

InVitria Unveils Optibumin 25: First Recombinant 25% Human Serum Albumin for Closed-System Biomanufacturing

Recombinant alternative to plasmaderived HSA enables safer, scalable, closed-system cell & gene therapy manufacturing.

JUNCTION CITY, KS, UNITED STATES, April 29, 2025 /EINPresswire.com/ --InVitria Unveils Optibumin 25: The First-of-Its-Kind Recombinant 25% Human Serum Albumin for Cell & Gene Therapy Manufacturing

InVitria[®], a leading provider of recombinant, chemically defined biomanufacturing and formulation



Optibumin® 25 in 100 mL bags: The first recombinant 25% human serum albumin solution designed for closed-system biomanufacturing.

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 <u>closed-system biomanufacturing</u> in cell and gene therapy.

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Optibumin 25 provides a direct replacement for 25% plasma-derived HSA while delivering unmatched consistency, reliability, and regulatory alignment." *Scott Deeter, CEO, InVitria* 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 Optibumin 25, 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 – Seamless drop-in replacement for plasma-derived HSA.

-Chemically Defined & Animal-Free – Eliminates blood-derived risks and improves consistency. -GMP-Ready – Manufactured in a cGMP-compliant, ISO 9001-certified facility.

-Scalable to Metric Tons – Reliable supply for clinical through commercial scale.

-Enhanced Stability & Process Sterility – Supports closed-system production.

-Cost-Effective – Avoids expensive pathogen testing required with serum-based components.

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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