Glassia
[Alpha$_1$-Proteinase Inhibitor (Human)]

THE FIRST FDA-APPROVED

# LIQUID AUGMENTATION THERAPY

## FOR SEVERE ALPHA$_1$-ANTITRYPSIN DEFICIENCY WITH CLINICALLY EVIDENT EMPHYSEMA[1]

## THE ONLY LIQUID ALPHA$_1$-ANTITRYPSIN DEFICIENCY AUGMENTATION THERAPY WITH 12 YEARS OF MARKET EXPERIENCE[1]

### THE ONLY LIQUID AUGMENTATION THERAPY APPROVED FOR SELF-ADMINISTRATION*[1]

*If self-administration is deemed appropriate, ensure that the patient/caregiver receives detailed instructions and adequate training on how to administer in the home or other appropriate setting and has demonstrated the ability to independently administer GLASSIA.

### APPROXIMATELY 15-MINUTE INFUSION TIME

with a maximum rate of 0.2 mL/kg/min and a recommended dosage of 60 mg/kg[1]

**VISIT GLASSIALIQUID.COM/HCP FOR MORE INFORMATION.**

## INDICATION AND LIMITATIONS OF USE:

GLASSIA is an Alpha$_1$-Proteinase Inhibitor (Human) (Alpha$_1$-PI) indicated for chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of Alpha$_1$-PI (alpha$_1$-antitrypsin deficiency). GLASSIA increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha$_1$-PI.

The effect of augmentation therapy with GLASSIA or any Alpha$_1$-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha$_1$-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with GLASSIA are not available. GLASSIA is not indicated as therapy for lung disease in patients in whom severe Alpha$_1$-PI deficiency has not been established.

## IMPORTANT SAFETY INFORMATION

### Contraindications

- Immunoglobulin A (IgA) deficient patients with antibodies against IgA
- History of anaphylaxis or other severe systemic reaction to Alpha$_1$-PI products.

**Please see additional Important Safety Information on reverse and the accompanying GLASSIA Full Prescribing Information.**

The GLASSIA® OnePath® Start Form is available from your Takeda sales representative.

## For your patients with severe Alpha$_1$-antitrypsin deficiency with clinically evident emphysema:

1

**GLASSIA®** [Alpha$_1$-Proteinase Inhibitor (Human)] Injection Solution is the first and only liquid Alpha$_1$-antitrypsin deficiency augmentation therapy with 12 years of market experience.[1]

2

**YOUR TAKEDA SALES REPRESENTATIVE**

serves as a resource dedicated solely to Alpha$_1$ and knowledgeable on Takeda augmentation products and services.

3

**ONEPATH®** is Personalized Product Support after you and your patient choose a treatment path. OnePath provides a range of product support services throughout your patient's GLASSIA treatment journey. From the moment your patient enrolls in OnePath, a dedicated Patient Support Manager will work with your patient one-on-one to help him or her to access the support and treatment needed.*

**OnePath is open to all patients taking GLASSIA for its indicated use and who sign the GLASSIA OnePath Start Form which provides OnePath with consent to provide services.*


## IMPORTANT SAFETY INFORMATION, CONTINUED

### Warnings and Precautions

**Hypersensitivity:** GLASSIA may contain trace amounts of IgA. Monitor vital signs continuously and observe the patient throughout the infusion. If hypersensitivity symptoms occur, discontinue the infusion and administer appropriate emergency treatment. Have epinephrine and/or other appropriate supportive therapy available for any acute anaphylactic or anaphylactoid reaction.

**Transmissible Infectious Agents:** Because GLASSIA is made from human plasma it may carry a risk of transmitting infectious agents such as viruses, the variant Creutzfeldt-Jakob disease (vCJD) and theoretically, the Creutzfeldt-Jakob disease (CJD) agent and other pathogens. No seroconversions for hepatitis B or C or human immunodeficiency virus or any other known infectious agent were reported with the use of GLASSIA during the clinical trials.

### Adverse Reactions

The serious adverse reaction observed during clinical trials with GLASSIA was exacerbation of chronic obstructive pulmonary disease (COPD).

The most common adverse reactions (>0.5% of infusions) in clinical trials were headache and upper respiratory infection.

**Please see the accompanying GLASSIA Full Prescribing Information.**

### Reference

1. GLASSIA [Alpha$_1$-Proteinase Inhibitor (Human)] Injection Solution, prescribing information. Lexington, MA: Baxalta US Inc. June 2017.

Takeda