

# CSL Behring

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## Divisions

### **CSL Limited (parent company)**

Global, specialty biopharmaceutical company that researches, develops, manufactures and markets products to treat and prevent serious human medical conditions.

### **CSL Behring**

Develops, manufactures and markets protein-based therapies for rare and serious diseases.

### **CSL Plasma**

One of the largest collectors of human plasma in the world (subsidiary of CSL Behring).

### **bioCSL**

Manufacturer of influenza vaccine to 27 countries. Provides vaccines, antivenoms and other pharmaceutical products in Australia and New Zealand.

# CSL Behring

CSL Behring is a leader in the plasma protein therapeutics industry. Committed to saving lives and improving the quality of life for people with rare and serious diseases, the company manufactures and markets a range of plasma-derived and recombinant therapies worldwide. CSL Behring therapies are used around the world to treat coagulation disorders, including hemophilia and von Willebrand disease, primary immune deficiencies, hereditary angioedema and inherited respiratory disease, and neurological disorders in certain markets. The company's products are also used in cardiac surgery, organ transplantation, burn treatment, to reverse the effects of warfarin, and to prevent hemolytic disease in the newborn. CSL Behring operates one of the world's largest plasma collection networks, CSL Plasma. CSL Behring is a global biopharmaceutical company and a member of the CSL Group of companies. The parent company, CSL Limited (ASX:CSL), is headquartered in Melbourne, Australia. For more information, visit <http://www.cslbehring.com/>.

## Products (U.S.)

### **Alpha-1**

- Alpha<sub>1</sub>-Proteinase Inhibitor (Human), marketed as Zemaira

### **Inhibitors**

- C1 Esterase Inhibitor (Human), marketed as Berinert

### **Coagulation**

- Factor XIII Concentrate (Human), marketed as Corifact
- Antihemophilic Factor (Recombinant) Formulated with Sucrose, marketed as Helixate FS
- Antihemophilic Factor/von Willebrand Factor Complex (Human), marketed as Humate-P
- Antihemophilic Factor (Human) Factor VIII:C Pasteurized Monoclonal Antibody Purified, marketed as Monoclate-P
- Coagulation Factor IX (Human) Monoclonal Antibody Purified, marketed as Mononine

- Fibrinogen Concentrate (Human), marketed as RiaSTAP
- (Desmopressin acetate) Nasal Spray, 1.5 mg/mL, marketed as Stimate

### **Critical Care & Immunology**

- Albumin (Human), marketed as AlbuRx 5, AlbuRx 25, Albuminar 5, Albuminar 20 and Albuminar 25
- Prothrombin Complex Concentrate (Human), marketed as Kcentra

### **Rh Immunoprophylaxis**

- Rho(D) Immune Globulin Intravenous (Human), marketed as Rhophylac

### **Immune Mediated Disorders**

- Immune Globulin Intravenous (Human), marketed as Carimune NF Nanofiltered
- Cytomegalovirus Immune Globulin Intravenous (Human) (CMV-IVIG), marketed as Cytogam
- Immune Globulin Subcutaneous (Human) 20% Liquid, marketed as Hizentra
- Immune Globulin Intravenous (Human) 10%, marketed as Privigen

## A Legacy of Innovative Therapies

CSL Behring and its parent company, CSL Limited, share a legacy of innovation in patient care and novel therapies used to treat people with rare and serious medical conditions. The company's origin dates back to 1904. CSL Behring's founder, Dr. Emil von Behring, was the first recipient of the Nobel Prize in Physiology and Medicine. It was Dr. von Behring who established Behringwerke to produce sera and vaccines to combat infectious diseases.

CSL Behring produced the first pasteurized (heat-treated in aqueous solution) plasma protein solution in 1954. In 1962, CSL Behring researchers developed a new plasma fractionation method that provided significantly better yields of the valuable proteins isolated from human plasma. Behringwerke introduced the first pasteurized factor VIII product in the world for the treatment of patients with hemophilia A in 1981. This was followed by an approved monoclonal antibody purified factor IX product for the treatment of factor IX deficiency, or hemophilia B, in 1992.

## Patient Group Recognition

CSL Behring has consistently been recognized by patient groups and the industry for its innovative lifesaving therapies. The European Organization for Rare Disorders presented its EURORDIS Award to CSL Behring for "pioneering work in developing and manufacturing therapies used to treat rare and serious medical conditions." Forbes has included CSL Behring in its Top 50 list of the world's most innovative companies. In addition, in 2011, the National Organization for Rare Disorders recognized CSL Behring for developing and marketing the first treatment in the U.S. for acute bleeding episodes in patients with congenital fibrinogen deficiency. That same year, the company received FDA approval for the first 20%

subcutaneous immunoglobulin for the treatment of patients with primary immune deficiency. This therapy requires no refrigeration throughout its 30-month shelf-life, offering patients and physicians convenience and portability.

## Expanding Manufacturing Capacity

Progress in developing new therapies would not be possible without state-of-the-art manufacturing capabilities. In 1998, a major 50 million euro capital project to modernize CSL Behring's Marburg, Germany, production facilities took place, enhancing and increasing production capacity. CSL Behring continued to expand its production capacity, receiving approval by the FDA and other international regulatory agencies in 2009 for module I of the new state-of-the-art immunoglobulin manufacturing plant in Bern, Switzerland. This was an ambitious expansion that occurred in two phases, with module II receiving approval in 2011. Modules I and II are two identical independent production facilities using the same clean rooms (special areas where conditions such as temperature, humidity and pressure are controlled and maintained). To further maximize efficiencies, technical areas also are shared by both plants. Our new world-class cell culture facility in Melbourne, Australia, will add to the supply chain for material to enable Phase I, II and III clinical trials, and play a key role in developing recombinant products for cancer and bleeding disorders, along with other new therapies progressing through our product pipeline. We have further expanded our manufacturing capacity to keep pace with the growing demand for immune globulin and albumin, including construction of new facilities at our Broadmeadows, Australia, and Kankakee, United States, sites. We are committed to insuring the continued availability of these important products.



Paul Perreault, Chief Executive Officer,  
CSL Limited

## Research and Development

CSL Behring and the collective group of CSL companies have a heritage of outstanding contributions to medicine and human health that spans more than a century. These contributions have been possible because we continually grow our investment in R&D, making balanced investments in life cycle management and market development of existing products. We also make strategic investments in longer-term, new product development activities in areas aligned with our core capabilities and commercial strengths.

Today, CSL Behring has a rich product pipeline of therapeutic proteins derived from human plasma, and several promising candidates designed with recombinant technology. For more than 100 years, CSL Behring has specialized in providing safe and effective therapies to improve the quality of life for people with rare and serious diseases worldwide. The company has received 18 regulatory approvals for new rare disease products or indications since 2008 in the U.S. and Europe. With a strong pipeline and solid track record for research and development activities, CSL Behring will continue to meet the global demand for our life-enhancing and in many cases lifesaving therapies into the future. ❖