

## **Bio Products Laboratory Announces Launch of ALBUMINEX® 5% and ALBUMINEX® 25% With Supply Immediately Available in the United States**

DURHAM, NC – May 27, 2020

Bio Products Laboratory (BPL), a leading manufacturer of plasma-derived protein therapies with US headquarters in Durham, North Carolina, and worldwide headquarters and manufacturing facilities in Elstree, UK, today announced the US launch of ALBUMINEX 5% (human albumin) solution for injection and ALBUMINEX 25% (human albumin) solution for injection, with supply immediately available. ALBUMINEX 5% and ALBUMINEX 25% are approved by the US Food and Drug Administration for the treatment of hypovolemia, ascites, hypoalbuminemia including from burns, acute nephrosis, acute respiratory distress syndrome (ARDS), and cardiopulmonary bypass.

ALBUMINEX 5% and ALBUMINEX 25% are albumin products derived from human plasma using a four-step process that results in  $\geq 99\%$  purity. BPL has a long history in the manufacture and supply of plasma protein therapies, including over 25 years of global experience with albumin. For additional information, including how to order ALBUMINEX 5% and ALBUMINEX 25%, please visit [www.albuminex.com](http://www.albuminex.com) or call 1-844-4BPLUSA.

“BPL is pleased to add ALBUMINEX to our portfolio of products in the United States,” said Bob Rossilli, Chief Commercial Officer and President of US Business Operations for BPL. “This introduction of ALBUMINEX is our third product launch in the US in the past five years, and it reflects our corporate mission of providing a continuous supply of reliable, high quality plasma-derived products worldwide, supporting both healthcare professionals and patients every day.”

### **About ALBUMINEX 5% and ALBUMINEX 25%**

ALBUMINEX 5% and ALBUMINEX 25% are indicated for:

- Hypovolemia
- Ascites
- Hypoalbuminemia, including from burns
- Acute nephrosis
- Adult respiratory distress syndrome (ARDS)
- Cardiopulmonary bypass

ALBUMINEX 5% and ALBUMINEX 25% are contraindicated in patients with:

- Hypersensitivity to human albumin or any of the excipients
- Severe anemia or cardiac failure with normal or increased intravascular volume

Please see additional Important Safety Information about ALBUMINEX 5% and ALBUMINEX 25% below, and the Full Prescribing Information at [www.albuminex.com](http://www.albuminex.com).

### **Important Safety Information**

Suspicion of allergic or anaphylactic reactions requires immediate discontinuation of the infusion and implementation of appropriate medical treatment.

Hypervolemia may occur if the dosage and rate of infusion are not adjusted to the patient's volume status. At the first clinical signs of cardiovascular overload (headache, dyspnea, jugular venous distention, increased blood pressure), the infusion must be slowed or stopped immediately. Use albumin with caution in conditions where hypervolemia and its consequences or hemodilution could represent a special risk to the patient.

Colloid-osmotic effect of human albumin 25% is approximately five times that of blood plasma. Therefore, when concentrated albumin is administered, care must be taken to assure adequate hydration of the patient. Patients should be monitored carefully to guard against circulatory overload and hyperhydration.

Albumin is a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) is also considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for ALBUMINEX 5% or ALBUMINEX 25%.

The most common adverse reactions associated with infusion of human albumin solutions are rigors, hypotension/decreased BP, tachycardia/increased heart rate, pyrexia, feeling cold (chills), nausea, vomiting, dyspnea/bronchospasm, rash/pruritus. Reactions usually resolve when the infusion is slowed or stopped.

### **About Bio Products Laboratory USA (BPL USA)**

*BPL USA, headquartered in Durham, NC, focuses on providing access to BPL's plasma-derived therapies to the US market. BPL USA is dedicated to delivering transformative therapies to patients in the areas of Immunology, rare bleeding disorders, and critical care. In addition to five currently available specialty medicines in the US market, BPL is also investing in the development of a robust pipeline of future product candidates for patients with rare and orphan diseases. Since receiving its first US FDA approval in 2009, BPL has proudly built a strong culture and reputation as an industry leader with specialty pharmacies, healthcare professionals, and patient advocacy organizations. BPL USA is part of a global company, Bio Products Laboratory, which boasts a vibrant 60-year heritage in plasma research, technology, and manufacturing. For more information about BPL in the United States, please visit [www.bpl-us.com](http://www.bpl-us.com).*

### **About Bio Products Laboratory (BPL)**

*Recognizing the power of plasma and with over 60 years heritage in the industry, BPL supplies high-quality plasma derived medicines to meet the needs of clinicians, patients and customers globally.*

*Headquartered in the United Kingdom and with plasma collection centers across the United States, we are dedicated to producing medicines for the treatment of immune deficiencies, bleeding disorders and infectious diseases as well for critical care. BPL invests in the latest R&D, technology and manufacturing methods, and continuously adapts to ensure that we continue to serve all our stakeholders effectively. For more information visit <http://www.bplgroup.com>*

*BPL consists of two operating divisions - BPL Plasma and BPL Therapeutics. BPL Plasma, headquartered in Austin, Texas and operating in the USA, collects plasma from donors, in around 51 centers across the US. BPL Plasma employs over 2000 staff, to support the needs of donors and to ensure high-quality plasma collection in all their centers. Plasma collection is regulated by both FDA and MHRA, and BPL Plasma follow industry guidelines. BPL Plasma operates clean and safe plasma facilities, staffed with trained personnel, dedicated to supporting donors through the process that leads to the donation of plasma. Plasma is shipped to the headquarters of BPL Therapeutics in Elstree, United Kingdom. The plasma is fractionated, purified, and filled through the efforts of our over 1000 employees involved in production, quality, R&D, commercial, customer services and administrative activities. BPL's plasma derived medicines are commercially available in the UK, USA and 30 plus other countries around the world through our network of local distribution partners.*