

FOR IMMEDIATE RELEASE

InVitria Unveils Optibumin 25: The First-of-Its-Kind Recombinant 25% Human Serum Albumin for Cell & Gene Therapy Manufacturing

Junction City, KS – February 20, 2025 – InVitria®, a leading provider of recombinant, chemically defined biomanufacturing and formulation components, today announced the launch of Optibumin® 25, the first and only recombinant human serum albumin (rHSA) available as a 25% solution—offering a safe and reliable alternative to plasma-derived HSA for closed-system biomanufacturing in cell and gene therapy.

Serum-derived HSA, which comprises approximately 25% of human serum proteins, has long been a standard in biologics manufacturing. However, its reliance on human blood donations introduces batch-to-batch variability, potential pathogen risks that require batch release testing, and supply chain instability. Optibumin 25 eliminates these risks by offering a chemically defined, animal-origin-free alternative with GMP compliance for seamless adoption in regulated biomanufacturing.

"With the introduction of <u>Optibumin 25</u>, we are addressing a critical gap in cell & gene therapy manufacturing. This product provides a direct replacement for 25% plasma-derived HSA while delivering unmatched consistency, reliability, and regulatory alignment," said Scott Deeter, CEO at InVitria.

A Breakthrough in Closed-System Biomanufacturing

Optibumin 25 is the first recombinant 25% HSA designed specifically to meet the performance, consistency, and scalability requirements of GMP-compliant, closed-system workflows in cell therapy, gene therapy, vaccine production, and regenerative medicine.

Key benefits include:

- **The First Recombinant 25% HSA Solution** A like-kind replacement for plasma-derived 25% HSA, ensuring seamless integration into existing workflows.
- **Chemically Defined & Animal-Free** Eliminates risks associated with blood-derived components while improving batch-to-batch consistency.
- **GMP-Ready** Manufactured in a cGMP-compliant, ISO 9001-certified facility to meet clinical and commercial biomanufacturing requirements.
- **Scalable to Metric Tons** Reliable supply for seamless scale-up to commercial production.
- Enhanced Stability & Process Sterility Optimized for closed-system processing, reducing contamination risks.
- **Cost-Effective** Provides a high-quality, recombinant alternative without the need for high-cost pathogen testing requirements.



Future-Proofing Cell & Gene Therapy Manufacturing

As biopharmaceutical companies advance to late-stage clinical trials, regulatory agencies strongly encourage the adoption of chemically defined materials to minimize variability and improve product safety. Optibumin 25 enables manufacturers to meet these evolving requirements without process disruptions—reducing regulatory hurdles and de-risking late-stage transitions.

Availability

Optibumin 25 is now available for order, providing biopharma innovators with an industry-first, scalable alternative to plasma-derived albumin—ensuring greater regulatory alignment and long-term supply security

For more information, visit <u>www.invitria.com/optibumin25</u> or contact info@invitria.com.

About InVitria

InVitria is a global leader in the development and manufacture of high-performance blood-free cell culture and recombinant protein products designed to improve biomanufacturing and facilitate faster approval of life-changing therapies. The company provides unparalleled high-performance solutions for elimination of human and animal serum-derived raw materials in clinical manufacturing and commercial production of cell and gene therapies, vaccines, regenerative medicine, and medical devices. InVitria adheres to the FDA, and EMA regulations and offers cGMP and ISO compliant manufacturing capabilities scaled to meet growing global demand for chemically defined production of biologics.

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