SERIOUS ADVERSE EVENT FORM AGO

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| **EVENT N°: *(site\chronologic number of event; e.g. UZ Gent\001)*** ................... **\** .................. |

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| **Report Type:** | ❑ Initial Report  ❑ Follow-up Report n°………………… |

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| **STUDY DRUG INFORMATION:** | |  | **SUBJECT INFORMATION:** | |
| Name drug (INN, trade name if possible): |  |  | Subject number: |  |
| Daily dose: |  |  | Year of birth: |  |
| Route of administration: |  |  |  |  |
| Therapy days (from/to, time of day): |  |  |  |  |

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| **DESCRIPTION OF SAE:** |  |
| Previously reported as :  (if applicable) |  |
| Criterion for considering the AE as serious.  Any untoward medical occurrence that at any dose: | ❑ Results in death  ❑ Is life-threatening  ❑ Requires inpatient hospitalization or prolongation of existing hospitalization  ❑ Results in persistent or significant disability or incapacity  ❑ Is a congenital anomaly or birth defect  ❑ Is considered as an important medical event |
| Date (yyyy-mm-dd) and time of onset of the reaction: |  |
| Date of study personnel’s awareness of the event (yyyy-mm-dd) |  |
| Severity or CTCAE-Grade | **CTCAE-Grade:** ❑ Grade 1 ❑Grade 2 ❑Grade 3 ❑Grade 4 ❑Grade 5  **Or**  **Intensity:** ❑ mild ❑ moderate ❑ severe |
| Actions taken:  *(please provide all actions taken, i.e. diagnostic procedures, treatment, referral to other departments,…)* |  |
| Outcome of the event: | ❑ Resolved, date (yyyy-mm-dd): ………...............................................................  ❑ Resolved with sequelae, date (yyyy-mm-dd): ………........................................  ❑ Ongoing  ❑ Death, date of death (yyyy-mm-dd): ………......................................................  ❑ Unknown, explain ……………………………………………………………... |
| Changed Outcome of the event in case of Follow-up Report: | ❑ Resolved, date (yyyy-mm-dd): ………..............................................................  ❑ Resolved with sequelae, date (yyyy-mm-dd): ……….......................................  ❑ Ongoing  ❑ Death, date of death (yyyy-mm-dd): ………......................................................  ❑ Unknown, explain ……………………………………………………………... |
| De-challenge and/or re-challenge information: |  |
| Setting (hospital, home, …): |  |

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| **SAE NARRATIVE:**  Give a detailed description of the serious adverse event, including full description of the signs or symptoms, event duration, treatment administered, actions taken and outcome. Also describe any relevant history. |
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| **CONCOMITANT MEDICATIONS:**  **(Including additional (non-)investigational study drugs)** | | | |
| **Drug Name**  **(Trade name, if possible)** | **Dose, route of administration, regimen** | **Start & stop dates**  **(yyyy-mm-dd)** | **Reason for administration** |
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| **RELEVANT LABORATORY AND DIAGNOSTIC TESTS OR PROCEDURES:** | | |
| **Date (yyyy-mm-dd)** | **Test** | **Results (+ normal range if applicable)**  **Please attach report when possible** |
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| **ASSESSMENT OF CAUSALITY BY (PRINCIPAL) INVESTIGATOR:** | | |
| Is SAE related to trial medication? | | ❑ Not related  ❑ Unlikely  ❑ Possibly  ❑ Probably  ❑ Definitely |
| **REMARKS:** | | |
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| **SIGNATURES:** | | |
| Report completed by:  Print Name:  Signature: | ..............................................................................  .............................................................................. Date (yyyy-mm-dd): ............................ | |
| I have reviewed this serious adverse event report and find it to be complete and accurate.  Signature of Investigator: .............................................................................. Date (yyyy-mm-dd): ............................ | | |

*Only for completion by Coordinating Investigator U(Z) Gent*

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| **ASSESSMENT COORDINATING INVESTIGATOR (or delegate):** | | |
| Is SAE related to the trial medication (i.e. investigational medicinal product, comparator or placebo)?  *(see study protocol for definition)* | ❑ Not related  ❑ Unlikely  ❑ Possibly  ❑ Probably  ❑ Definitely | |
| Is the SAE unexpected?  (e.g. not listed in IB, SmPC) | ❑ Yes, unexpected  ❑ No  Explain and mention source: ............................................................... | |
| Is this a SUSAR?  (A SUSAR is a SAE which is at least possibly related **and** unexpected) | ❑ Yes  ❑ No | Note: For SUSARs, send form **immediately** to HIRUZ CTU for reporting to EMA through the Eudravigilance database. |

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| **SIGNATURE COORDINATING INVESTIGATOR:** | |
| I agree with the assessment of this serious adverse event report. | |
| Print Name Coordinating Investigator or delegate:  Signature Coordinating Investigator (or delegate):  Date (yyyy-mm-dd) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |