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| **SITE & REPORT INFORMATION** | Kirby Protocol Number: VHCRP1510 EDURACT Number:       Pharma Protocol Number : MSD\_MISP 56015 (If applicable) (If applicable)To: Kirby Institute, VHCRP Fax No: +61 2 9385 9214To: Merck worldwide product safety Fax No: +1 215 993 1220 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:       Subject date of birth: Click here to enter a date.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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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 Onset Date: Click here to enter a date. Severity: [ ]  Mild [ ]  Moderate [ ]  Severe [ ]  Life Threatening

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| Investigator Narrative: describe the event , suspected causes and timing |
| Include:Signs & SymptomsInvestigationsCourse of EventsTimingsTreatment for SAESuspected CausesConcomitant medicinesConcurrent conditionsOther Comments |       |

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| Drug: Elbasvir/grazoprevir | Drug: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Drug: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Causality:[ ]  Not related[ ]  Unlikely[ ]  Possibly[ ]  Probably | Causality:[ ]  Not related[ ]  Unlikely[ ]  Possibly[ ]  Probably | Causality:[ ]  Not related[ ]  Unlikely[ ]  Possibly[ ]  Probably |
| Action Taken:[ ]  Drug withdrawn[ ]  Drug interrupted[ ]  Dose reduced[ ]  Dose increased[ ]  Dose not changed[ ]  Unknown[ ]  Not applicable | Action Taken:[ ]  Drug withdrawn[ ]  Drug interrupted[ ]  Dose reduced[ ]  Dose increased[ ]  Dose not changed[ ]  Unknown[ ]  Not applicable | Action Taken:[ ]  Drug withdrawn[ ]  Drug interrupted[ ]  Dose reduced[ ]  Dose increased[ ]  Dose not changed[ ]  Unknown[ ]  Not applicable |

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| **SAE INFORMATION CONTINUED** |

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| SAE Outcome:[ ]  Recovered/ResolvedRecovery date: Click here to enter a date.[ ]  Recovered with sequalae[ ]  Recovering/Resolving[ ]  Not recovered/not resolved[ ]  Fatal (complete death details)[ ]  Unknown | SAE Outcome:[ ]  Recovered/ResolvedRecovery date: Click here to enter a date.[ ]  Recovered with sequalae[ ]  Recovering/Resolving[ ]  Not recovered/not resolved[ ]  Fatal (complete death details)[ ]  Unknown | SAE Outcome:[ ]  Recovered/ResolvedRecovery 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)[ ]  Hospitalisation Required[ ]  Prolonged Hospitalisation[ ]  Life Threatening[ ]  Persistent/Significant disability[ ]  Congenital anomaly/birth defect[ ]  Cancer[ ]  Overdose[ ]  Other medically important condition[ ]  Pregnancy (if applicable) | SAE Seriousness Category:[ ]  Death (complete death details)[ ]  Hospitalisation Required[ ]  Prolonged Hospitalisation[ ]  Life Threatening[ ]  Persistent/Significant disability[ ]  Congenital anomaly/birth defect[ ]  Cancer[ ]  Overdose[ ]  Other medically important condition[ ]  Pregnancy (if applicable) | SAE Seriousness Category:[ ]  Death (complete death details)[ ]  Hospitalisation Required[ ]  Prolonged Hospitalisation[ ]  Life Threatening[ ]  Persistent/Significant disability[ ]  Congenital anomaly/birth defect[ ]  Cancer[ ]  Overdose[ ]  Other medically important condition[ ]  Pregnancy (if applicable) |
| Study Drug Dosing: Elbasvir/grazoprevirStart Date: Click here to enter a date.Stop Date*:* Click here to enter a date.Dose: 100/50Unit: mgFrequency: Once dailyRoute: OrallyBatch/Lot No.:       | Study Drug Dosing:Start Date*:* Click here to enter a date.Stop Date*:* Click here to enter a date.Dose:      Unit: Frequency: Route: Batch/Lot No.:       | Study Drug Dosing:Start Date*:* Click here to enter a date.Stop Date*:* Click here to enter a date.Dose:      Unit: Frequency: Route: Batch/Lot No.:       |

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