**The Diabetes Virus Detection and Intervention Trial (DiViD Int)**

**Serious Adverse Event**

**Project manager and medical officer:**

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**Coordinating Investigator, principal investigator for Norway, and back-up medical officer:**

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* Please complete form, sign and then e-mail form within 24 hours of awareness to coordinating investigator.
* Coordinating investigator to be contacted as soon as possible by mobile telephone **+47 922 33 550.**
* Original completed form to be stored in Trial Master File/ Investigator Site File.
* Please ensure event to be recorded in patient medical journal in hospital, and eCRF where applicable.

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| Initial report |  |

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| Follow-up report |  |

Report information

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| Follow-up report number: |  |

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| Date of birth (dd-mm-yyyy): | Male: | Female: |

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| **INVESTIGATIONAL MEDICINAL PRODUCT (IMP)** |
| Name of IMP: | Indication:  | Participant in DiViD Int.  |
| **Pleconaril** | Dosage: | Dosage form: Oral solution | Dose/ unit: 40 mg/ml | Route:X 2 | Frequency: Morning + evening |
| **Ribavirin** | Dosage: | Dosage form:Oral solution | Dose/ unit: 40 mg/ml | Route:X 2 | Frequency: Morning + evening |
| **Placebo** | Dosage: | Dosage form:Oral solution | Dose/ unit: 40 mg/ml | Route:X 2 | Frequency: Morning + evening |
| Date of first dose IMP: |
| Date of most recent dose IMP: |

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| **MAIN SERIOUS ADVERSE EVENT** |
| **SAE term:**Clearly related sign/symptoms should preferably be recorded as a single diagnosis or syndrome. Please describe symptoms of the diagnosis in the narrative field. |
| Start date: | Stop date: |
| **Intensity:**  | **Relatedness to study drug:** | **Outcome:** |
|  | Mild |  | Not related |  | Ongoing |
|  | Moderate |  | Unlikely related |  | Recovering |
|  | Severe |  | Possible related |  | Recovered |
|  | Life-threatening |  | Probable related |  | Recovered with sequelae |
|  |  | Definitely related |  | Death |
|  |  |  | Unknown |

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| **Narrative and comments**Description of event, including presenting symptoms, pertinent risk factors specific to the event(s), treatment, procedure, final diagnosis and event outcomes. Please note that the description may be written in Norwegian. |
| **Action taken regarding the IMP due to this event** | **Seriousness criteria** |
|  | None |  | A congenital anomaly or birth defect |
|  | Dose reduced |  | Persistent or significant disability/ incapacity |
|  | Drug interrupted |  | Hospitalization/ prolongation of hospitalization |
|  | Drug discontinued |  | Life-threatening |
|  | NA |  | Death |
|  |  | Other important medical event(is medically significant or require intervention to prevent one or other of the outcomes listed above) |
|  | Date of death: |
| **Did event abate after stopping IMP?** | **Could patient original condition, or other illness, account for the adverse event?** |
|  | Yes |  | No |
|  | No |  | Yes | If Yes, please specify: |
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| **Concomitant medications ongoing at time of event(s), (exclude those used to treat event):** |
| Drug name/ Strength | Indication for use | Start Datedd.mm.yyyy | Stop Datedd.mm.yyyy |
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| **Reporter information** |
| Name (signature) | Name (block capitals) | Title | Date |
|  |  |  |  |

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| **SPONSOR EVALUATION** |
| Name (signature) | Name (block capitals) | Relationship to IMP | Was this event | Date |
|  |  |  | Not related |  | Expected |  |
|  | Unlikely related |  | Unexpected |
|  | Possible related |  |
|  | Probable related |
|  | Definitely related |

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| Investigator signature: | Date: |