that these materials should be thoroughly assessed and qualified through a comprehensive, risk-based approach. Viral inactivation of Human AB Serum promises to significantly reduce the risk of one of the more complex ancillary materials common in cell therapy manufacturing.

"After years of working with Octapharma, we are taking our relationship to the next level to create a powerful resource for the cell therapy market," explained David Smith, President and Chief Commercial Officer at Akron Biotech. "The products that result from Octapharma's plasma technologies and Akron Biotech's manufacturing and commercialization will enable the global industry to move forward with greater confidence and safety."

"Octapharma is proud to support the growing cell and gene therapy market with Octaplas[®] converted materials," notes Flemming Nielsen, President Octapharma USA, Inc. & Board Member Octapharma Group. Octaplas[®] is manufactured with batch to batch consistency of plasma proteins and carries the added benefit of being virally inactivated with FDA approval (for intravenous infusion). With the continued advance of clinical and commercial cell therapies, it is increasingly important that the materials used are of the highest quality and safety standards available. This partnership coupled with Akron Biotech's investment in state-of-the-art manufacturing facilities will be essential to support this growing market.

For more information on this partnership, and to learn more about Akron's Human AB Serum converted from Octaplas[®], please reach out to info@akronbiotech.com.

About Akron Biotechnology

Akron is a leading materials manufacturer and services provider to the regenerative medicine industry. An ISO 13485-certified company operating in line with cGMP guidelines and international standards, Akron leverages more than 100,000 square feet of development and manufacturing capacity to provide advanced therapy developers the scale, compliance, and regulatory support necessary to drive novel treatments from discovery to commercialization. For more information, please visit www.akronbiotech.com.

About Octapharma

Headquartered in Lachen, Switzerland, Octapharma is one of the largest human protein manufacturers in the world, developing and producing human proteins from human plasma and human cell lines. Octapharma employs more than 10,000 people and has seven R&D sites and six state-of-the-art manufacturing facilities in Austria, France, Germany, Mexico and Sweden.

In addition, Octapharma operates more than 140 plasma donation centers across Europe and the US. For more information, please visit www.octapharma.com and www.octaplasus.com.

More about this product: [Human AB Serum, Converted from Octaplas[®], Pooled Plasma \(Human\), Xeno-Free, Virus Inactivated](#)