AstraZeneca Oncology Patient Support Program

PrTRUQAP™ (capivasertib tablets)
Enrollment and Consent Form

AstraZeneca ONCOLOGY PATIENT SUPPORT PROGRAM

Patient section Physician section

Form cannot be processed without physician's and patient's/legal representative's consent.
Fax the completed form to **1-877-280-6221** or email to **enrollment@azoncologypsp.ca**.
Please complete **all fields** to minimize delays. For immediate inquiries, please call **1-877-280-6208**.

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

SECTION 1: PATIENT INFORMATION (Patient Section)

Clear Form

First Name: _____ Last Name: _____

Date of Birth (DD/MM/YYYY): _____ Sex: ☐ M ☐ F ☐ Other Language: ☐ En ☐ Fr

Legal Representative Name (if applicable): _____

Home Address: _____ City: _____

Province/Territory: _____ Postal Code: _____

Email Address: _____

Mobile Phone: _____ Alternative Phone: _____

Best time to be reached: ☐ Morning ☐ Afternoon ☐ Evening Best method of contact: ☐ Call ☐ Email

May we leave a voicemail or a message with someone who answers? ☐ Yes ☐ No

Insurance Type: ☐ Private ☐ Public ☐ Unsure

SECTION 2: PATIENT CONSENT (Patient Section)

SEE FULL PATIENT CONSENT AND PRIVACY INFORMATION SECTION ON PAGE 4. 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): _____

OR

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 Collected (DD/MM/YYYY): _____

OPTIONAL INFORMATION (Patient Section)

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 a real-world study.

☐ **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 diagnostic testing initiatives.

SECTION 3: PRESCRIBING PHYSICIAN INFORMATION (Physician Section)

First Name: _____ Last Name: _____

Clinic Name and Address: _____

Administrator/Office Contact Name: _____

City: _____ Province: _____

Postal Code: _____ Office Contact Email Address: _____

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 TRUQAP as per the indication in the Product Monograph.

For Treatment In:

☐ TRUQAP is indicated, in combination with fulvestrant, for the treatment of adult females with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer with one or more *PIK3CA/AKT1/PTEN* alterations following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

Other Required Information:

1. ECOG performance status:
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

2. AKT alteration status (check all that apply) and **include the corresponding test result report:**
☐ *PIK3CA* ☐ *AKT1* ☐ *PTEN* mutation

3. Developed recurrence while on or within 12 months of completing adjuvant endocrine therapy: ☐ Yes ☐ No

4. Number of prior lines of endocrine therapy in the metastatic setting: ☐ 0 ☐ 1 ☐ 2 ☐ >2

5. Number of prior lines of chemotherapy for treatment (to disease progression or toxicity) in the metastatic setting:
☐ 0 ☐ 1 ☐ >1

6. Progression on prior treatment with fulvestrant:
☐ Yes ☐ No

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 Patient 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 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 Date (DD/MM/YYYY)

AKT=serine/threonine protein kinases; *AKT1*=serine/threonine protein kinase 1; ECOG=Eastern Cooperative Oncology Group; HER2=human epidermal growth factor receptor 2; HR=hormone receptor; *PIK3CA*=phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha; *PTEN*=phosphatase and tensin homolog.

SECTION 6: PRESCRIPTION INFORMATION (Physician Section)

Patient initials: _____ Allergies: ☐ None ☐ or specify: _____

Route of Administration: Oral

Dosage Instructions:

- The recommended dose of TRUQAP in combination with fulvestrant is 400 mg (two 200 mg tablets) taken orally (PO) twice daily (BID) (approximately 12 hours apart) with or without food, for 4 days followed by 3 days off treatment.
- When used in combination with TRUQAP, the recommended dose of fulvestrant is 500 mg administered on Cycle 1, Days 1 and 15, and then at Day 1 of a 28-day cycle. Refer to the fulvestrant Product Monograph for detailed conditions of use.
- Treatment with TRUQAP should continue until disease progression or unacceptable toxicity occurs.

Selected TRUQAP dosing strength:

☐ **Recommended dosage:**
TRUQAP (capivasertib) **400 mg**
PO BID (2 X 200 mg tablets BID)
Quantity: _____ month(s)
Repeat: _____

☐ **Reduced dosage:**
TRUQAP (capivasertib) **320 mg**
PO BID (2 X 160 mg tablets BID)
Quantity: _____ month(s)
Repeat: _____

☐ **Reduced dosage:**
TRUQAP (capivasertib) **200 mg**
PO BID (1 X 200 mg tablet BID)
Quantity: _____ month(s)
Repeat: _____

☐ For pre-/peri-menopausal women, TRUQAP plus fulvestrant should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist. I understand that funding of the LHRH agonist must be secured for use in combination with TRUQAP plus fulvestrant, outside of the AstraZeneca Oncology Patient Support Program.

☐ I understand that funding of fulvestrant must be secured for use in combination with TRUQAP outside of the AstraZeneca Oncology Patient Support Program.

Both TRUQAP and fulvestrant should be started on the same day (Day 1 Week 1 Cycle 1).

Please consult the TRUQAP Product Monograph for more details on dosing, administration, and dose modification following adverse reactions.

Medical Directive:
I approve the patient to start TRUQAP in combination with fulvestrant (as per the indication) immediately upon approval in the Patient Support Program.

☐ **Yes** *By checking this box, I confirm that I understand this medical directive is valid for 14 days within receipt of enrollment.*

☐ **No (pending test results)** ☐ **No (other, please specify: _____)**

License #: _____ Physician Signature: _____

Date (DD/MM/YYYY): _____

Consult the Product Monograph at **truqap-en.azpm.ca** for complete dosing information.

LHRH=luteinizing hormone-releasing hormone.

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 its third-party service provider, NavieGo Patient Programs Ltd & Affiliates (the "**Program Administrator**"). AstraZeneca may, at its sole discretion, appoint a new program administrator at any time.

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. AstraZeneca reserves the right to modify, discontinue or terminate the Program at any time, without prior notice. You do not have to sign this consent form. If you do not sign this consent form, you will not be able to participate in the Program, but 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. If you choose to participate in the Program, you can withdraw at any time. You may also be withdrawn from the Program (for example, if your doctor has decided that you should no longer be prescribed the product).

Privacy Information

In order to provide the Program services, the Program Administrator will collect your name and contact information, information about your insurance, and health information including information about your prescriptions, medical condition, and diagnostic test results ("**Personal Information**"). The Program Administrator may collect this information directly from you, or from your insurer or health care providers.

The Program Administrator will use your Personal Information to:

- Provide the Program services, such as reimbursement navigation, the delivery of Product to your home, and Program monitoring.
- Communicate with you in connection with the Program; if you have provided a mobile telephone number, this may include sending you Program-related communications via text message, which may be subject to charges from your phone plan provider. You can unsubscribe from text messages at any time by replying "STOP".

The Program Administrator may share your Personal Information with:

- AstraZeneca for Program auditing and troubleshooting purposes and to fulfill its legal adverse drug event reporting and complaints handling obligations to Health Canada (see Drug Safety section below for more detailed information);
- public and private insurers for the purpose of investigating your drug reimbursement options;
- healthcare provider(s), who may share your personal information with your insurers for the purpose of investigating drug reimbursement options; and
- any successor program administrator appointed by AstraZeneca to administer the Program; your prescription will also be shared with the successor administrator.

Coded Data: Coded data is information that has been modified by replacing direct identifiers with a code. Only the Program Administrator has the key to that code. AstraZeneca will have access to your coded Personal Information for auditing purposes and internal evaluation purposes (such as to determine whether certain aspects of this Program require improvement), for real-world evidence research (with research ethics board approval), and to create aggregated data, as further described below.

Aggregated Data: AstraZeneca may use your coded data to generate fully anonymous 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, other research projects, market research, clinical publications and generating insights to be used in activities geared at improving patient care. It may also share Aggregated Data with third parties for research or to improve future programs. any third parties that receive Aggregated Data must agree that they will not attempt to make the information personally identifiable, such as by combining it with other databases.

Safeguards

The Program Administrator and AstraZeneca have reasonable physical, administrative, and technical safeguards in place to protect Personal Information in our control against loss, theft and unauthorized access, use or disclosure. Please note that no security measures can guarantee absolute security. If you choose to communicate Personal Information by email, we encourage you to use appropriate security measures, such as encryption.

The Program Administrator is required to maintain Personal Information in Canada. However coded Personal Information may be processed or stored outside your province of residence or outside of Canada including in Ireland, Mexico or India.

Drug Safety

AstraZeneca is legally required to report adverse drug events to various local and international health authorities and to monitor Product complaints. Identifiable Personal Information provided to the Program Administrator may be (i) monitored by AstraZeneca for safety related data to ensure compliance with these legal reporting requirements and (ii) reported to local or international health authorities. The Program Administrator or AstraZeneca may contact you or your physician for additional information to fulfill these obligations.

Your Privacy Rights

You may have the right under applicable law to request access to or correction of your Personal Information, or to request that your Personal Information be transferred to another person. These rights are subject to applicable legal restrictions. If you withdraw your consent, you may no longer be able to participate in the Program. The withdrawal of your consent will not be retroactive and any activities relating to your Personal Information prior to your withdrawal will not be affected. To exercise any of your privacy rights or to ask any questions about privacy and compliance please contact 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**.

Please consult the **TRUQAP Product Monograph** 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.

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