

SUSAR Line Listing (Blinded)

Report Criteria :

Initial/FU Receipt Date Period :	Dec 9, 2020 12:00 AM - Mar 9, 2021 12:00 AM
Project ID :	
Study ID :	
Product Name :	CASIRIVIMAB AND IMDEVIMAB, Placebo (REGN10933-10987)
Reporting Destination :	
<i>Includes cases with observe study types : Interventional, Interventional IIS and Non Company Sponsored Studies</i>	
<i>Excludes invalid and deleted cases and cases with follow-up version justification = Non-Medically Significant Follow-up</i>	

Case Number	Country Of Occurrence	Study ID	Patient Number	Patient Gender	Patient Age (in Years)	Product Name (Blinded)	Event Verbatim	MedDRA PT	Reporter Causality	Company Causality	Event Seriousness	Product-Event Listedness IB	SUSAR?
2020-80783	UNITED STATES	R10933-10987-COV-2067-PHASE2	840025-004	Male	71	REGN10933-10987, REGN10989 OR PLACEBO	ADVERSE MEDICATION REACTION-DIAPHORESIS	Hyperhidrosis	Related	Related	Serious	Unlisted	Yes
2020-80783	UNITED STATES	R10933-10987-COV-2067-PHASE2	840025-004	Male	71	REGN10933-10987, REGN10989 OR PLACEBO	Adverse medication reaction-decreased responsiveness	Hyporesponsive to stimuli	Related	Related	Serious	Unlisted	Yes
2020-80783	UNITED STATES	R10933-10987-COV-2067-PHASE2	840025-004	Male	71	REGN10933-10987, REGN10989 OR PLACEBO	Adverse medication reaction-nausea	Nausea	Related	Related	Serious	Unlisted	Yes
2020-80783	UNITED STATES	R10933-10987-COV-2067-PHASE2	840025-004	Male	71	REGN10933-10987, REGN10989 OR PLACEBO	adverse medication reaction-vomitting	Vomiting	Related	Related	Serious	Unlisted	Yes
2020-88833	UNITED STATES	R10933-10987-COV-2066-PHASE2	840068-003	Male	84	REGN10933-10987 OR PLACEBO	HYPERKALEMIA	Hyperkalaemia	Related	Not Related	Serious	Unlisted	Yes
2020-92088	UNITED STATES	R10933-10987-COV-2066-PHASE2	840021-008	Male	74	REGN10933-10987 OR PLACEBO	HOSPITALIZED ACQUIRED PNEUMONIA	Pneumonia	Not Related	Not Related	Serious	Unlisted	No
2020-92088	UNITED STATES	R10933-10987-COV-2066-PHASE2	840021-008	Male	74	REGN10933-10987 OR PLACEBO	Respiratory failure	Respiratory failure	Not Related	Not Related	Serious	Unlisted	No
2020-92088	UNITED STATES	R10933-10987-COV-2066-PHASE2	840021-008	Male	74	REGN10933-10987 OR PLACEBO	Respiratory failure	Respiratory failure	Related	Not Related	Serious	Unlisted	Yes
2020-94760	UNITED STATES	R10933-10987-COV-2066-PHASE2	840104-012	Male	55	REGN10933-10987 OR PLACEBO	ALLERGIC REACTION	Hypersensitivity	Related	Related	Serious	Unlisted	Yes
2020-94760	UNITED STATES	R10933-10987-COV-2066-PHASE2	840104-012	Male	55	REGN10933-10987 OR PLACEBO	WORSENING RESPIRATORY FAILURE	Respiratory failure	Not Related	Not Related	Serious	Unlisted	No
2020-96163	UNITED KINGDOM	RECOVERY	1211335	Female	72	CASIRIVIMAB AND IMDEVIMAB	Acute allergic reaction	Hypersensitivity	Related	Related	Serious	Unlisted	Yes
2020-96559	UNITED STATES	R10933-10987-COV-2066-PHASE2	840053-035	Female	85	REGN10933-10987 OR PLACEBO	NON ST ELEVATED MYOCARDIAL INFARCTION	Acute myocardial infarction	Not Related	Not Related	Serious	Unlisted	No
2020-96559	UNITED STATES	R10933-10987-COV-2066-PHASE2	840053-035	Female	85	REGN10933-10987 OR PLACEBO	RESPIRATORY FAILURE	Respiratory failure	Not Related	Not Related	Serious	Unlisted	No
2020-96559	UNITED STATES	R10933-10987-COV-2066-PHASE2	840053-035	Female	85	REGN10933-10987 OR PLACEBO	THROMBOCYTOPENIA	Thrombocytopenia	Related	Not Related	Serious	Unlisted	Yes
2021-11631	UNITED STATES	R10933-10987-COV-2066-PHASE2	840045-097	Male	88	REGN10933-10987 OR PLACEBO	HYPOXIA	Hypoxia	Related	Not Related	Serious	Unlisted	Yes
2021-12289	UNITED STATES	R10933-10987-COV-2066-PHASE2	840044-012	Male	74	REGN10933-10987 OR PLACEBO	HYPERSENSITIVITY REACTION	Hypersensitivity	Related	Related	Serious	Unlisted	Yes
2021-14348	UNITED KINGDOM	RECOVERY	1279245	Female	43	CASIRIVIMAB AND IMDEVIMAB	Seizure	Seizure	Related	Related	Serious	Unlisted	Yes
2021-15916	UNITED STATES	R10933-10987-COV-2069	840085-004	Female	37	REGN10933-10987 OR PLACEBO	COVID-19	COVID-19	Not Reported	Not Related	Serious	Unlisted	Yes
2021-17084	UNITED STATES	R10933-10987-COV-2067-PHASE3	840138-030	Female	48	REGN10933-10987 OR PLACEBO	PNEUMONIA	Pneumonia	Related	Not Related	Serious	Unlisted	Yes
2021-17318	UNITED KINGDOM	RECOVERY	1315786	Female	88	CASIRIVIMAB AND IMDEVIMAB	Acute allergic reaction	Hypersensitivity	Related	Related	Serious	Unlisted	Yes
2021-18151	UNITED STATES	R10933-10987-COV-2066-PHASE2	840088-148	Male	71	REGN10933-10987 OR PLACEBO	TACHYCARDIA	Tachycardia	Related	Related	Serious	Unlisted	Yes
2021-20997	UNITED STATES	R10933-10987-COV-2067-PHASE3	840131-044	Male	55	REGN10933-10987 OR PLACEBO	WORSENING OF COVID 19 SX AFTER INFUSION	COVID-19	Related	Not Related	Serious	Unlisted	Yes
2021-21822	UNITED STATES	R10933-10987-COV-2066-PHASE2	840087-063	Female	49	REGN10933-10987 OR PLACEBO	CHEST PAIN	Chest pain	Related	Not Related	Serious	Unlisted	Yes
2021-21822	UNITED STATES	R10933-10987-COV-2066-PHASE2	840087-063	Female	49	REGN10933-10987 OR PLACEBO	Neck pain	Neck pain	Related	Not Related	Serious	Unlisted	Yes
2021-23864	UNITED STATES	R10933-10987-COV-2066-PHASE2	840016-019	Male	65	REGN10933-10987 OR PLACEBO	WORSENING HYPOXIA	Hypoxia	Related	Not Related	Serious	Unlisted	Yes
2021-27379	UNITED STATES	R10933-10987-COV-2067-PHASE3	840124-113	Male	40	REGN10933-10987 OR PLACEBO	BODYACHES	Pain	Not Reported	Not Related	Serious	Unlisted	Yes
2021-27379	UNITED STATES	R10933-10987-COV-2067-PHASE3	840124-113	Male	40	REGN10933-10987 OR PLACEBO	COUGH	Cough	Not Reported	Not Related	Serious	Unlisted	Yes
2021-27379	UNITED STATES	R10933-10987-COV-2067-PHASE3	840124-113	Male	40	REGN10933-10987 OR PLACEBO	FEVER	Pyrexia	Not Reported	Not Related	Serious	Unlisted	Yes

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2021-27379	UNITED STATES	R10933-10987-COV-2067-PHASE3	840124-113	Male	40	REGN10933-10987 OR PLACEBO	HEADACHES	Headache	Not Reported	Not Related	Serious	Unlisted	Yes
2021-27379	UNITED STATES	R10933-10987-COV-2067-PHASE3	840124-113	Male	40	REGN10933-10987 OR PLACEBO	SHORTNESS OF BREATH	Dyspnoea	Not Related	Not Related	Serious	Unlisted	No
2021-27379	UNITED STATES	R10933-10987-COV-2067-PHASE3	840124-113	Male	40	REGN10933-10987 OR PLACEBO	WEAKNESS	Asthenia	Not Reported	Not Related	Serious	Unlisted	Yes
2021-29550	BRAZIL	R10933-10987-COV-2066-PHASE2	076008-011	Male	69	REGN10933-10987 OR PLACEBO	VENTILATORY WORSENING	Respiratory failure	Related	Not Related	Serious	Unlisted	Yes

Glossary/Logic

- a) The search is based on most current data in Argus on the date of the report is generated.
- b) Based on the search criteria, the report includes cases where at least one event met the SUSAR criteria (Event is serious , unexpected and related to the suspect drug by either investigator or company)
- c) For identified SUSAR cases, all reported events are presented. Including events that do not meet SUSAR criteria
- d) Each row represents a unique combination of suspect products and events.
- e) Use the column 'SUSAR' to filter events that are considered SUSARs.
- f) Report excludes invalid cases.