16.2.2.4 Adverse Events

~ 1 !	Adverse Event/Primary	~	_ ,	~ '		Relationship	
Subject	System Organ	Start	End	Serious		to	
Number	Class/Preffered term		Date/Time	Event		enStudy Drug	Outcome
AA-2020-06-104001	21	2021-04-02	2021-04-02	N	Dose Not	Possibly	RECOVERED/RES
	disorders/Hypotension				Changed	related	OLVED
AA-2020-06-104004		2021-05-10	2021-06-01	N	Dose Not	Not related	RECOVERED/RES
	bronchitis/Infections				Changed		OLVED
	and						
	infestations/Bronchiti	L					
	S						
AA-2020-06-104007		2021-09-02T16:		N	Not	Possibly	NOT
	hematocrit/Investigati	L 35			Applicable	related	RECOVERED/NOT
	ons/Haematocrit						RESOLVED
	decreased	0001 00 00=16					
	decreased	2021-09-02T16:		N	Not	Possibly	NOT
	hemoglobin/Investigati	L 35			Applicable	related	RECOVERED/NOT
	ons/Haemoglobin decreased						RESOLVED
	decreased red blood	2021-09-02T16:		N	Not.	Possibly	NOT
				IN		related	
	cells/Investigations/F	33			Applicable	related	RECOVERED/NOT
	decreased						RESOLVED
77-2020-06-105001	Left Upper Quadrant	2021-03-14	2021-03-14	N	Dose Not	Unlikelv	RECOVERED/RES
AA 2020 00 103001	Abdominal	2021 03 14	2021 03 14	14	Changed	related	OLVED OLVED
	Pain/Gastrointestinal				Changed	reraced	OHVED
	disorders/Abdominal						
	pain upper						
	Nose Bleed/Respiratory	2021-03-15	2021-03-15	N	Dose Not	Unlikely	RECOVERED/RES
	thoracic and	,2021 03 13	2021 03 13	14	Changed	related	OLVED
	mediastinal				changea	ICIACCA	OHVHD
	disorders/Epistaxis						
	arboracrb, Eprocantb						

16.2.2.4 Adverse Events

	Adverse Event/Primary					Relationship	
Subject	System Organ	Start	End	Serious		to	
Number	Class/Preffered term	Date/Time	Date/Time	Event	Action take	enStudy Drug	Outcome
AA-2020-06-105001	Bradycardia/Cardiac	2021-03-16T18:	2021-03-16T19:	N	Dose Not	Unlikely	RECOVERED/RES
	disorders/Bradycardia	00	30		Changed	related	OLVED
	COVID-19	2021-03-16	2021-03-25	Y	Drug	Unlikely	RECOVERED/RES
	Pneumonia/Infections				Withdrawn	related	OLVED
	and						
	infestations/COVID-19						
	pneumonia						
	Syncope/Nervous system	n 2021-03-16T18:	2021-03-16T19:	N	Dose Not	Unlikely	RECOVERED/RES
	disorders/Syncope	00	30		Changed	related	OLVED
AA-2020-06-105009	Acute Hypertension of	2021-08-12	2021-08-17	N	Not	Unlikely	RECOVERED/RES
	unknown				Applicable	related	OLVED
	etiology/Vascular						
	disorders/Hypertension						
	Hypokalemia/Metabolism	n 2021-08-12	2021-08-17	N	Not	Unlikely	RECOVERED/RES
	and nutrition				Applicable	related	OLVED
	disorders/Hypokalaemia	à					
	diarrhea/Gastrointesti	2021-08-02	2021-08-17	N	Drug	Possibly	RECOVERED/RES
	nal disorders/Diarrhoe	a			Withdrawn	related	OLVED
	vomiting	2021-08-04	2021-08-17	N	Not	Possibly	RECOVERED/RES
					Applicable	related	OLVED

16.2.2.4 Adverse Events

	Adverse Event/Primary					Relationship	
Subject	System Organ	Start	End	Serious		to	
Number	Class/Preffered term	Date/Time	Date/Time	Event	Action take	nStudy Drug	Outcome
AA-2020-06-105009	**:	2021-08-12T10: 21	2021-08-17	Y	Drug Withdrawn	Unlikely related	RECOVERED/RES OLVED
	Shortness of Breath/Respiratory, thoracic and mediastinal disorders/Dyspnoea	2021-08-12	2021-08-17	N	Not Applicable	Unlikely related	RECOVERED/RES OLVED
	Transaminitis/Investig ations/Transaminases increased	2021-08-12	2021-08-17	N	Not Applicable	Unlikely related	RECOVERED/RES OLVED
AA-2020-06-105011	diarrhea/Gastrointesti nal disorders/Diarrhoea		2021-09-05	N	Dose Not Changed	Possibly related	RECOVERED/RES OLVED
	<pre>vomiting/Gastrointesti nal disorders/Vomiting</pre>		2021-09-05	N	Dose Not Changed	Possibly related	RECOVERED/RES OLVED
AA-2020-06-105012	panic attacks/Psychiatric disorders/Panic attack	2021-09-02	2021-09-15	N	Dose Not Changed	Not related	RECOVERED/RES OLVED
AA-2020-06-105014	sinus congestion/Respiratory , thoracic and mediastinal disorders/Sinus congestion	2021-09-13	2021-09-22	N	Dose Not Changed	Not related	RECOVERED/RES OLVED

16.2.2.4 Adverse Events

	Adverse Event/Primary					Relationship		
Subject	System Organ	Start	End	Serious		to		
Number	Class/Preffered term	Date/Time	Date/Time	Event	Action take	nStudy Drug	Outcome	
AA-2020-06-109001	Elevated ALT blood	2021-04-26	2021-06-04	N	Not	Unlikely	RECOVERED/RES	
	level/Investigations/A	A			Applicable	related	OLVED	
	lanine aminotransferase							
	increased							
AA-2020-06-117025	COVID-19	2021-08-25	2021-09-02	Y	Drug	Not related	RECOVERED/RES	
	Pneumonia/Infections				Withdrawn		OLVED	
	and							
	infestations/COVID-19							
	pneumonia							
	Trasaminitis	2021-08-25	2021-09-02	N	Drug	Not related	RECOVERED/RES	
					Withdrawn		OLVED	
AA-2020-06-119014	Generalized Rash/Skin	2021-08-23	2021-08-23	N	Dose Not	Possibly	RECOVERED/RES	
	and subcutaneous tissue	е			Changed	related	OLVED	
	disorders/Rash							
AA-2020-06-119021	Dizziness/Nervous	2021-08-20	2021-08-20	N	Dose Not	Not related	RECOVERED/RES	
	system				Changed		OLVED	
	disorders/Dizziness							