KIRBY INSTITUTE SERIOUS ADVERSE EVENT (SAE) FORM

SITE INFORMATION

Kirby Protocol Number: VHCRP1701 EDURACT Number: 2017-000694-37

To: Kirby Institute, VHCRP Fax No: +61 2 9385 9214 Email: smartc@kirby.unsw.edu.au

To: AbbVie Email: PPDINDPharmacovigilance@abbvie.com

Pages:_____ ☐ Initial Report ☐ Follow-up report Date of report *(dd/mon/yyyy)*: ____/_____/_____

Principal Investigator's Name: _____ Reported By: _____

Site Phone Number: _____ Site Fax No: _____

PATIENT

Subject ID Number: 1701-__ __ __ __ __-__ __ Subject date of birth *(dd/mon/yyyy)*: ____/ _____/ _____ Initials: ____-____

Date site became aware of the SAE *(dd/mon/yyyy)*: ____/ _____/ _____

Patient Gender: ☐ Male Height: _____ (cms) Weight: _____ (kgs)

☐ Female

☐ Transgender

☐ Unknown

INVESTIGATOR SIGN-OFF

INVESTIGATOR SIGN-OFF:

I verify that the information contained in this SAE is accurate and compatible with the source documents.

Investigator Name (Please print): _____

Investigator Signature: _____

Date *(dd/mon/yyyy):* ____/ _____/ _____

Reported to IRB/REC/EC/HREC: ☐ Yes ☐ No. If no, why? _____

Note: SAE form can be submitted without the investigator signature but must be signed and resubmitted once signature is complete.

KIRBY

Received date: _____ Received By: _____

SAE INFORMATION

SAE DETAILS:

Event name: _____

Event Onset Date *(dd/mon/yyyy)*: ____/ _____/ _____

Severity: ☐ Mild ☐ Moderate ☐ Severe ☐ Life Threatening

Investigator Narrative: describe the event , suspected causes and timing	
Include: Signs & Symptoms Investigations Course of Events Timings Treatment for SAE Suspected Causes Other Comments	

Drug: Glecaprevir/Pibrentasvir (GLE/PIB)

Causality:

- ☐ Not related
- ☐ Unlikely
- ☐ Possibly
- ☐ Probably

Action Taken:

- ☐ Drug withdrawn
- ☐ Drug interrupted
- ☐ No change to drug
- ☐ Unknown
- ☐ Not applicable

SAE INFORMATION CONTINUED

SAE Outcome:

☐ Recovered/Resolved

Recovery date (dd/mon/yyyy): ____/ _____/ _____

☐ Recovered with sequalae

☐ Recovering/Resolving

☐ Not recovered/not resolved

☐ Fatal (complete death details)

☐ Unknown

SAE Seriousness Category:

☐ Death (complete death details)

☐ Life Threatening

☐ Persistent or significant disability/incapacity

☐ Inpatient hospitalisation

☐ Prolongation of existing hospitalisation

☐ Congenital anomaly/birth defect

☐ Other medically important condition

Study Drug Dosing:

Start Date *(dd/mon/yyyy)*: ____/ _____/ _____

Stop Date*(dd/mon/yyyy)*: ____/ _____/ _____

Dose: 100/40

Unit: mg

Frequency: Once daily

Route: Oral

Batch/Lot No.: _____

DEATH

DEATH DETAILS

Date of Death *(dd/mon/yyyy):* ____/ _____/ _____

Autopsy Performed?: ☐ No ☐ Yes (if yes, attach a copy of report if available)