PLUVICTO®
lutetium (177Lu) vipivotide tetraxetan injection

PLUVICTO® ENROLLMENT FORM

RLTAssist™ Patient Support Program

Program fax: 1-844-349-8758 **Telephone:** 1-844-747-9758 **Email:** RLT.Assist@novartis.com

Unless encrypted, please be mindful that email communications may not be safe. One form per email.

Signatures are mandatory in prescriber and patient consent sections.

RLTAssist™

A. *PSP SERVICE SELECTION

☐ Diagnostics Coordination

Patient has access to private insurance: ☐ Yes ☐ No

Referral and Treatment Navigation:

☐ Patient education on treatment, expectations, and resources

☐ Acquiring/summarizing referring and/or treatment documentation

☐ RLTAssist™ Travel Assistance Program (TAP)

☐ Program to investigate provincial alternatives to the TAP, understanding that this may require additional work and coordination on my part.

*Should your patient only require TAP, please note that only fields marked with an **asterisk (*)** need to be completed.*

B. PHYSICIAN INFORMATION

***Completed by:** ☐ Referring Physician e.g oncologist, urologist

☐ Treating Physician e.g nuclear medicine physician

*First Name	*Last Name
*License Number	
*Office/Centre Address	

City	*Province	Postal Code
*Phone Number	Extension	
*Fax Number		
*Email		

C. *PRIMARY POINT OF CONTACT FOR PHYSICIAN

☐ Clinical Coordinator ☐ Drug Access Navigator ☐ Nurse

☐ Other: _____

First Name	Last Name
Phone Number	Extension
Fax Number	
Email	

D. *PATIENT SECTION

First Name	Last Name
Address	

City	Province	Postal Code
Date of Birth (DD/MMM/YYYY)	Language Preference ☐ English ☐ French	
Email		
Primary Phone Number	Alternate Phone Number	

May a message be left at either number? ☐ Yes ☐ No

Preferred Method of Contact? ☐ Email ☐ Phone ☐ SMS

☐ *I accept that, by providing my email and/or cell phone number, representatives of the Program may contact me via electronic means such as email and/or text message. **For SMS, message frequencies vary. Standard message rates apply.***

E. *DIAGNOSIS & ELIGIBILITY CRITERIA

☐ **Diagnosis:** PSMA-positive mCRPC (metastatic Castration-Resistant Prostate Cancer) who have received at least one ARPI and taxane-based chemotherapy. To be eligible for treatment, patient must: Have a confirmed diagnosis of mCRPC, have had their tumour PSMA-positivity verified, and have received at least one ARPI and taxane-based chemotherapy.

Last Date of Chemotherapy (dd/mm/yyyy) N/A ☐

Last Date of PSMA PET SCAN (dd/mmm/yyyy) N/A ☐

Date of Tumour Board Review/MCC (dd/mmm/yyyy) N/A ☐

F. PRESCRIPTION & TREATMENT INFORMATION

The recommended PLUVICTO® dose is 7.4 GBq (7400 MBq) (200 mCi) intravenously every 6 weeks for up to 6 doses, or until disease progression, or unacceptable toxicity. Please see the PLUVICTO® Product Monograph for complete dosing and administration information. Dosing is subject to change based on treating physician's determination.

Has patient started treatment? ☐ Yes ☐ No

If YES, how many cycles has patient received? _____

Last cycle date (DD/MMM/YYYY) _____

***Treatment Centre Name**

***Treatment Centre Contact (phone number and/or email)**

***Reference Number Used for Orders**

Reference Number refers to the unique identifier used when ordering product for treatment (also known as a ROME ID).

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PRESCRIBER CONSENT (MANDATORY)

Signature	Date (DD/MMM/YYYY)

ACKNOWLEDGEMENTS AND UNDERTAKINGS

The above prescription parameters comply with the indications set forth in the Product Monograph. I represent, certify and warrant that I can legally order a prescription of the drug product in focus for this PSP.

I have discussed the Patient Support Program ("PSP") with the patient who wishes to enroll and has consented that I share their personal information (name, email, contact number, prescription information) in this form with the PSP to contact patient and confirm enrollment. Additionally, I have explained the uses and communication of the patient's personal information to the patient, as described in the consent section (below).

PERSONAL INFORMATION

I have read and agree to the collection, use and disclosure of my personal information for the purpose of managing the PSP, as set out in the consent section (below).

PSP CONSENT (MANDATORY)

I would like to be enrolled in the RLTAssist™ Patient Support Program. I have read and agree to the collection, use and disclosure of my personal information as explained in the consent section (below). I understand that Novartis reserves the right to modify or terminate the Program without prior notice. The Program may wish to contact me via electronic means; I will have the opportunity to opt out from such communications.

Signature	Date (DD/MMM/YYYY)

IMPORTANT: If written consent cannot be obtained from patient/legal representative, please document when verbal consent was obtained and by whom. This will allow the RLTAssist™ Patient Support Program to proceed with enrollment.

Verbal consent obtained by the HCP from: ☐ Patient ☐ Legal Representative

Name	Relationship
Phone Number	**Email**

Verbal consent obtained by (Name)

Signature	Date (DD/MMM/YYYY)

PSP CONSENT

Welcome to the Novartis Pharmaceuticals Canada Inc. ("Novartis", "we") RLTAssist™ patient support program for PLUVICTO®.

The PSP services are available to any patient meeting the eligibility requirements for enrollment, which typically consist at minimum in a prescription for a drug treatment from an HCP as well as current eligibility under a federal or provincial health insurance plan.

CONSENT TO THE COLLECTION, USE AND DISCLOSURE OF PERSONAL INFORMATION (for more information, see the "Details" section)

Why do we collect personal information for the PSP?

We collect personal information to provide our services. This information can directly identify you (like your name) or indirectly identify you (with enough details). We may also use personal information to comply with regulatory reporting requirements, and for analytical purposes. We will ask for your specific consent if we need to use it for other reasons, unless the law allows us to use it without your consent.

What type of personal information is collected?

Patients: We collect your name, address, phone number, date of birth, health information such as disease information and test results, and caregiver's name.

HCPs: We will collect your name, address, and information about your patients in the PSP, including the number of patients enrolled.

Caregivers or legal guardians: We collect your name, address, and phone number.

Who collects and has access to personal information? Novartis or its appointed company manages the PSP. They collect and store your information securely and may share with HCPs, insurance companies, or other organizations, such as pharmacies, labs, and clinics that provide a service as part of the program.

Will we collect other personal information outside of the PSP? No, we will ask for your additional consent to collect personal information not related to the PSP services. For example, we may ask for your permission to participate in market research.

How can you request access or corrections to your personal information in the PSP?

For questions, access or corrections to your information, or to withdraw consent, you can reach the Novartis Privacy Officer at global.privacy_operations@novartis.com or the Novartis RLTAssist™ patient support program for PLUVICTO® at 1-844-747-9758.

For more information on our privacy practices, you may also consult our Canadian Privacy Notice at: https://www.novartis.com/ca-en/privacy.

How can you withdraw consent from the PSP?

You can withdraw consent anytime. Without it, we may not be able to provide services. Withdrawal stops future use of your information and new collection, but already collected information will remain in our database or adverse events database until it can be deleted as per health authorities' guidelines.

We may contact you by email or text to inform you about the PSP services. For SMS, message frequency varies and standard messaging rates may apply. You can opt out of these messages, but this may limit your use of the PSP services.

DETAILS ON HOW WE COLLECT, USE AND SHARE PERSONAL INFORMATION FOR THE PSP

Why do we collect personal information to run the PSP?

We collect personal information to:

- Confirm and manage prescriptions.
- Communicate with HCPs, patients or legal guardians/caregivers about treatment, patient care, and where applicable, regarding adverse events.
- Ensure we are connecting with the right patient or caregiver.
- Process insurance claims.
- Coordinate with service providers.†
- Provide program services, like injection training, lab test coordination, and sending medical tests results.
- Arrange travel if the PSP offers travel assistance.
- Confirm patient prescriptions.
- Monitor the program's performance and service quality.
- Support business planning, optimization and strategy development.
- Compile information on treatment usage and disease management.

These analyses help us improve our services, create awareness campaigns, patient brochures, and provide drug information for HCPs. Most analyses use de-identified (replacing identifying data with a code or label) or anonymized data.

†In the event that you opt to benefit from any external service provider, referred by the Program, you understand that these are third parties who are in no way affiliated with Novartis. Novartis cannot be held responsible for the information or services these third parties may provide to you.

Do we collect any other personal information not connected to a PSP service?

No, unless we have obtained additional consent to collect and use personal information for research to advance the knowledge and data on drug, treatment or disease. These analyses conducted may not benefit you directly but are valuable to the healthcare community.

Who collects the personal information, and how is it protected?

The program administrator, Novartis or a company acting on behalf of Novartis, collects and stores personal information in a secure database using:

Encryption (converting personal information into a secret code).

Restricted access (individual usernames and passwords).

Only authorized personnel can access your information, including:

- Call centre agents managing PSP requests.
- PSP HCPs providing treatment training.
- PSP staff overseeing program activities or handling complaints.
- Patient safety agents for managing adverse events.

External service providers, including drug reimbursement specialists, travel agencies, pharmacies, labs, and clinics, must protect personal information similarly.

Novartis personnel may access your information for supervision, audits, or reporting adverse events.

Also, any entity who the law allows could have access to your personal information.

Can personal information be transferred outside your province or Canada?

Personal information may be transferred outside of your province of residence or of Canada when:

- It is stored in a database outside your province or country of residence.
- It must be reported to health authorities worldwide in case of an adverse event.

The privacy laws that apply where we store or process your personal information may differ from those that apply in your location. While personal information is stored in another location, it may be accessed by courts, law enforcement, and national security authorities. For more information about our policies and practices regarding international transfers of personal information, contact us at global.privacy_operations@novartis.com.

What happens if you withdraw your consent?

Without your consent, we may not be able to provide the services. Withdrawal stops future use and new collection of your information, but already collected information will remain in our database or adverse events database until it can be deleted as per legal requirements and health authority guidelines.

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Novartis Pharmaceuticals Canada Inc.
700 Saint-Hubert St., Suite 100
Montreal (Quebec) H2Y 0C1
www.novartis.ca
Phone: (514) 631-6775 | Fax: (514) 631-1867
Medical Information: 1-800-363-8883 or
medinfo.canada@novartis.com

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