PLUVICTO™ and LUTATHERA® ENROLLMENT FORM

RLTAssist™ Patient Support Program

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

RLTAssist™

1. PATIENT INFORMATION AND CONSENT (Please print)

Last Name:	First Name:	
Date of Birth: (DD/MM/YYYY)	Health Card #:	
Address:		
City:	Province:	Postal Code:
Phone (Mobile): Consent to leave voice message: ☐ Yes ☐ No Consent to text message: ☐ Yes ☐ No	Phone (Home): Consent to leave voice message: ☑ Yes ☐ No	
Email:	Preferred language: ☑ English ☐ French	
Allergies:		

Insurance Coverage for Pluvicto™

Insurance Company:	Plan Holder Name:
Plan Number:	ID Number:

Patient Consent:

I would like to be enrolled in the Novartis RLTAssist™ Program. I have read and agree to the collection, use and disclosure of my personal information as explained in the consent section (Section A).

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/MM/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™ Program to proceed with enrollment.

Verbal consent obtained by the HCP from: ☑ Patient ☐ Legal representative

Name:	Relationship:
Verbal consent obtained by: Name:	
Signature	Date: (DD/MM/YYYY)

2. ELIGIBILITY* (Please print) *All boxes must be checked for PLUVICTO™ or LUTATHERA® in order for the patient to be eligible.

PLUVICTO™	LUTATHERA®
Confirmed diagnosis of mCRPC: ☐ Yes Patient tumour PSMA-positivity has been verified: ☐ Yes Patient has received at least one ARPI and taxane-based chemotherapy: ☐ Yes	Confirmed diagnosis of unresectable or metastatic, well-differentiated, GEP-NETs: ☐ Yes Patient tumour somatostatin-receptor positivity has been verified: ☐ Yes
PLUVICTO™ (lutetium (^{177}Lu) vipivotide tetraxetan injection) is indicated for the treatment of adult patients with PSMA-positive mCRPC who have received at least one ARPI and taxane-based chemotherapy.	LUTATHERA® (lutetium (^{177}Lu) oxodotreotide injection) is indicated for the treatment of unresectable or metastatic, well-differentiated, somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adults with progressive disease.

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PLUVICTO™ lutetium (^{177}Lu) vipivotide tetraxetan injection

LUTATHERA® Lutetium (^{177}Lu) oxodotreotide injection

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3. PRESCRIBED THERAPY (Please print) Please select one

☐ **PLUVICTO™:** 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.	☐ **LUTATHERA®:** The recommended LUTATHERA® dose is 7.4 GBq (7400 MBq) (200 mCi) intravenously over 30 minutes, every 8 weeks, for a total of 4 doses. Please see the LUTATHERA® Product Monograph for complete dosing and administration information.

Dose:	Frequency:	Total number of cycles:
Other Instructions:	Pre-medication(s):	
Treatment Site Name:		
Treatment Site Contact Info (Name, Role, Phone, Email, Fax):		

ARPI=androgen receptor pathway inhibitor; GBq=gigabecquerel; GEP-NET=gastroenteropancreatic neuroendocrine tumours; mCi=millicurie; mCRPC=metastatic castration-resistant prostate cancer; PSMA=prostate-specific membrane antigen

4. RLTAssist™ TRAVEL ASSISTANCE PROGRAM

The Travel Assistance Program is designed to assist PLUVICTO™ or LUTATHERA® patients and their spouse/caregiver who may require travel assistance when travelling more than 200 km from the patient's home address to an authorized PLUVICTO™ or LUTATHERA® treating hospital.†

☐ SHOULD THE PATIENT BE ELIGIBLE PER ABOVE CRITERIA, THE PATIENT WOULD LIKE TO BE CONTACTED BY THE RLTAssist™ TRAVEL ASSISTANCE PROGRAM.

† Applying for the Travel Assistance Program is not a guarantee that assistance will be available. Patient must meet eligibility criteria.

5. PHYSICIAN INFORMATION AND CONSENT (Please print)

Name of Referring Physician:		License #:
Address:	Preferred Method of Communication: ☑ Phone ☐ Fax ☐ Email	
City:	Province:	Postal Code:
Email:	Phone #:	Fax #:

Physician Consent (MANDATORY)

ACKNOWLEDGEMENTS AND UNDERTAKINGS

- The above prescription parameters comply with the indications set forth in the Product Monograph.
- 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 (Section A).
- I acknowledge that adverse events may be reported about my patients participating in the Program and understand I may be contacted by Novartis or its agents to provide follow-up information. As adverse event reports may need to be processed in and outside of Canada and forwarded to Canadian and foreign regulatory authorities, I understand that my information may be stored or processed outside of Canada.

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 (Section A).

Physician's Signature	Date Signed: (DD-MM-YYYY)

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PLUVICTO™ lutetium (¹⁷⁷Lu) vipivotide tetraxetan injection

LUTATHERA® Lutetium (¹⁷⁷Lu) oxodotreotide injection

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SECTION A: CONSENT

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

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, including disease information, 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.

Only those who need your information to run the PSP can access it.

Is personal information transferred outside your province of residence or Canada?

Yes, your information is stored securely in the USA.

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 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™ and LUTATHERA® at 1-844-747-9758.

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.

When you join the PSP, we will notify you by email or text at the contact information you provided to inform you about the PSP services. 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 center 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.

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.

Please consult the Product Monographs (**PLUVICTO™**: https://www.novartis.com/ca-en/content/pluvicto) or (**LUTATHERA®**: https://www.novartis.com/ca-en/content/lutathera) for important information relating to contraindications, warnings, precautions, adverse reactions, drug interactions, conditions of clinical use, and dosage and administration information which has not been discussed in this piece.

The Product Monographs are also available by emailing medinfo.canada@novartis.com or by calling 1-800-363-8883.

Please fax completed form to 1-844-349-8758

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PLUVICTO™ lutetium (177Lu) vipivotide tetraxetan injection

LUTATHERA® Lutetium (177Lu) oxodotreotide injection

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MEMBER OF INNOVATIVE MEDICINES CANADA