SOTORASIB

full description

INDICATIONS:
Monotherapy for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), who have progressed on, or are intolerant to, platinum-based chemotherapy and/or anti PD-1/PD-L1 immunotherapy.

DOSING:
Sotorasib PO 960mg od continuously.
Every 28 days

regimen name	SOTORASIB
diagnosis	KRAS G12C-mutated Adeno NSCLC , KRAS G12C-mutated NSCLC NOS , KRAS G12C-mutated Squamous NSCLC
version number	2.00

version no	amended date	amended by	summary
1	Tue Oct 19 2021 15:49:41 GMT+0100 (British Summer Time)	[redacted]	
2	Thu Jan 13 2022 12:52:23 GMT+0000 (Greenwich Mean Time)		Random glucose test added

Treatment day: 1 day type: O slots: 2

drug name	route	vehicle	dose	dose calc	infus. time	frequency	duration	start time	line	fluid vol..	fluid calc
critical test:	HB100, HAEMOGLOBIN>100 , range: 100-> 172										
critical test:	PLAT50, PLATELETS > 50 , range: 50-> 600										
critical test:	WBC 2, WBC> 2.0 , range: 2-> 11										
critical test:	NEUT1, NEUTROPHILS > 1.0 , range: 1-> 7.5										
critical test:	CREAT, CREATININE (umol/l) , range: 40-> 135										

drug name	route	vehicle	dose	dose calc	infus. time	frequency	duration	start time	line	fluid vol..	fluid calc
critical test:	GFR>60, GFR >60ml/min , range: 60.01-> 125										
critical test:	ALT<3ULN, ALT<3ULN , range: 0-> 129										
critical test:	BIL1.5ULN, BILIRUBIN <1.5ULN , range: 0-> 32										
critical test:	RANBG, Random blood glucose , range: 3-> 12										
SOTORASIB	Oral	None	960 mg	FLAT		od	28 days			0	
note:	Swallow whole with plenty of water. Take at the same time each day with or without food. PHARMACY: supply in original pack(s).										
LOPERAMIDE	Oral		2 mg	FLAT						0	
note:	Take 4mg at onset of diarrhoea then take 2mg after each loose stool. Max 16mg in 24 hours. PHARMACY: dispense original pack on cycle 1 only.										

Treatment day: 28 day type: X slots: 0

drug name	route	vehicle	dose	dose calc	infus. time	frequency	duration	start time	line	fluid vol..	fluid calc
review											

CLINICAL DETAILS

DOSE REDUCTIONS (FOR INFORMATION / ADVICE CONTACT A PHARMACIST)

RENAL IMPAIRMENT:
Based on population pharmacokinetic analysis, no dose adjustment is recommended for patients with mild renal impairment (creatine clearance, CrCL, = 60 mL/min). LUMYKRAS has not been studied in patients with moderate or severe renal impairment (CrCL < 60 mL/min)

HEPATIC IMPAIRMENT:
No dose adjustment is recommended for patients with mild hepatic impairment (AST or ALT < 2.5 × ULN or total bilirubin < 1.5 × ULN). LUMYKRAS has not been studied in patients with moderate or severe hepatic impairment

Grade 2 (>3xULN) ALT with symptoms / or Grade >= 3 ALT (>5xULN) - Stop treatment until recovered to <= grade 1 or to baseline grade. After recovery, resume treatment at the next dose reduction level.

ALT > 3 × ULN with total bilirubin > 2 × ULN, in the absence of alternative causes - Permanently discontinue treatment

BASELINE / ADDITIONAL MONITORING REQUIREMENTS:
Interstitial Lung Disease (ILD)/Pneumonitis

If toxicity events occur, a maximum of two dose reductions are permitted. See SmPC for details of dose reduction levels.

ALT and total bilirubin must be monitored prior to the start of LUMYKRAS, every 3 weeks for the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop transaminase and/or bilirubin elevations. Based on the severity of the laboratory abnormalities, treatment with LUMYKRAS must be stopped until recovered to <= grade 1 or to baseline grade, and the dose must either be modified or permanently discontinue treatment as recommended

Sotorasib is a moderate CYP3A4 inducer. Co-administration of sotorasib with CYP3A4 substrates led to a decrease in their plasma concentrations, which may reduce the efficacy of these substrates.
Avoid co-administration of LUMYKRAS with CYP3A4 substrates with narrow therapeutic indices. If co-administration cannot be avoided, adjust the CYP3A4 substrate dosage in accordance with the current summary of product characteristics.

Avoid co-administration of LUMYKRAS with P-gp substrates, for which minimal concentration changes may lead to serious toxicities. If co-administration cannot be avoided, decrease the P-gp substrate dosage in accordance with its Prescribing Information.

Co-administration of PPIs and H2 receptor antagonists with LUMYKRAS is not recommended because the impact on sotorasib efficacy is unknown. If treatment with an acid-reducing agent is required, LUMYKRAS should be taken 4 hours before or 10 hours after administration of a local antacid

Dose reduction advice from: SmPC

ADD NOTE="HbA1C must be checked at the start of treatment but if a result is not available for the first cycle go ahead with treatment and ensure a result obtained before the next cycle. Blood glucose should be checked at each cycle unless otherwise stated by prescriber. If the result is >12mmol/L refer to Glycaemia protocol. "

Regimen Entry		**Pharmacist - PSU Date**	
Regimen		**Pharmacist - QA Date**	
Regimen Verified		**Consultant Date**	

Medical Director

Date