ASPiRATION Referral

An observational cohort study to assess the clinical impact of comprehensive genomic profiling in metastatic lung cancer patients. The study is open to adults with newly diagnosed, pathologically confirmed mNSCLC, with sufficient and accessible tissue for molecular screening. In parallel with standard of care (SoC) testing (e.g. IHC/FISH/PCR for EGFR, ALK and ROS1), Comprehensive Genomic Profiling (CGP) will be performed on tumour tissue. A report containing any actionable genomic alterations and corresponding treatment recommendations will be issued to the treating clinician.

Date of referral: ____ / ____ / ____

Contact details

E: most@garvan.org.au
T: +61 2 9355 5768
F: +61 2 8088 8003

❑ Face-to-face appointment

Please send this form & histopathology report to the selected study site.

For a list of study sites that are **open**, please visit https://www.omico.com.au/about-us/our-network/

- ❑ Royal North Shore Hospital, St Leonards, NSW – Dr Malinda Itchins
- ❑ Westmead Hospital, Westmead, NSW – Dr Adnan Nagrial
- ❑ Chris O'Brien Lifehouse, Camperdown, NSW – Dr Steven Kao
- ❑ St George Hospital, Kogarah, NSW – A/Prof Chee Lee
- ❑ The Canberra Hospital, Garran, ACT – Dr Geoffrey Peters
- ❑ Peter MacCallum Cancer Centre, Parkville, VIC – Prof Ben Solomon
- ❑ Austin Hospital, Heidelberg, VIC – Dr Sagun Parakh
- ❑ St Vincent's Hospital Melbourne, Fitzroy, VIC – Dr Melissa Moore
- ❑ Royal Hobart Hospital, Hobart, TAS – Dr Rebecca Tay
- ❑ Princess Alexandra Hospital, Woolloongabba, QLD – Prof Ken O'Byrne
- ❑ The Prince Charles Hospital, Chermside, QLD – Dr Brett Hughes
- ❑ Royal Adelaide Hospital, Adelaide, SA – Prof Michael Brown
- ❑ Linear Clinical Research, Nedlands, WA – Prof Michael Millward
- ❑ Royal Darwin Hospital, Tiwi, NT – Dr Michail Charakidis

❑ Remote consent by the Garvan Institute of Medical Research

Remote consent is available for patients who are unable to travel to a study site for molecular screening. Please note, if found eligible, patients will need to travel to a study site to access treatment on a clinical substudy.

Treating clinician details:	
Surname	First name
Treating Institute	Email

❑ I would like to **opt out** of being contacted by Roche regarding SAE reporting.

Clinical follow-up contact: Every 3 months in the first year, and 6 monthly thereafter, a patient's referring clinician will be asked to complete a clinical follow-up form. Is there anyone else you would like to include in this correspondence?	
Email:	❑ Other clinician ❑ Nurse care coordinator or study/research coordinator ❑ Secretary ❑ Other

Section 1: Patient Details

Patient Details			
Surname		First name	
Date of birth	/ /	Sex	❑ M ❑ F
Address			
Phone		Email	
Next of Kin (if patient is not the preferred contact)			

Inclusion Criteria *(Patients must fulfil all of the following criteria to be eligible for this study).*	
Aged 18 years and older.	❑ Yes ❑ No
Newly diagnosed pathologically confirmed metastatic non-squamous non-small cell lung cancer that have not commenced systemic therapy. *Exception: patients with a typical pattern of disease recurrence following treatment with curative intent may not require a confirmatory repeat biopsy, unless the diagnosis is unclear, such as an isolated pulmonary nodule, in which case repeat biopsy should be considered per standard practice. In exceptional circumstances, patients may be considered eligible without the need for histopathological confirmation of disease recurrence after approval from the ASPiRATION study chair or delegates;* *Mixed or other histologies:* • *Eligible: Mixed adenosquamous where adenocarcinoma is dominant, carcinoma not otherwise specified (NOS) favouring adenocarcinoma or sarcomatoid carcinoma* • *Ineligible: Mixed small cell lung cancer or Large cell neuroendocrine carcinoma*	❑ Yes ❑ No
ECOG performance status 0 or 1.	❑ Yes ❑ No
Sufficient and accessible tissue for molecular screening. • *Preferred samples are core biopsies (minimum surface area = 5mm^2, ideal surface area = 25mm^2)* • *FNA samples (EBUS or CT guided) may be considered on a case-by case basis, provided there is sufficient tumour cell content within the FFPE / cell block.* • *Archival biopsies or lung resection specimens may be suitable in some cases* • *Pleural effusion samples are not considered sufficient*	❑ Yes ❑ No
Willing and able to comply with study requirements, including: *Willing to provide signed written informed consent to participate in molecular profiling and linkage to Medicare data, and in principle willing to consider participation in a MoST sub-study if found to have an appropriate biomarker.*	❑ Yes ❑ No
Life expectancy of at least 12 weeks.	❑ Yes ❑ No

Exclusion Criteria (Patients will any one of the following characteristics will not be eligible for this study).	
Current enrolment or participation in another clinical study with an unregistered investigational product during the last 12 months. *Current participation in an observational (non-interventional) clinical study or during the follow-up period of an interventional study must first be discussed the study team before study enrolment.*	❑ Yes ❑ No
Previous treatment for metastatic non-squamous NSCLC. • *For patients with symptomatic or bulky disease, where it would be detrimental to delay treatment, systemic therapy may be commenced at the clinician's discretion whilst awaiting CGP results (this is not 'previous' treatment). Patients who have had prior treatment with curable intent are eligible.* • *Up to 2 cycles of systemic treatment may be permitted prior to treatment on an ASPiRATION therapeutic substudy.*	❑ Yes ❑ No
Comorbidities or conditions (e.g. psychiatric) which may contraindicate participation and/or ability to receive any systemic therapy(s).	❑ Yes ❑ No
History of another primary malignancy. *The following are permitted:* • *Malignancy treated with curative intent and with no known active disease within 2 years before consent to molecular screening and of low potential risk for recurrence* • *Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease* • *Adequately treated carcinoma in situ without evidence of disease*	❑ Yes ❑ No

Section 2: Cancer Diagnosis & Staging

Diagnosis	
Date of initial diagnosis	/ /
Topography (ICD-O-3)	❑ Upper lobe, lung ❑ Middle lobe, lung ❑ Lower lobe, lung ❑ Main bronchus ❑ Overlapping lesion ❑ Lung, NOS ❑ Other, please specify:
Predominant Morphology	❑ Non-small cell carcinoma ❑ Adenocarcinoma ❑ Adenosquamous carcinoma ❑ Carcinoma ❑ Sarcomatoid carcinoma ❑ Other, please specify:
Cancer Stage at trial entry	
Current stage of disease	❑ Metastatic ❑ Recurrent, locally advanced
Was the cancer metastatic, at time of initial diagnosis?	❑ Yes ❑ No If no, date of metastatic disease diagnosis: / /
Staging methods	❑ CT ❑ MRI ❑ PET ❑ Clinical
Are there any distant (extrathoracic) metastasis	❑ Yes ❑ No
If yes, site of metastasis	❑ CNS ❑ Liver ❑ Bone ❑ Other
Have the metastasis been treated?	❑ Yes ❑ No
TNM Stage at trial entry (IASLC 8th Edition)	
T (primary tumour)	❑ Tx ❑ T1 ❑ T2 ❑ T3 ❑ T4 ❑ Unknown
N (regional lymph nodes)	❑ Nx ❑ N0 ❑ N1 ❑ N2 ❑ N3 ❑ Unknown
M (distant metastasis)	❑ M0 ❑ M1a ❑ M1b ❑ M1c
Clinical Data	
ECOG	❑ 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4
Presentation	❑ Symptomatic ❑ Asymptomatic

Section 3: Histopathology

For each procedure (biopsy or surgery) where tumour tissue has been collected, answer the following:

Pathology 1				
Date of procedure	/ /			
Type of procedure	❑ FNA	❑ Core biopsy	❑ Resection	❑ Cytology
Reason for procedure	❑ Diagnosis	❑ Molecular screening	❑ Therapeutic	
Site	❑ Primary site	❑ Metastatic site		
Standard of Care Biomarkers (EGFR, ALK, ROS1)	❑ Histopathology report attached, with biomarker results			
	❑ Histopathology report attached, biomarker results pending			
	❑ Histopathology attached, no standard of care biomarkers requested on this sample			
Pathology 2				
Date of procedure	/ /			
Type of procedure	❑ FNA	❑ Core biopsy	❑ Resection	❑ Cytology
Reason for procedure	❑ Diagnosis	❑ Molecular screening	❑ Therapeutic	
Site	❑ Primary site	❑ Metastatic site		
Standard of Care Biomarkers (EGFR, ALK, ROS1)	❑ Histopathology report attached, with biomarker results			
	❑ Histopathology report attached, biomarker results pending			
	❑ Histopathology attached, no standard of care biomarkers requested on this sample			
Pathology 3				
Date of procedure	/ /			
Type of procedure	❑ FNA	❑ Core biopsy	❑ Resection	❑ Cytology
Reason for procedure	❑ Diagnosis	❑ Molecular screening	❑ Therapeutic	
Site	❑ Primary site	❑ Metastatic site		
Standard of Care Biomarkers (EGFR, ALK, ROS1)	❑ Histopathology report attached, with biomarker results			
	❑ Histopathology report attached, biomarker results pending			
	❑ Histopathology attached, no standard of care biomarkers requested on this sample			

Section 4: Past History

Comorbidities – Charlson Index	Score
Myocardial infarction (history, not ECG changes only) e.g. Heart Attack	1 ❑
Congestive heart failure e.g Heart Failure	1 ❑
Peripheral vascular disease (includes aortic aneurysm ≥6cm) e.g. Ischemia, Embolism, Thrombus Block	1 ❑
Cerebrovascular disease: CVA (Stroke) with mild or no residual deficits or TIA (Transient Ischemic Attack)	1 ❑
Dementia	1 ❑
Chronic obstructive pulmonary disease e.g. Emphysema, Chronic Bronchitis, Bronchiectasis	1 ❑
Connective tissue disease e.g. Rheumatoid Arthritis, Scleroderma	1 ❑
Peptic Ulcer Disease	1 ❑
Mild liver disease (cirrhosis without portal hypertension, includes chronic hepatitis)	1 ❑
Diabetes: no end-organ complications	1 ❑
Diabetes: end-organ complications (retinopathy, neuropathy, nephropathy, brittle)	2 ❑
Hemiplegia e.g. Stroke with paralysis	2 ❑
Mod-severe Renal Disease	2 ❑
Second tumour without metastases (exclude if >5y from diagnosis)	2 ❑
Lymphoma	2 ❑
Leukaemia (acute or chronic)	2 ❑
Mod-severe liver disease (moderate: cirrhosis with portal hypertension but without bleeding; severe: cirrhosis, portal hypertension and a history of variceal bleeding)	3 ❑
Acquired immune deficiency syndrome (not just HIV positive)	6 ❑
Second metastatic solid tumour	6 ❑
TOTAL	
Add one point for each decade over 50 (eg 1 point if 51-60, 2 pts if 61-70)	
TOTAL	

Has the patient had any transplants?	❑ No ❑ Yes, please specify:

Prior Cancer ❑ Yes ❑ No			
Cancer type		**Age of diagnosis**	
Last treatment date		**Treating Institute**	
Treatment	❑ Surgery	❑ Systemic	❑ Radiation

Family history of cancer ❑ Yes ❑ No		
Relation	**Cancer type**	**Age of onset**

Prior genetic testing / conditions			
Has the patient had previous genetic testing?	❑ No	❑ Yes, please specify details below	
Germline or tumour?	❑ Germline	❑ Tumour	❑ Both
Please detail genetic findings			
Is there a known familial syndrome?	❑ No ❑ Yes, please specify:		