Entrectinib (Rozlytrek®) for ROS1-positive Non-Small Cell Lung Cancer Application Form

For MMP Use Only	
Case Reference	*Date Received*

ALL SECTIONS OF THIS FORM MUST BE COMPLETED

Date of application:	

Part 1: Patient Details

Name of patient:	
Date of birth:	
Address:	
GMS / DPS / PPS Number: (Please tick and insert number)	GMS ☐ DPS ☐ PPSN ☐ Number:

Part 2: Consultant Details

Name of consultant:	
Medical Council number:	
Contact Details:	Hospital:
	Address:
	Telephone:
	Email:

Please refer to the HSE Managed Access Protocol for Entrectinib for ROS1-positive Non-small Cell Lung Cancer (NSCLC) when completing parts 3, 4 and 5 of this application form

Part 3: Patient Diagnosis

Section 1: Confirmed diagnosis of advanced NSCLC

Please indicate whether the patient meets this criteria (*please tick which apply and complete requested detail*)

1. Patient has a histological diagnosis of advanced NSCLC **Yes** ☐ **No** ☐

2. Please confirm the tumour is American Joint Committee on Cancer stage IIIB, C or IV
Yes ☐ **No** ☐

Please attach a copy of relevant pathology reports **Enclosed** ☐

Section 2: Confirmed ROS1 genetic alteration

3. Patient has a confirmed ROS1 genetic alternation in the tumour, without a known acquired resistance mutation, as determined by an accurate and validated testing method.
Yes ☐ **No** ☐

Please attach a copy of the confirmatory test **Enclosed** ☐

Part 4: Patient Clinical History/Status

Please indicate the current status of the patient in relation to the following clinical parameters (*please tick which apply and complete requested detail overleaf*)

Refer to section 2.4 of the Managed Access Protocol - Patient clinical history/status, to the Summary of Manufacturer's Product Characteristics (SmPC), and to the eligibility and exclusion criteria detailed in the NCCP national regimen for entrectinib for ROS1-positive NSCLC.

The patient:	Yes	No
meets any of the contraindications to treatment as outlined in the relevant SmPC		
meets any of the exclusion criteria for treatment as outlined in the relevant NCCP national regimen		

If **yes** has been answered in the above table, please provide relevant information in the box provided below:

I confirm that the patient meets the performance status as outlined in the eligibility criteria in the NCCP national regimens for entrectinib for ROS1-positive advanced NSCLC

Yes ☐ **No** ☐

Part 5: Place in Therapy

1. I confirm that entrectinib will be prescribed and administered as monotherapy for the treatment of ROS1-positive advanced NSCLC in this patient.

Yes ☐ **No** ☐

2. I confirm that this patient has not previously received prior treatment with a ROS1 inhibitor, including through compassionate use programmes or clinical trials.

Yes ☐ **No** ☐

Additional space for supporting information

Completed forms should be returned by:
Email (using secure email, e.g. HSE email or healthmail) to mmp@hse.ie
Please note that the MMP will always acknowledge receipt of each application.

Authorisation of Request	
Signature of Approved Consultant	
Institution	

Data Protection Notice

- The information on this form will be used by the Health Service Executive (HSE) to assess the suitability of the items listed to be provided under Section 20 of the Health (Pricing and Supply of Medical Goods) Act 2013.
- Details of prescription items dispensed to the named person may be notified to the HSE by the dispensing pharmacist to ensure that the names person receives the items required.
- The named person may access information relating to themselves only, on prescription claims processed in their name by the HSE.
- We may share information with the Department of Health, healthcare practitioners and other healthcare bodies.
- We may also disclose information to other parties if the law requires us to do so.
- The PCRS privacy statement can be located at www.pcrs.ie.