AstraZeneca Oncology Patient Support Program CALQUENCE Enrollment and Consent Form



Form cannot be processed without physician's and patient's/legal representative's consent.

Fax the completed form to <u>1-877-280-6221</u> or email to <u>enrollment@azoncologypsp.ca</u>.

Please complete all fields to minimize delays. For immediate inquiries, please call 1-877-280-6208.

CALQUENCE (acalabrutinib tablets) is indicated:1

- in combination with obinutuzumab or as monotherapy for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL).
- as monotherapy for the treatment of patients with CLL who have received at least one prior therapy.

SECTION 1: PATIENT INFORMATION (Patient Section)

- in combination with bendamustine and rituximab for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are ineligible for autologous stem cell transplant.
- for the treatment of patients with MCL who have received at least one prior therapy.

The use of the word "Product" in this form is a reference to CALQUENCE (acalabrutinib tablets).

Patient First Name:					Patient Last Name:							
Date of Birth (DD/MM/YYYY):					Sex:	М	F	Other	Language:	En	Fr	
Legal Representative Name												
Patient Home Address:					City:							
Province/Territory:					Postal Code:							
Email Address:												
Mobile Phone:					Alternative Phone:							
Best Time to be Reached:	ime to be Reached: Morning Afternoon			Ever	Evening							
Best Method of Contact:	Call	Ema	il									
May we leave a voicemail or a message with someone who answers? Yes No												
Health Card Number:				Insura	nce Typ	e:	Priva	te Pul	olic			
SECTION 2: PATIENT CONSENT (Patient Section)												
SEE FULL PATIENT CONSENT AND PRIVACY INFORMATION SECTION ON PAGE 3. PLE 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 has given verbal consent to proceed with enrollment at							
Patient Signature					Name of Person Collecting Verbal Consent							
Date (DD/MM/YYYY):					<u> </u>							
					Signature Date Verbal Consent							
		Collected (DD/MM/YYYY):										
OPTIONAL INFORMATION	(Patient	Sectio	n)									
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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 contacted by an AstraZeneca Medical Evidence Lead, or a third party working on its behalf, to understand your interest in participating in real-world evidence.
 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 AstraZeneca's behalf, for purposes of market research to help improve our support programs, patient and clinician information and any diagnostic testing initiatives.

SECTION 3: PRESCRIBING PHYSICIAN INFORMATION (Physician Section) First Name: Last Name: Clinic Name and Address: Administrator/Office Contact Name: Province: City: Office Contact Email Address: Postal Code: Office Phone: Office Fax: Preferred Method of Communication: **Email** Fax Both Secondary Point of Contact Name: Email: **SECTION 4: PATIENT ELIGIBILITY (Physician Section)** I hereby confirm the patient is ≥18 years of age and is being prescribed CALQUENCE in accordance with one of the following indications. A. First-line setting CLL In combination with obinutuzumab or as monotherapy Genomic aberrations: del17p TP53 Unknown, FISH test results have been ordered. Date ordered: If del17p and/or TP53 genomic aberrations, please provide mutational status if known. Note, mutational status is not required to initiate the enrollment process. umIGHV mIGHV IGHV unknown, test results have been ordered. Date ordered: Has received at least one prior therapy B. Previously treated CLL C. First-line setting MCL In combination with bendamustine and rituximab Date of bendamustine and rituximab Cycle #1 (DD/MM/YYYY): Is the patient eligible for autologous stem cell transplant? ECOG Performance Status: 0 1 Has the patient received prior systemic anticancer therapies for MCL? No D. Previously treated MCL Has received at least one prior therapy del17p=deletions in chromosome 17p; ECOG=Eastern Cooperative Oncology Group; IGHV=Immunoglobulin Heavy Chain Variable region genes; mIGHV=mutated Immunoglobulin Heavy Chain Variable region genes; TP53=tumour protein p53; umlGHV=unmutated Immunoglobulin Heavy Chain Variable region genes. SECTION 5: PRESCRIBING 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 AstraZeneca Oncology Support Program (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 within Canada where local laws apply. Questions regarding privacy and compliance may be addressed to the Program Administrator's Privacy Officer via email (privacyofficer@bioscript.ca) or telephone (toll free: 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 Date (DD/MM/YYYY) **SECTION 6: PRESCRIPTION INFORMATION (Physician Section)** Allergies: None or specify: Recommended Dosage: CALQUENCE (acalabrutinib tablets): 100 mg twice daily[†] Doses should be separated by approximately 12 hours. Treatment with CALQUENCE should continue until disease progression or unacceptable toxicity. Quantity: month(s) Repeat: License #:

† Consult the Product Monograph at calquence-tablet-en.azpm.ca for complete dosing information.

Date (DD/MM/YYYY)

Physician Signature

Patient Consent and Privacy Information

About the Program

The purpose of the AstraZeneca Oncology Patient Support Program ("Program") is to provide patients with support including reimbursement navigation and 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 healthcare 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-identified 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 representatives 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 (1-888-734-3814).

For more information on the Product, please consult the patient medication information section of the Product Monograph at https://www.astrazeneca.ca/en/our-medicines.html.

Consult the Product Monograph at <u>calquence-tablet-en.azpm.ca</u> for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available through our medical department. Call AstraZeneca Canada at 1-800-668-6000.

Reference: 1. CALQUENCE (acalabrutinib tablets) Product Monograph. AstraZeneca Canada Inc.



AstraZeneca **2**

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