

FOR ADULT PATIENTS WITH PRIMARY IMMUNODEFICIENCY (PI)

**Alyglo**<sup>®</sup>  
immune globulin  
intravenous, human-stwk  
10% liquid

It's  
*glo*  
time

**>99%**  
FX1a FREE

### EXTRA PURIFICATION

Manufactured with the extra step of **G-XI™ Technology**<sup>a</sup>

**0.03**  
ASBIs

### PROVEN PROTECTION

In the phase 3 clinical trial, ALYGLO demonstrated<sup>b\*</sup>:

- **0.03 acute serious bacterial infections (ASBIs) per patient year**  
- Upper one-sided 99% confidence limit was 0.31, which met the predefined success rate of <1 ASBI per patient year (intent-to-treat [ITT] population)

**>98%**  
Infusions

### DEMONSTRATED TOLERABILITY

In the phase 3 clinical trial<sup>c</sup>:

- **>98% of infusions were completed without discontinuation, interruption, or rate reduction**

\* Study design: Efficacy, safety, and tolerability of ALYGLO were evaluated in a prospective, open-label, 12-month study of 33 adults aged 17-70 years. Primary endpoint: ASBIs per patient year with a predefined success rate of <1 ASBI per patient year. Secondary endpoints: annual rate of days of other infection, use of antibiotics, days out of work/school/daycare or unable to perform normal activities due to infection, and days of hospitalization due to infection.

## IMPORTANT SAFETY INFORMATION

### WARNING: THROMBOSIS, RENAL DYSFUNCTION and ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin intravenous (IGIV) products, including ALYGLO. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.
- Renal dysfunction, acute renal failure, osmotic nephropathy, and death may occur with the administration of IGIV products in predisposed patients.
- Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. ALYGLO does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction or renal failure, administer ALYGLO at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Please see additional Important Safety Information on the back, and accompanying full Prescribing Information inside pocket.



For adult patients 17 and older with primary immunodeficiency

# It's time for ALYGLO

## Product Characteristics

- Undetectable levels of FXIa<sup>a</sup>
- IgA  $\leq$  20 mcg/mL<sup>b</sup>
- Osmolality:  
240 – 360 mOsm/kg<sup>b</sup>

## True Partnership

- **GC Biopharma** has been delivering effective plasma-derived therapies to patients globally for more **than 50 years**

## ALYGLO Assist

- Patient Co-Pay Program provides up to **\$15,000** per calendar year for **Alyglo** deductible, co-pay, and/or coinsurance for commercially insured patients\*

\*Terms, conditions, and eligibility requirements apply. See [alyglo.medmonk.com](http://alyglo.medmonk.com) for full details.

ALYGLO® is indicated for the treatment of primary humoral immunodeficiency (PI) in adults aged  $\geq$ 17 years. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency (CVID), Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

## IMPORTANT SAFETY INFORMATION (CONT.)

- **Contraindications:** ALYGLO is contraindicated in patients who have a history of anaphylactic or severe systemic reaction to the administration of human immune globulin and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.
- **Hypersensitivity:** In case of hypersensitivity, discontinue infusion immediately and institute appropriate treatment. Epinephrine should be available for immediate treatment of severe acute hypersensitivity reactions.
- **Hyperproteinemia, Increased Serum Viscosity, and Hyponatremia:** Hyperproteinemia, increased serum viscosity, and hyponatremia may occur.
- **Aseptic Meningitis Syndrome (AMS):** Aseptic meningitis syndrome (AMS) may occur, especially with high doses or rapid infusion. AMS usually begins within several hours to 2 days following ALYGLO treatment. Discontinuation of treatment has resulted in remission of AMS within several days without sequelae.
- **Hemolysis:** Delayed hemolytic anemia due to enhanced red blood cell (RBC) sequestration and acute hemolysis consistent with intravascular hemolysis have been reported. Cases of severe hemolysis-related renal dysfunction/failure or disseminated intravascular coagulation have occurred following infusion of IGIV. Closely monitor patients for clinical signs and symptoms of hemolysis, particularly patients with risk factors.
- **Transfusion-Related Acute Lung Injury:** Noncardiogenic pulmonary edema (transfusion-related acute lung injury [TRALI]) may occur. TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal left ventricular function, and fever. Patients with TRALI may be managed using oxygen therapy with adequate ventilator support. Monitor patients for pulmonary adverse reactions.
- **Transmissible Infectious Agents:** Because ALYGLO is made from human blood, it may carry a risk of transmitting infectious agents (eg, viruses, the variant Creutzfeldt-Jakob disease [vCJD] agent and, theoretically, the Creutzfeldt-Jakob disease [CJD] agent).
- **Interference with Laboratory Tests:** After infusion of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for a misleading interpretation.
- **Adverse reactions** (observed in  $\geq$  5% of study subjects) were headache, nausea/vomiting, fatigue, nasal/sinus congestion, rash, arthralgia, diarrhea, muscle pain/aches, infusion site pain/swelling, abdominal pain/discomfort, cough, and dizziness.
- It is recommended that ALYGLO be administered separately from other drugs or medications.

Please see additional Important Safety Information on the front and full Prescribing Information inside pocket.

**Reference:** a. Kang GB, Huber A, Lee J, et al. Cation exchange chromatography removes FXIa from a 10% intravenous immunoglobulin preparation. *Front Cardiovasc Med.* 2023;10:1253177. b. ALYGLO Prescribing Information. GC Biopharma; 2025. c. Data on file. GC Biopharma; 2025.

