Canada Vigilance AER#:	E2B_03693699 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20201224 CCYYMMDD
	HC Initial Received Date:	20201224 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GILEAD-2020-0510019(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	No
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20201217 CCYYMMDD	20201217 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	
	Company number (A.1.10.2)
	CA-GILEAD-2020-0510019

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
GILEAD	CA-GILEAD-2020-0510019

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - GILEAD

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
	Adult		34 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
29 Weeks			
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

Canada Vigilance AER#:	E2B_03693699 (0)	

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** REMDESIVIR	
Active Substance names (B.4.k.2.2) remdesivir		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 100 Milligram,1 every 1 (Days)		
Dosage text (B.4.k.6) 100 mg, QD		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intravenous drip	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 25.0	**Indication (B.4.k.11b)** COVID-19
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Dosage maintained	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Maternal exposure during pregnancy	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Related
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Maternal exposure during pregnancy	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Related
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Premature delivery	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Premature delivery	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Reported

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNSURE IF RDV GIVEN PRIOR TO BIRTH OF PREMATURE INFANT & QUERY IF PT CAN BREAST FEED [PREMATURE DELIVERY]

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
25.0	Premature delivery
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
25.0	Premature delivery

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Recovered/resolved

Reaction/event as reported by primary source (B.2.i.0) Current reaction

UNSURE IF RDV GIVEN PRIOR TO BIRTH OF PREMATURE INFANT & QUERY IF PT CAN BREAST FEED [PREGNANCY]

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
25.0	Maternal exposure during pregnancy
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
25.0	Maternal exposure during pregnancy

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Recovered/resolved

Summary (B.5)

Case narrative (B.5.1)

This case, manufacturer control number 2020-0510019 is a spontaneous report (received from local affiliate CA-LAM) referring to a(n) Adult (Age: 34 years, Gender: Female) patient. The Pharmacist reported the following event(s) for this case: Unsure if RDV given prior to birth of premature infant & query if Pt can breast feed [Pregnancy],Unsure if RDV given prior to birth of premature infant & query if Pt can breast feed [Premature delivery].

Medical history included:

Current condition(s): COVID-19 (COVID-19) Start Date: Date not provided

Historical condition(s): None Reported

Historical drug(s): None Reported

On an unspecified date, the patient received VEKLURY 100 mg, QD (once daily), IV drip route of administration for treatment of COVID-19.

Concomitant medications were not reported by the Pharmacist.

On an unspecified date, the patient became pregnant and potentially experienced a drug exposure during pregnancy. It was not known if the mother was actually treated with Remdesivir during the pregnancy. The reporting HCP suspected it might have been started after the birth but was not sure. On an unspecified date, the baby was born prematurely at gestational age of 29 and 1/7 weeks via C-section. No additional details regarding delivery or status of baby were provided. It was confirmed by reporter that mother had not breastfed the baby at the time of this report.

No laboratory/diagnostic tests were reported.

The action taken with VEKLURY was No Change
Dechallenge: N/A
Rechallenge: N/A

The Pharmacist assessed the event of Unsure if RDV given prior to birth of premature infant & query if Pt can breast feed [Pregnancy] as Serious (Hospitalized), causality of Not Related for VEKLURY. The outcome of this event was Resolved.

The Pharmacist assessed the event of Unsure if RDV given prior to birth of premature infant & query if Pt can breast feed [Premature delivery] as Serious (Hospitalized), causality of Not Reported for VEKLURY. The outcome of this event was Resolved.

The initial report was received on 17-DEC-2020.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

1 in 12 births may result in premature delivery and may represent background incidence. Notably, it was unknown if the mother was treated with Veklury during pregnancy or started after birth.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
25.0	COVID-19	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	Yes	

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	**Indication** (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	**Reaction** (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm)** (B.1.10.5)	**Sex** (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing** (B.1.10.7.1d)	**End date** (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Canada Vigilance AER#:	E2B_03693699 (0)	

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)			
Drug start date (B.1.10.8c)		Drug end date (B.1.10.8e)	
MedDRA version for Indication (B.1.10.8f.1)		Indication (B.1.10.8f.2)	
MedDRA version for reaction (B.1.10.8g.1)		Reactions (B.1.10.8g.2)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Pharmacist
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Canada Vigilance AER#:	E2B_03693699 (0)	

Receiver (A.3.2)		
Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

Canada Vigilance AER#:	E2B_04074310 (1)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210429 CCYYMMDD
	HC Initial Received Date:	2021 CCYY

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GILEAD-2021-0526660(2)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	No
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210421 CCYYMMDD	20210426 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-GILEAD-2021-0526660

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
GILEAD	CA-GILEAD-2021-0526660

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - GILEAD

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY	Female	161 Centimeter	59 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
1967[redacted] CCYYMMDD	Adult		53 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Canada Vigilance AER#:	E2B_04074310 (1)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	REMDESIVIR	
Active Substance names (B.4.k.2.2)		
remdesivir		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
200 Milligram		
Dosage text (B.4.k.6)		
200 mg 4 PM		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous (not otherwise specified)	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	25.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20210420 CCYYMMDD		
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
1 Days		
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
25.0	Overdose	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Not Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	

25.0	Overdose	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Related
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Overdose	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Related
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Overdose	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Related
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Overdose	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Related
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Overdose	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Related

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	DEXAMETHASONE	
Active Substance names (B.4.k.2.2)		
dexamethasone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PATIENT RECEIVED 200 MG VEKLURY AT 4PM & ANOTHER 200 MG AT 10 PM (OVERDOSE) OVERDOSE]

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
25.0	Overdose		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
25.0	Overdose		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	20210420 CCYYMMDD	20210420 CCYYMMDD	1 Days
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
1 Days		Recovered/resolved	

Summary (B.5)

Case narrative (B.5.1)

This case, manufacturer control number 2021-0526660 is a spontaneous report (received from local affiliate CA-LAM) referring to a(n) Adult (Age: 53 years, Gender: Female)patient. The Pharmacist reported the following event(s) for this case: Patient received 200 mg VEKLURY at 4pm yesterday & another 200 mg at 10 pm yesterday (overdose)[overdose].

Medical history was not provided.

On 20-APR-2021, the patient received 200 mg intravenous route of administration for treatment of drug use for unknown indication.

Concomitant medications were not reported by the Pharmacist.

On 20-Apr-2021, the patient experienced Patient received 200 mg VEKLURY at 4pm. The patient was transferred to another hospital and received another dose of Veklury 200 mg at 10 pm (overdose) [overdose] No adverse events, or signs and symptoms were reported. The physician wanted to know if they could continue with 100 mg infusion for 4 more days.

No laboratory/diagnostic tests were reported.

The action taken with VEKLURY was Not applicable

The Pharmacist assessed the event of Patient received 200 mg VEKLURY at 4pm yesterday & another 200 mg at 10 pm yesterday (overdose) [Overdose] as Serious (Hospitalized), causality of Not Related for VEKLURY. The outcome of this event was Not Reported

In the Pharmacist's opinion, other possible etiological factors were not reported.

The initial report was received on 21-APR-2021.

Follow-up information was received from a Pharmacist (via local affiliate) on 26-APR-2021:

It was confirmed that the patient did not experience any adverse events as a result of the Overdose.

Patient demographics provided (height, weight, DOB),

Concomitant/treatment medication (not specified) included DEXAMETHASONE, 6 mg oral (captured as concomitant medication).

REMDESIVIR was reduced to 100 mg (as prescribed) - date not specified.

The event of Overdose was Resolved on 20-APR-2021 as it was confirmed that the patient did not experience any adverse events and dose was reduced.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Patient received 2 initial doses of RDV in 2 hospitals same day with no reported adverse event.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Canada Vigilance AER#:	E2B_04074310 (1)	Page#6

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Pharmacist
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Canada Vigilance AER#:	E2B_04074310 (1)	Page#7

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

Canada Vigilance AER#:	E2B_05207951 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220131 CCYYMMDD
	HC Initial Received Date:	20220131 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GILEAD-2022-0567514(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220127 CCYYMMDD	20220127 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-GILEAD-2022-0567514

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
GILEAD	CA-GILEAD-2022-0567514

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - GILEAD

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Canada Vigilance AER#:	E2B_05207951 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
25.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	REMDESIVIR	
Active Substance names (B.4.k.2.2)		
remdesivir		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	25.0	Product used for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
25.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
25.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Related

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DEATH

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
25.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
25.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This case, manufacturer control number 2022-0567514 is a spontaneous report referring to a patient. The Consumer or other Non HCP reported the following event for this case: Death.

Medical history was not provided.

Concomitant medications were not reported by the Consumer or other Non HCP.

On an unspecified date, the patient received VEKLURY, Unknown route of administration for treatment of an unknown indication.

On an unspecified date, the patient experienced Death
Date of Death: Not Reported.
Cause of Death: Unknown cause of death.
Autopsy Performed: Unknown

No laboratory/diagnostic tests were reported.

The action taken with VEKLURY was Not applicable

The Consumer or other Non HCP reported the event of Death, assessed as Serious (Death, Medically Significant), causality of Related for VEKLURY. The outcome of this event was Fatal.

The initial report was received on 27-JAN-2022, and f/u received on 28-JAN-2022, and both reports were processed together.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Events of Death with lack of clinical information (including full details of the event, VEKLURY indication, cause of death, all medical history, diagnostic test results, concomitant medications) which limits causality assessment in this case.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
25.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Canada Vigilance AER#:	E2B_05207951 (0)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada	Qualification (A.2.1.4) Consumer/other non health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Canada Vigilance AER#:	E2B_05207951 (0)	Page#6

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

Canada Vigilance AER#:	E2B_05488631 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220421 CCYYMMDD
	HC Initial Received Date:	20220421 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GILEAD-2022-0578032(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220413 CCYYMMDD	20220413 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-GILEAD-2022-0578032

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
GILEAD	CA-GILEAD-2022-0578032

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

No

Source (A.1.4)

MAH - GILEAD

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)
	Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)
25.0	Unknown cause of death

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	REMDESIVIR	
Active Substance names (B.4.k.2.2)		
remdesivir		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Canada		
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Unknown	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	25.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Not Applicable		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
25.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PHARMACEUTICAL COMPANY	Global Introspection	Related
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
25.0	Death	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
PRIMARY SOURCE REPORTER	Global Introspection	Related

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HIS FRIEND WAS GIVEN REMDESIVIR AND DIED

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
25.0	Death
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
25.0	Death

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes			

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Fatal

Summary (B.5)

Case narrative (B.5.1)

This case, manufacturer control number 2022-0578032 is a spontaneous report referring to a(n) Missing patient identifier case. The Consumer or other Non HCP reported the following event(s) for this case: his friend was given Remdesivir and died.

Medical history was not provided.

Concomitant medications were not reported by the Consumer or other Non HCP.

On an unspecified date, the patient received VEKLURY , Unknown route of administration for treatment of Drug use for unknown indication.

,On an unspecified date , the patient experienced his friend was given Remdesivir and died. The reporter stated that serious side effects are suspected with this medication including death.

The patient died on an unknown date. The cause of death and whether an autopsy was performed were not reported.

No laboratory/diagnostic tests were reported.

The action taken with VEKLURY was Not applicable

The Consumer or other Non HCP assessed the event of his friend was given Remdesivir and died.as Serious (Death, and Medically Significant per Gilead), causality of Related for VEKLURY. The outcome of this event was Unknown

The initial report was received on 13-APR-2022. Follow-up information was received on 13-Apr-2022. Both reports were processed together.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Insufficient clinical information is available for causality assessment of the event of death.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
25.0	Unknown cause of death	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Canada Vigilance AER#:	E2B_05488631 (0)	

Past drug therapy (B.1.8)

Drug name (B.1.8a)		
Start date (B.1.8c)	End date (B.1.8e)	
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)	
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)	

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Consumer/other non health professional

Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Canada Vigilance AER#:	E2B_05488631 (0)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

Canada Vigilance AER#:	E2B_05524174 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220503 CCYYMMDD
	HC Initial Received Date:	20220503 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GILEAD-2022-0580113(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	No
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220502 CCYYMMDD	20220502 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-GILEAD-2022-0580113

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
GILEAD	CA-GILEAD-2022-0580113

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - GILEAD

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN			
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Canada Vigilance AER#:	E2B_05524174 (0)	

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** REMDESIVIR	
Active Substance names (B.4.k.2.2) remdesivir		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 25.0	**Indication (B.4.k.11b)** Drug use for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Unknown	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Bradycardia	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Bradycardia	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related

Canada Vigilance AER#:	E2B_05524174 (0)	

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SEVERE REMDESIVIR ASSOCIATED BRADYCARDIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
25.0	Bradycardia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
25.0	Bradycardia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes	20220413		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Summary (B.5)

Case narrative (B.5.1)

This case, manufacturer control number 2022-0580113 is a spontaneous report (received from local affiliate CA-LAM) referring to a(n) Missing patient identifiers case . The Physician reported the following event(s) for this case: Severe Remdesivir associated bradycardia.

Medical history was not provided.

Concomitant medications were not reported by the Physician.

On an unspecified date, the patient received VEKLURY, Unknown route of administration for treatment of Drug use for unknown indication; (no dosing details were provided.

On 13-APR-2022, the patient experienced Severe Remdesivir associated bradycardia. No further information was provided.

No laboratory/diagnostic tests were reported.

The action taken with VEKLURY was Unknown

The Physician assessed the event of Severe Remdesivir associated bradycardia as Serious (Medically Significant), causality of Related for VEKLURY. The outcome of this event was Unknown

The initial report was received on 02-MAY-2022.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Lack of clinical information including the patient's age and gender, start date and indication of VEKLURY, event details, relevant diagnostic evaluations (and baseline values), and treatment rendered, limits causality assessment for the event of bradycardia.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Canada Vigilance AER#:	E2B_05524174 (0)	Page#5

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d) PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3) Canada		Qualification (A.2.1.4) Physician
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

Canada Vigilance AER#:	E2B_05610312 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220531 CCYYMMDD
	HC Initial Received Date:	20220531 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GILEAD-2022-0583447(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	No
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220525 CCYYMMDD	20220525 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-ROCHE-3091742

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
ROCHE GILEAD	CA-ROCHE-3091742 CA-GILEAD-2022-0583447

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - GILEAD

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
UNKNOWN	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
	Adult		49 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Canada Vigilance AER#:	E2B_05610312 (0)	

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** REMDESIVIR	
Active Substance names (B.4.k.2.2) remdesivir		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intravenous (not otherwise specified)	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 25.0	**Indication (B.4.k.11b)** Drug use for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Unknown	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Pancreatitis	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Pancreatitis	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Not Reported

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** ACTEMRA	
Active Substance names (B.4.k.2.2) tocilizumab		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Drug Dose First Administered is Not Provided		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Unknown	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 25.0	**Indication (B.4.k.11b)** Drug use for unknown indication
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B.4.k.15)**
Action(s) taken with drug (B.4.k.16) Unknown	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	DEXAMETHASONE	
Active Substance names (B.4.k.2.2)		
dexamethasone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Drug Dose First Administered is Not Provided		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
	25.0	Drug use for unknown indication
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Unknown		
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PANCREATITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
25.0	Pancreatitis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
25.0	Pancreatitis		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
Yes			
Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)	
		Recovered/resolved	

Summary (B.5)

Case narrative (B.5.1)

This case, manufacturer control number 2022-0583447 is a spontaneous report received from regulatory authority (RA_EMA) (CA-ROCHE-3091742)referring to a(n) Adult (Age: 49 years, Gender: Male) patient. The Other HCP reported the following event(s) for this case: PANCREATITIS.

Medical history was not provided.
Concomitant medications were not reported by the Other HCP.

On an unspecified date, the patient received VEKLURY UNK, Intravenous route of administration for DRUG USE FOR UNKNOWN INDICATION.

On an unspecified date, the patient received ACTEMRA Drug Dose First Administered is Not Provided, Unknown route of administration for treatment of DRUG USE FOR UNKNOWN INDICATION.

On an unspecified date, the patient received DEXAMETHASONE Drug Dose First Administered is Not Provided, Unknown route of administration for treatment of DRUG USE FOR UNKNOWN INDICATION.

On an unspecified date , the patient experienced PANCREATITIS that resulted in hospitalization on unreported dates.

No laboratory/diagnostic tests were reported.

The action taken with VEKLURY was Unknown.
The action taken with ACTEMRA was Unknown.
The action taken with DEXAMETHASONE was Unknown.

The Other HCP assessed the event of PANCREATITIS as Serious (Hospitalized, also considered by Gilead to be Medically Significant), causality of Not Reported for VEKLURY. The outcome of this event was Resolved.

The initial report was received on 25-MAY-2022. Follow up information was received on 26-MAY-2022 (information processed together).

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Lack of information including clinical course of the event, medical history and concomitant medications limits causality assessment.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Canada Vigilance AER#:	E2B_05610312 (0)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	
Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)	
	Canada	Other health professional	
Literature reference(s) (A.2.2)			
Study name (A.2.3.1)		Project No	
Sponsor Study no. (A.2.3.2)		Observed study type (A.2.3.3)	

Canada Vigilance AER#:	E2B_05610312 (0)	

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		

Canada Vigilance AER#:	E2B_05773380 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220721 CCYYMMDD
	HC Initial Received Date:	20220721 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-GILEAD-2022-0582505(1)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	No
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20220519 CCYYMMDD	20220720 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-GILEAD-2022-0582505

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
HealthCanada GILEAD	CA-HealthCanada-000985945 CA-GILEAD-2022-0582505

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - GILEAD

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
PRIVACY		175 Centimeter	90.703 Kilogram
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2)
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Canada Vigilance AER#:	E2B_05773380 (0)	

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1) Suspect	**Medicinal product name (B.4.k.2.1)** REMDESIVIR	
Active Substance names (B.4.k.2.2) remdesivir		
Country drug obtained (B.4.k.2.3) Canada	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5) 100 Milligram,1 every 1 (Days) Cumulative dose to first reaction: 100 Milligram		
Dosage text (B.4.k.6) 100 mg, QD		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intravenous (not otherwise specified)	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 25.0	**Indication (B.4.k.11b)** COVID-19
Start date of drug (B.4.k.12) 20210104 CCYYMMDD	**Drug end date (B.4.k.14)** 20210105 CCYYMMDD	
Start period (B.4.k.13.1) 2 Days	**Last period (B.4.k.13.2)** 1 Days	**Duration of drug Admin (B. 4.k.15)** 1 Days
Action(s) taken with drug (B.4.k.16) Drug discontinued	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Pancreatitis	
Source of assessment (B.4.k.18.2) PHARMACEUTICAL COMPANY	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Pancreatitis	
Source of assessment (B.4.k.18.2) PRIMARY SOURCE REPORTER	**Method of assessment (B.4.k.18.3)** Global Introspection	**Result (B.4.k.18.4)** Related

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ENOXAPARIN SODIUM	
Active Substance names (B.4.k.2.2)		
enoxaparin sodium		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20210104 CCYYMMDD	20210107 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
2 Days		3 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	DOXYCYCLINE	
Active Substance names (B.4.k.2.2)		
doxycycline		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20201230 CCYYMMDD	20210106 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** DECADRON [DEXAMETHASONE]	
Active Substance names (B.4.k.2.2) DEXAMETHASONE		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12) 20210104 CCYYMMDD	**Drug end date (B.4.k.14)** 20210106 CCYYMMDD	
Start period (B.4.k.13.1) 2 Days	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)** 2 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	CEFTRIAXONE	
Active Substance names (B.4.k.2.2)		
ceftriaxone		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
UNK		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20210103 CCYYMMDD	20210106 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B.4.k.15)**
3 Days		3 Days
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PANCREATITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
25.0	Pancreatitis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
25.0	Pancreatitis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
Yes	20210105 CCYYMMDD	20210107 CCYYMMDD	2 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
2 Days 3 Days	1 Days	Recovered/resolved

Summary (B.5)

Case narrative (B.5.1)

This case, manufacturer control number 2022-0582505 is a spontaneous report (received from local affiliate CA-LAM) from RA CA-HealthCanada-000985945 referring to a(n) patient (identifiers withheld for privacy). The Pharmacist reported the following event(s) for this case: Pancreatitis.

Medical history included:

Current condition(s): COVID-19 (COVID-19) Start Date: Date not provided

Historical condition(s): None Reported

Historical drug(s): None Reported

Concomitant medications included LOVENOX [ENOXAPARIN SODIUM],DOXYCYCLINE,DECADRON [DEXAMETHASONE],CEFTRIAXONE.

On an unspecified date, the patient received VEKLURY 100 mg, QD, IV drip route of administration for treatment of COVID-19.

On an unspecified date , the patient experienced Pancreatitis and was hospitalized.

No laboratory/diagnostic tests were reported.

The action taken with VEKLURY was Unknown

The Pharmacist assessed the event of Pancreatitis as Serious (Hospitalized, Medically Significant), causality of Not Reported for VEKLURY. The outcome of this event was Resolved

The initial report was received on 19-MAY-2022.

Follow-up information was received on 30-JUN-2022 and received by Gilead on 30-JUN-2022. No new medically significant information was received.

Follow-up was received on 05-JUL-2022 from RA CA-HealthCanada-000985945 via local affiliate CA-LAM.

No new medically significant information was received.

Follow-up information was received via local affiliate on 20-JUL-2022 and received by Gilead on 20-JUL-2022:

Additional medical history included:

Current condition(s): Polykystic renal disease (Congenital cystic kidney disease) Start Date: Date not provided, Chronic Renal Failure (Chronic kidney disease) Start Date: Date not provided, Hypertension (Hypertension) Start Date: Date not provided

Dates were added for concomitant medications previously reported.

On 04-JAN-2021, the patient received VEKLURY 100 mg, QD, Intravenous use route of administration for treatment of COVID-19.

Pancreatitis onset was provided as 05-JAN-2021 and stopped on 07-JAN-2021, outcome remains as previously reported Resolved, causality updated to Related for VEKLURY (previously Not Reported).

Relevant laboratory/diagnostic tests included:
Lipase
Test Date: 04-JAN-2021, Notes: (Treatment started) 31
Test Date: 05-JAN-2021, Notes: Increased lipase; 321
Test Date: 06-JAN-2021, Notes: Increased lipase (treatment stopped after 2 doses); 604
Test Date: 07-JAN-2021, Notes: Decreased; 101

The action taken with VEKLURY was updated from Unknown to Drug Discontinued.

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

The event of pancreatitis occurred 1 day after the administration of VEKLURY. The labs showed elevated lipase which is confounded by underlying chronic renal failure in this patient with the underlying COVID-19.

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
20210104 CCYYMMDD	Lipase		
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
20210105 CCYYMMDD	Lipase		
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
20210106 CCYYMMDD	Lipase		
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No
Test date (B.3.1b)	**Test name (B.3.1c)**	**Test result (B.3.1d)**	
20210107 CCYYMMDD	Lipase		
Unit (B.3.1e)	**Normal low range (B.3.1.1)**	**Normal high range (B.3.1.2)**	**More info (B.3.1.3)**
			No

Results of tests and procedures (B.3.2)

Lipase, 04-JAN-21, (Treatment started)
31: Lipase, 05-JAN-21, Increased lipase;
321: Lipase, 06-JAN-21, Increased lipase (treatment stopped after 2 doses);
604: Lipase, 07-JAN-21, Decreased;
101:

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
25.0	COVID-19	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Yes	
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name (B.1.7.1a.2)**	
25.0	Polycystic kidney	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name (B.1.7.1a.2)**	
25.0	Chronic renal failure	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	
Comments (B.1.7.1g)		
MedDRA version (B.1.7.1a.1)	**Episode name (B.1.7.1a.2)**	
25.0	Hypertension	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
	Unknown	
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Canada Vigilance AER#:	E2B_05773380 (0)	Page#10

Past drug therapy (B.1.8)

Drug name (B.1.8a)		
Start date (B.1.8c)	End date (B.1.8e)	
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)	
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)	

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		
Relevant medical history / Concurrent conditions text (B.1.10.7.2)		

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
			PRIVACY
Reporter organization (A.2.1.2a)		Reporter department (A.2.1.2b)	
Reporter street (A.2.1.2c)			
Reporter city (A.2.1.2d)		Reporter state (A.2.1.2e)	

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Pharmacist

Literature reference(s) (A.2.2)	
Study name (A.2.3.1)	Project No
Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Canada Vigilance AER#:	E2B_05773380 (0)	Page#11

Sender (A.3.1)

Type (A.3.1.1)		Organization (A.3.1.2)
Department (A.3.1.3a)		Title (A.3.1.3b)
Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)
Street (A.3.1.4a)		
City (A.3.1.4b)		State (A.3.1.4c)
Postcode (A.3.1.4d)		Country code (A.3.1.4e)
Tel No. (A.3.1.4f)		Fax no. (A.3.1.4i)
Email Address (A.3.1.4l)		

Receiver (A.3.2)

Type (A.3.2.1)		Organization (A.3.2.2a)
Department (A.3.2.2b)		Title (A.3.2.2c)
Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)
Street (A.3.2.3a)		
City (A.3.2.3b)		State (A.3.2.3c)
Postcode (A.3.2.3d)		Country (A.3.2.3e)
Tel no. (A.3.2.3f)		Fax no. (A.3.2.3i)
Email address (A.3.2.3l)		