Connect 360 Patient Support Program

Saphnelo™ anifrolumab for injection

# SAPHNELO™ Enrollment and Consent Form – Connect 360 Patient Support Program

SAPHNELO™ (anifrolumab for injection) is indicated in addition to standard therapy for the treatment of adult patients with active, autoantibody positive systemic lupus erythematosus (SLE).

**Form cannot be processed without physician's and patient's/legal representative's consent. Physicians may certify that they have obtained verbal consent of the patient for enrolment. The use of the word "Product" in this form is a reference to SAPHNELO™.**

Fax the pages of the completed form to **1-833-814-0259** or email to **support@connect360sle.ca**. Please complete all fields to minimize delays. For immediate inquiries, please call **1-833-814-0258**.

## 1. Patient Information (Patient Section)

First Name: | Last Name: | Gender: ☐ M ☐ F | Date of Birth (DD/MM/YYYY): ____ /____ /____ | Preferred Language: ☐ EN ☐ FR

Health Card Number: | Home Address: | City: | Province: | Postal Code:

Email Address: | Home Phone: | Cell Phone: | Best Time to Be Reached: ☐ Morning ☐ Afternoon ☐ Evening | Permission to Leave a Message: ☐ Yes ☐ No | Permission to Send a Text Should We Have Texting Capabilities In The Future: ☐ Yes ☐ No

Authorization to Speak to Patient's Caregiver: ☐ Yes ☐ No | Caregiver Name (First, Last): | Relationship to the Patient: | Caregiver Phone Number:

## 2. Patient Consent (Patient Section)

**Required consent statement (patient OR verbal):**

SEE FULL PATIENT CONSENT AND PRIVACY INFORMATION SECTION ON PAGE 2. PLEASE ENSURE YOU HAVE READ AND FULLY UNDERSTAND THIS INFORMATION.

☐ I have read and understand the Patient Consent and Privacy Information on the reverse and agree to the collection, use and disclosure of my personal information and health information in accordance with those terms.

Patient Signature: _____ Date (DD/MM/YYYY): ____ /____ /____

☐ Patient has given verbal consent to proceed with enrollment at this time, and the Program Administrator will provide the Patient Consent and Privacy Information at a later date.

Name of Person Collecting Verbal Consent: | Signature: | Date Verbal Consent Was Collected (DD/MM/YYYY): ____ /____ /____

**Optional consent statements:**

*Your decision on the following checkboxes will have no impact on your ability to access the products and services through this program.*

Do you consent to:

☐ Yes ☐ No Be connected with patient advocacy organization(s) for patient advocacy opportunities.

☐ Yes ☐ No Be contacted by AstraZeneca's Program Administrator or a third party working on its behalf for purposes of market research to help improve our support programs, patient and clinician information and diagnostic testing initiatives.

☐ Yes ☐ No Be contacted by an AstraZeneca Medical Evidence Lead or a third party working on its behalf, to understand your interest in participating in a real-world study.

## 3. Prescription (Physician Section)

**SAPHNELO™**

300 mg IV Q4W x ____ repeats

**Medical Directive:**

I approve to start SAPHNELO™ upon enrolment to the Connect360 Patient Support Program.

☐ Yes ☐ No Anticipated Start Date (DD/MM/YYYY): ____ /____ /____

Physician Name: | Physician Signature: | License Number: | Date (DD/MM/YYYY): ____ /____ /____

## 4. Prescribing Physician Information (Physician Section)

Physician First Name: | Physician Last Name: | Administrator/Office Contact Name:

Office Address: | City: | Province: | Postal Code:

Office Contact E-mail Address: | Office Phone: | Office Fax: | Preferred Contact Method: ☐ Email ☐ Phone ☐ Fax | Would You Like to Receive Post Infusion Reports: ☐ Yes ☐ No

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## 5. Patient Eligibility (Physician Section)

☐ I hereby confirm the patient is ≥18 years of age and is being prescribed SAPHNELO™ in addition to standard therapy for the treatment of adult patients with active, autoantibody positive systemic lupus erythematosus (SLE) as per the Product Monograph.

Recent SLE index score: _____ ☐ SLEDAI 2K Date of score (DD/MM/YYYY): ____ /____ /_____

Treatment for SLE (please indicate the medications the patient is receiving or received in the past, including the most recent dose)

| | Medication and dosage | If discontinued, indicate reason |
|---|---|---|
| Steroids | ☐ Prednisone: ☐ ≥1 and <7.5 mg ☐ ≥7.5 and <10 mg ☐ ≥10 mg Frequency: _____ ☐ PO ☐ IV | |
| Steroids | ☐ Other steroid: _____ : _____ mg Frequency: _____ ☐ PO ☐ IV | |
| Antimalarials | ☐ Hydroxychloroquine: _____ mg PO | |
| Antimalarials | ☐ Chloroquine: _____ mg Frequency: _____ ☐ PO ☐ IV | |
| Immunosuppressants | ☐ Methotrexate: _____ mg Frequency: _____ ☐ PO ☐ IM | |
| Immunosuppressants | ☐ Mycophenolate mofetil: _____ mg Frequency: _____ ☐ PO ☐ IV | |
| Immunosuppressants | ☐ Azathioprine: _____ mg Frequency: _____ ☐ PO ☐ IV | |
| Immunosuppressants | ☐ Cyclophosphamide: _____ mg Frequency: _____ ☐ PO ☐ IV | |
| Immunosuppressants | ☐ Other Immunosuppressants: _____ | |
| | ☐ Prior biologic: _____ | |

## 6. Physician Authorization (Physician Section)

I certify that I am the patient's prescribing physician and confirm that the patient has been prescribed the Product as per the Canadian Product Monograph. This Product has been prescribed for this patient based on my independent medical judgment and the patient's informed consent.

I agree to be contacted by NavieGo Patient Programs Ltd & Affiliates, or the current administrator of the Program, if different (the "Program Administrator"), about the patient, the Product, the connect 360 (the "Program") and any adverse events or Product complaints.

I consent to the use of my prescribing information for the purpose of administering, monitoring, and assessing the Program. My personal information will be collected, stored and processed for use as described in this informed consent form.

Questions regarding privacy and compliance may be addressed to the Program Administrator's Privacy Officer via email (privacyofficer@bioscript.ca) or telephone (1-888-734-3814).

I authorize the Program Administrator in the context of the Program to be my designated agent to forward the prescription by fax or other mode of delivery to the pharmacy chosen by the above-named patient.

This prescription represents the original prescription drug order.

I agree to keep all confidential information provided to me about the Program in strict confidence and shall not, without AstraZeneca's prior written consent, disclose any confidential information to any third party.

Physician Signature: License Number: Date (DD/MM/YYYY): ____ /____ /_____

**Patient Consent and Privacy Information**

The purpose of the Connect360 Patient Support Program ("Program") is to provide patients with support including reimbursement navigation and/or services related to the Product.

The Program is being managed by AstraZeneca Canada Inc. ("AstraZeneca") and is administered by NavieGo Patient Programs Ltd & Affiliates ("Program Administrator"), an independent third party. AstraZeneca may, at its sole discretion, appoint a new program administrator at any time. By signing this informed consent form, you consent to the transfer of your Personal Information, as well as the prescription itself (if applicable), to any future program administrator, if required.

You understand that the Program is not intended to provide medical advice or medical diagnoses. You should always seek the advice of your physician if you have any health concerns. You have discussed the benefits and risks of the Product with your physician and have decided to start treatment. You understand that (i) it is your right to refuse to sign this consent form, (ii) if you do not give such consent, you will not be provided with access to the Program, and (iii) you do not need to participate in the Program to obtain the Product; however, AstraZeneca and the Program Administrator do not provide support for Product not obtained via the Program.

AstraZeneca reserves the right at any time, without notice, to modify, discontinue or terminate the Program.

By signing this form you agree to enroll in the Program and authorize for your information, including contact information and information about your insurance, prescriptions, medical condition, diagnostic test results and other health information from your health care providers ("Personal Information") to be collected, used and disclosed as described in this informed consent form. In addition, you consent to the Program Administrator contacting you to provide the Program services.

**Personal Information: Collection, Use and Disclosure**

To participate in the Program, you are required to provide your Personal Information to the Program Administrator and you authorize the Program Administrator to contact your insurer and your healthcare providers for additional information.

AstraZeneca will have access to Personal Information for Program auditing and troubleshooting purposes and when required to fulfill its legal adverse drug event reporting and complaints handling obligations to Health Canada.

Information collected during your participation in the Program by the Program Administrator may be provided to AstraZeneca in a coded format which may be used by AstraZeneca for internal evaluation purposes, such as and to determine whether certain aspects of the Program require refinement. Coded information means that information that can personally identify you is replaced by a code. Only the Program Administrator has a key to that code.

Your Identifiable Personal Information will be confidentially collected, used and disclosed by the Program Administrator to provide the Program services, such as the delivery of the Product to your home and the administration and monitoring of the Program, and may be shared with:

- AstraZeneca for Program auditing and troubleshooting purposes and to fulfill its legal adverse drug event reporting and complaints handling obligations to Health Canada;
- public and private insurers for the purpose of investigating drug reimbursement options; and
- healthcare provider(s), who may share your personal information with your insurers for the purpose of investigating drug reimbursement options.

Personal information may also be shared with or accessible by service providers of the Program Administrator or AstraZeneca (including affiliates acting in this capacity). Some of these service providers may be located outside of Canada, including in Ireland, Mexico, and India.

Your Personal Information collected as part of the Program will be protected by reasonable physical, administrative, and technical safeguards to protect it against loss, theft and unauthorized consultation, communication, copying, use or alteration.

**Aggregated Data**

AstraZeneca may also use your coded data to generate fully de-identifiable aggregated data that does not contain Personal Information (the "Aggregated Data"). AstraZeneca may use the Aggregated Data for any lawful purpose, including but not limited to: clinical research, market research and clinical publications. It may also share it with third parties for research purposes and to determine whether certain aspects of the Program require refinement. Any third parties who receive such Aggregated Data must agree that they will not attempt to make the information personally identifiable, such as by combining it with other databases.

**Drug Safety**

AstraZeneca is legally required to report adverse drug events to Health Canada and to monitor Product complaints. As such, AstraZeneca, its representative and the Program Administrator may use and report your personal information for these purposes. The Program Administrator may contact you or your physician for additional information to fulfill these obligations.

**Consents can be Withdrawn**

You may withdraw your consent and authorizations at any time by sending a letter to NavieGo Patient Programs Ltd & Affiliates at 1234 Main St., Suite 400 Moncton, NB, Canada E1C 1H7.

You understand that withdrawal of your consent and authorizations will end further uses and disclosures of the Personal Information and may end your enrollment in the Program. The withdrawal of consent and authorizations will not be retroactive and any activities relating to your Personal Information prior to your withdrawal will not be affected. You may ask any questions about privacy and compliance to the Program Administrator's Privacy Officer by email (privacyofficer@bioscript.ca) or telephone (toll free: 1-888-734-3814).

For more information on the Product, please consult the Consumer Information section of the Product Monograph at https://www.astrazeneca.ca/content/dam/az-ca/downloads/productinformation/saphnelo-product-monograph-en.pdf.

Consult the Product Monograph at https://www.astrazeneca.ca/content/dam/az-ca/downloads/productinformation/saphnelo-product-monograph-en.pdf for contraindications, warnings, precautions, adverse reactions, drug interactions, dosing information, and conditions of clinical use. The Product Monograph is also available through our medical department. Call us at 1-800-668-6000.

SAPHNELO™ (anifrolumab for injection) is indicated in addition to standard therapy for the treatment of adult patients with active, autoantibody positive systemic lupus erythematosus (SLE).

Please consult the SAPHNELO™ Product Monograph at https://www.astrazeneca.ca/content/dam/az-ca/downloads/productinformation/saphnelo-product-monograph-en.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, drug interactions, dosing information and conditions of clinical use. The Product Monograph is also available by calling us at 1-800-668-6000.

Connect 360 Patient Support Program is administered by NavieGo Patient Programs Ltd & Affiliates on behalf of the Sponsor AstraZeneca Canada Inc., whose policy on terms of use can be found at https://www.astrazeneca.ca/en.

**PHONE: 1-833-814-0258 PROGRAM FAX: 1-833-814-0259 E-MAIL: support@connect360sle.ca**

**Reference: 1.** SAPHNELO™ Product Monograph. AstraZeneca Canada Inc. November 30, 2021.

Please complete all sections in their entirety to ensure accuracy of the submission. Fax ALL pages of the completed form to 1-833-814-0259 or email to support@connect360sle.ca.

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REVIEWED BY PAAB

AstraZeneca