Amicus assist™

ENROLMENT AND CONSENT FORM

Tel: 1-833-239-6139 Fax: 1-833-297-8808
Email: AmicusAssistProgram@innomar-strategies.com

1.0 PATIENT INFORMATION

Name (Last, First): _____ Gender: ☐ M ☐ F Date of Birth (MM/DD/YYYY): _____

Address: _____ City: _____ Province: _____ Postal Code: _____

Home Phone: _____ Work Phone: _____ Cell Phone: _____

Preferred Language: ☐ English ☐ French ☐ Other _____

Time to Contact: ☐Morning ☐Afternoon ☐Evening Preferred Number: ☐Home ☐Work ☐Cell OK to Leave Message: ☐Home ☐Work ☐Cell

Email: _____ Health Card Number: _____

Diagnosis: Late Onset Pompe Disease: Yes / No Other: _____

Current Medications: _____

_____

2.0 PATIENT CONSENT

This Program does not provide medical advice and does not replace the need for you/the patient you are signing on behalf of (collectively "you" or "your") to speak with your treating healthcare provider for medical related inquiries.

I, the undersigned, have read the terms and conditions and, I understand and agree with the service offered by the Program and the consent and permission on the **pages 3 and 4** of this form.

I confirm that the pharmacy indicated on this form, is my chosen pharmacy and is the intended recipient of the prescription provided by my healthcare professional.

Signature of Patient or Legal Representative: _____ Date (MM/DD/YYYY): _____

Printed Name of Patient or Legal Representative: _____ Legal Representative Relationship to Patient: _____

☐**Yes** ☐**No** I declare that I am 18 years or older. I consent to the receipt of electronic communications from the Administrator, and Program Personne and other third parties, as described in page 3 and 4 of this Form, for the purposes of determining my eligibility for the Program, conducting Program-related activities and in the delivery of Program services to me. Email communications may be sent to the address I have provided. I understand I can withdraw my consent at any time. Detail on the withdrawal of your consent are contained on page 4 of this document.

IMPORTANT: If healthcare provider is unable to obtain written consent from patient, please document when patient verbal consent was obtained. This will allow the program to continue with processing this enrolment. Written consent will be obtained by the program. Verbal consent obtained by healthcare provider.

Name: _____ Date (DD/MM/YYYY): _____

3.0 PHYSICIAN INFORMATION

Physician Name: _____ Specialty: _____

Address: _____ City: _____ Province: _____ Postal Code: _____

Telephone: _____ Fax: _____ Email: _____

Time to Contact: ☐Morning ☐Afternoon ☐Evening Method of Contact: ☐Telephone ☐Fax ☐Email

By providing your contact information, you consent to receiving communications related to the Program, your patient's health condition(s) or treatment(s). This consent is being requested by Amicus Therapeutics and the Administrator of the Program.

I understand that I may revoke this consent at any time by sending a signed request to the Administrator at: AmicusAssistProgram@innomar-strategies.com. Notwithstanding any withdrawal, my information may still be used or disclosed if permitted or required by applicable laws. For further information on the privacy practices of the Program, I may access a copy of the Administrator's privacy policy at https://www.innomar-strategies.com/privacy-policy and a copy of the Amicus Therapeutic's privacy policy is available here: https://www.amicustherapeutics.ca/privacy-notice

4.0 PRESCRIPTION

PATIENT NAME: _____

DATE OF BIRTH (MM/DD/YYYY): _____ PATIENT WEIGHT: _____

PRODUCT NAME: **PrOPFOLDA® (miglustat) 65 mg hard capsules**

PrOPFOLDA® is for oral use and should be taken on an empty stomach. The patient must fast 2 hours before and 2 hours after taking PrOPFOLDA®

☐ For patients weighing ≥50 kg, the recommended dose is 260 mg (4 capsules of 65 mg) every other week **Quantity:** _____ **Refill X:** _____

☐ For patients weighing ≥40 kg to <50 kg, the recommended dose is 195 mg (3 capsules of 65 mg) every other week **Quantity:** _____ **Refill X:** _____

PRODUCT NAME: **PrPOMBILITI® (cipaglucosidase alfa) 105 mg for infusion**

Number of 105 mg vials _____ per infusion **Quantity:** _____ **Refill X:** _____

Recommended dosage for PrPOMBILITI®: 20 mg/kg of actual body weight administered intravenously every other week

Calculating the dose

Determine the number of PrPOMBILITI® vials to be reconstituted based on patient's body weight.

1.Patient's body weight (kg) x dose (mg/kg) = Patient dose (mg)

2.Patient's dose (in mg) divided by 105 (mg per vial) = Number of vials to reconstitute

• If the number of vials includes a fraction, round up to the next whole number.

Example: in a 65 kg patient dosed at 20 mg/kg

• *Patient dose (mg): 65 kg x 20 mg/kg = 1300 mg total dose*

• *Number of vials to reconstitute: 1300 divided by 105 mg per vial = 12.38 vials and round up to 13 vials*

Special Instructions (eg, premedication and/or treatment during infusion with corticosteroids, oral antihistamines, and antipyretics may be administered to assist with signs and symptoms related to IARs): _____

_____

_____

By signing the above prescription, I confirm that:

- I am the patient's attending healthcare provider.
- I have read the Enrolment and Consent Form and understand the services offered within the Program.
- I have discussed the Amicus Assist Patient Support Program with the patient and the patient is interested in enrolling in the Program. The patient has consented to me filling out the Enrolment and Consent Form, which includes personal information of the patient, and communicating it to the Administrator for enrolment in the Program.
- The patient agrees to be contacted by the Administrator to initiate enrolment in the Program.
- I certify that my patient's condition is within the indications listed in the current POMBILITI and OPFOLDA Product Monographs and that the dosage is appropriate based on my clinical judgement.
- I understand that I may be contacted by the Administrator, as set forth in the "Physician Information" section of this form, to provide or be provided with information related to Program services provided to the patient.
- I authorize the Administrator to be my designated agent to forward this prescription by any mode of delivery to the pharmacy chosen by the patient. The prescription attached to this form is the original prescription.
- I understand that anonymized prescribing information may be used by Amicus Therapeutics or the Administrator for statistical analysis and research purposes relevant for business planning of the Program.
- I consent to the use and transfer of my name, license number, and coordinates to the appropriate payers to assist with the transfer of my patient into the reimbursement program (where applicable).
- I also agree to the disclosure of appropriate clinical documentation to third parties contracted by Amicus Therapeutics, to the extent that such disclosure is in accordance with the Terms and Conditions of this form. I understand that should my patient meet the criteria to continue in the Program, a new prescription will be required.
- I understand that should my patient continue in the Program, this consent extends to the duration of my patient's involvement in the Program.
- I understand that Amicus Therapeutics reserves the right to terminate, modify, and/or transfer the Program to another Program Administrator at any time for any reason. I understand that Adverse Events may be reported about patients participating in the Program and that I may be contacted by Amicus Therapeutics or the Program Administrator to provide follow-up information related to the Adverse Event. Adverse Event reports may be forwarded to Regulatory authorities in and outside of Canada.

Physician Signature: _____ License No.: _____ Date (DD/MM/YYYY): _____

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AGREEMENT TO DISCLOSE PERSONAL INFORMATION

Fax this form to: 1-833-297-8808

Administrator is Innomar Strategies Inc. located at 3470 Superior Court, Oakville, Ontario, L6L 0C4 and 2600 Alfred-Nobel, Ville Saint-Laurent, QC, H4S 0A9.
Personal Information includes, without limitation, my personal information (name, address, phone number, date of birth, financial information etc.) and personal health information (medical history, medical condition(s), information relating to my treatment, information relating to my health insurance, etc.).
Healthcare Providers include, without limitation, my doctors, nurses, pharmacists and health insurer(s).

Amicus Assist Program is the PROGRAM NAME and the personnel provided by Amicus for the purpose of assisting patients in obtaining access to PrGALAFOLD® (Migalastat) or POMBILITI (cipaglucosidase alfa) with OPFOLDA (miglustat). **Amicus Assist Program personnel** includes the employees and consultants of the Administrator.

Amicus (the "***Manufacturer***") has contracted with the Administrator to provide the Amicus Assist™ Program (the "***Program***").

As part of my enrolment in the Program, I agree and consent to the following:

- My Healthcare Providers, the Administrator, the Manufacturer and Amicus Assist personnel ("***Program Personnel***") may collect, use, disclose amongst each other and store my Personal Information for the purposes of determining my eligibility for the Program, conducting Program related activities and delivering Program services to me; and
- Program Personnel may contact me regarding my Personal Information or any other information required for the administration of the Program.

I further understand that:

- Enrolment is voluntary.
- The Administrator is required to collect, use and store my Personal Information at all times in accordance with applicable laws including the Personal Information Protection and Electronic Documents Act and any substantially similar applicable provincial legislation governing the protection of personal information.
- The Administrator, the Manufacturer and Program Personnel will not collect, use, disclose or store my Personal Information for any activity other than the activities outlined above, unless required or permitted by law.
- My Personal Information will be provided to health insurers and public organizations responsible for reimbursement of the medicines (if applicable)
- My anonymized information may be aggregated with other patient's information, and provided to the Manufacturer, the Administrator and Program Personnel, as well as public and private insurers, to report on, assess, audit, monitor, improve or evaluate the Program or use it for research, education, business analytics, marketing, forecasting, publication or to identify trends such as product utilization, adherence and outcomes.
- The Manufacturer/Administrator may provide my Personal Information to an affiliate or to a third-party service provider that will process or store my Personal Information for the purpose of administering the Program.
- The Manufacturer may provide my Personal Information to a new Administrator appointed by the Manufacturer to administer the Program if the Manufacturer chooses to work with a different Administrator.
- My Personal Information may be disclosed and/or transferred to an affiliate of the Manufacturer or to a third-party in the event of a proposed or actual purchase, sale, lease, merger, amalgamation or other type of acquisition, disposal, transfer, conveyance, or financing of the Manufacturer.
- My Personal Information may be collected, used, disclosed and/or stored outside of my province or territory or country, and that the laws of those countries regarding privacy may be less stringent than the laws of Canada and its provinces.
- My Personal Information will be retained for no longer than the maximum period allowed by law.
- This authorization will remain in effect only if my information is needed to fulfill the purposes for which it was collected and in order to be compliant with applicable laws.
- Notwithstanding the foregoing, the Manufacturer may, either directly or indirectly through a third party auditor, access Personal Information collected by Administrator for quality control purposes or to ensure Administrator's compliance with applicable law.
- The Manufacturer reserves the right to change or terminate the Program or any of its services and replacing any of its service providers, at any time, at the Manufacturer's sole discretion with notice to me.
- Except where prohibited by law, I may obtain a copy of my Personal Information and may correct any errors and/or direct any questions regarding the collection, use, disclosure and storage of my Personal Information to the Administrator at the address below.
- Telephone calls to or from the Administrator in the course of its administration of the Amicus Assist Program may be monitored or recorded for the mutual protection of me and the Administrator.
- This consent is valid for as long as I receive services from the Program and for a reasonable time thereafter. My Personal Information will be kept for the duration of my participation in the Program and will thereafter be deleted in accordance with the Manufacturer's document

retention policies, subject to legal and regulatory requirements.

- I may withdraw my consent at any time by mailing or faxing a signed request to the Administrator at the fax number set out above or to the Administrator at the address below, but if I do so, I understand that to the extent that such consent is necessary to provide the services under the Program, my participation in the Program may be terminated and, among other things, I may not be able to get help with reimbursement for [Pr]POMBILITI® and [Pr]OPFOLDA®.
- The Manufacturer may collect my Personal Information on my use of [Pr]POMBILITI® and [Pr]OPFOLDA® relative to any unwanted drug effects (side effects or adverse events) that I may experience while taking [Pr]POMBILITI®, [Pr]OPFOLDA®or other medications and by law, the Manufacturer must provide this information to Health Canada or other government agencies to track the safety record of medications. The Manufacturer may also contact my healthcare provider if they need more information on an adverse drug event.
- For further information on the privacy practices of the Program I may access a copy of the Manufacturer's Privacy Policy available here, https://www.amicustherapeutics.ca/privacy-notice or by writing to dataprivacyofficer@amicusrx.com,

- I am entitled to a copy of this document.
- I agree that:
    - medication provided through this Program is for my personal use only;
    - medication provided through this Program will not be sold, traded, bartered, transferred or returned for credit; and
    - any product provided to me through this Program will not be submitted to any third-party for reimbursement.

- By signing the form, I confirm that:
    - the information provided is complete and accurate;
    - I have read, understood, consent and agree to the use, disclosure and/or storage of my Health Information as outlined within this Enrolment and Consent Form;
    - I consent to enroll in the Program;

It is the express wish of the parties that this enrolment and consent form and all related documents, including notices and other communications, be drawn up in the English language only.

I consent to the use of my Personal Information for the purposes set out above.

Signature of Patient or Legal Representative

Date (DD/MM/YYYY)

Printed Name of Patient or Legal Representative