Small Cell Lung Cancer

AstraZeneca Oncology Patient Support Program

PrIMFINZI® 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.

Imfinzi, as monotherapy, is indicated for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy (CRT).

The use of the word "Product" in this form is a reference to IMFINZI (durvalumab).

SECTION 1: PATIENT INFORMATION (Patient Section)

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 AstraZeneca's behalf, to understand your interest in participating in a real-world study.

○ **Yes** ○ **No** Be connected with patient support and 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/Territory:

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 adult patient is being prescribed Imfinzi for the treatment of limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy (CRT).

Required Information:

ECOG performance status: ○ 0 ○ 1 ○ 2 ○ 3+

Select the type of platinum-based CRT (etoposide + carboplatin/cisplatin) the patient received:

○ Sequential

○ Concurrent

Date of CRT completion (dd/mm/yyyy): _____

Planned first infusion date of Imfinzi (dd/mm/yyyy): _____

Has the patient completed radiotherapy with one of the following regimens?

○ Total 60-66 Gy over 6 weeks (standard QD regimen)

○ Total 45 Gy over 3 weeks (hyperfractionated BID schedule)

○ Total 40-45 Gy over 3 weeks (accelerated QD regimen)

○ Other: _____

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) _____

SECTION 6: PRESCRIPTION INFORMATION (Physician Section)

Patient initials:

Allergies: ○ None or specify:

Route of Administration: Intravenous Infusion

Recommended Dosage:
The recommended dose of Imfinzi is 1500 mg every 4 weeks.

Patients with a body weight of 30 kg or less must receive weight-based dosing, equivalent to Imfinzi 20 mg/kg every 4 weeks as monotherapy until weight increases to greater than 30 kg.

Treatment should continue until disease progression, unacceptable toxicity, or a maximum of 24 months.

Please consult the IMFINZI Product Monograph for more details on dosing, administration, and dose modification following adverse reactions. Please also refer to the full prescribing information for the appropriate chemotherapeutic agents, in their respective Product Monographs.

Medical Directive:

I approve the patient to start IMFINZI immediately upon approval in the Patient Support Program.

This medical directive is valid for 6 weeks upon receipt of enrollment.

○ **Yes** ○ **No**

License #: _____ Physician Signature: _____

Date (DD/MM/YYYY): _____

Consult the Product Monograph for complete dosing information.

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 **IMFINZI 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.