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| **SITE & REPORT 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](mailto:smartc@kirby.unsw.edu.au)  To: **AbbVie** Email: [PPDINDPharmacovigilance@abbvie.com](mailto:PPDINDPharmacovigilance@abbvie.com)  Pages:     Initial Report  Follow-up report Date of report:Click here to enter a date.  Principal Investigator’s Name:       Reported By:  Site Phone Number:       Site Fax No: |

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| **PATIENT** | Subject ID Number: 1701-     -   Subject date of birth: Click here to enter a date. Initials:    -  Date site became aware of the SAE: Click here to enter a date.  Patient Gender:  Male Height:       (cms) Weight:       (kgs)  Female  Transgender  Unknown |

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| **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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  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. |

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| **KIRBY** | Received date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Received By: ­­­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **SAE INFORMATION** | SAE DETAILS:  Event name:  Event Onset Date: Click here to enter a date.  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Glecaprevir/Pibrentasvir (GLE/PIB) | | Causality:  Not related  Unlikely  Possibly  Probably | | Action Taken:  Drug withdrawn  Drug interrupted  No change to drug  Unknown  Not applicable | |

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| **SAE INFORMATION CONTINUED** | |  | | --- | | SAE Outcome:  Recovered/Resolved  Recovery date: Click here to enter a date.  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:Click here to enter a date.  Stop Date*:* Click here to enter a date.  Dose: 300/120  Unit: mg  Frequency: Once daily  Route: Oral (PO)  Batch/Lot No.: | |

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| **DEATH** | DEATH DETAILS  Date of Death*:* Click here to enter a date.  Autopsy Performed?:  No  Yes (if yes, attach a copy of report if available) |