EISAI SPONTANEOUS REPORT FORM FOR ADVerSE EVENTS

& EVENTS OF SPECIAL SITUATIONS

 Version (August 2020)

 Angaben können in deutscher oder englischer Sprache vorgenommen werden Page 1 of 3

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| A. REPORT INFORMATION |
| 1. Company Product:
 | 2. [ ]  Initial[ ]  Follow up  | 3. Country:       |
| **B. PATIENT INFORMATION** |
| 1. Initials:      | 2. Age:      Date of Birth:       | 3. Sex:[ ]  Male[ ]  Female | 4. Weight:       [ ]  kg [ ]  lb | 5. Height:       [ ]  cm[ ]  in | 6. Pregnancy:[ ]  Yes [ ]  No7.(       ) wks |
| 8. At the onset of initial AE: [ ]  Outpatient [ ]  Inpatient | 9. Inpatient admission date: (Mmm/DD/YYYY)       |
| 10. Concomitant Disease |       |
| 11. Past Medical History/Allergies/Risk factors |       |
| **C. EVENT INFORMATION** |
| 1. **Event:**
 |
| 2. Onset date(Mmm/DD/YYYY) | 3. Relationship toCompany Drug | 4. Seriousness(See below) | 5. Action taken with Company Drug | 6. Outcome(Date: Mmm/DD/YYYY) |
|       | [ ]  Not related[ ]  Possibly related[ ]  Probably related | [ ]  Non-serious (does not meet following criteria)[ ]  Death [ ]  Life-threatening \*Note1[ ]  Required hospitalization[ ]  Prolonged hospitalization[ ]  Persistent or significant disability/incapacity [ ]  Congenital anomaly[ ]  Important medical event \*Note2 | [ ]  Dose Maintained[ ]  Dose Increased*(Enter New Dose in Section D)*[ ]  Dose Reduced*(Enter New Dose in Section D)*[ ]  Discontinued[ ]  Not Applicable [ ]  Unknown | (Date       )[ ]  Recovered[ ]  Recovering[ ]  Not recovered[ ]  Recovered with sequelae[ ]  Death *(Provide details in C10)*[ ]  Unknown |
| 1. **Event:**
 |
|       | [ ]  Not related[ ]  Possibly related[ ]  Probably related | [ ]  Non-serious (does not meet following criteria)[ ]  Death [ ]  Life-threatening \*Note1[ ]  Required hospitalization[ ]  Prolonged hospitalization[ ]  Persistent or significant disability/incapacity [ ]  Congenital anomaly[ ]  Important medical event \*Note2 | [ ]  Dose Maintained[ ]  Dose Increased*(Enter New Dose in Section D)*[ ]  Dose Reduced*(Enter New Dose in Section D)*[ ]  Discontinued[ ]  Not Applicable [ ]  Unknown | (Date      )[ ]  Recovered[ ]  Recovering[ ]  Not recovered[ ]  Recovered with sequelae[ ]  Death *(Provide details in C10)*[ ]  Unknown |
| 1. **Event:**
 |
|       | [ ]  Not related[ ]  Possibly related[ ]  Probably related | [ ]  Non-serious (does not meet following criteria)[ ]  Death [ ]  Life-threatening \*Note1[ ]  Required hospitalization[ ]  Prolonged hospitalization[ ]  Persistent or significant disability/incapacity [ ]  Congenital anomaly[ ]  Important medical event \*Note2 | [ ]  Dose Maintained[ ]  Dose Increased*(Enter New Dose in Section D)*[ ]  Dose Reduced*(Enter New Dose in Section D)*[ ]  Discontinued[ ]  Not Applicable [ ]  Unknown | (Date      )[ ]  Recovered[ ]  Recovering[ ]  Not recovered[ ]  Recovered with sequelae[ ]  Death *(Provide details in C10)*[ ]  Unknown |
| Note 1: “Life-threatening” refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. Note 2: “Important medical events” are those that do not meet other serious criteria, but may require intervention to prevent one of the outcomes listed above (e.g. seizure, blood dyscrasias). |

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| **C. EVENT INFORMATION (continued)** |
| 7. Description of the event(s): Include signs, symptoms and treatment of the events       |
| 8. Was the event considered a drug interaction? [ ]  No [ ]  Yes, If Yes, please indicate the interacting drugs here:      *(Please provide details in Section C.7 above)* |
| If outcome of event was death: 9. Death date: Mmm/DD/YYYY (     )10. Cause of Death: (     )11. Autopsy? [ ]  No, [ ]  Yes (     ) |
| 12.Did event(s) reappear after reintroducing the Company Product? *(Please provide details in Section C.7 above)* | for Event 1 | [ ]  Yes [ ]  No [ ]  Not applicable |
| for Event 2 | [ ]  Yes [ ]  No [ ]  Not applicable |
| for Event 3 | [ ]  Yes [ ]  No [ ]  Not applicable |
| **D. DRUG INFORMATION** |
| 1. Drugs (generic name): | 2. Total daily dose (unit) | 3. Route | Date of administration | 6. Indication | **7. Lot Number** |
| 4. Start date(Mmm/DD/YYYY) | 5. End date（Mmm/DD/YYYY)or cont.  |
| Suspect drugs:      |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
| Other drugs:      |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
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| **D. DRUG INFORMATION (continued)**  |
| 1. Drugs used to treat events (generic name): | 2. Total daily dose (unit) | 3. Route | Date of administration | 6. Indication | **7. Lot Number** |
| 4. Start date(Mmm/DD/YYYY) | 5. End date（Mmm/DD/YYYY)or cont.  |
| Treatment Drugs:      |       |       |       |       |       |       |
|       |       |       |        |       |       |       |
|       |       |       |        |       |       |       |
| **E. LABORATORY TESTS RESULTS (Please attach lab data or describe here)** |
| (Baseline, During administration, At the time of AE, F-up, etc.)      |
| **F. REPORTER’S COMMENTS** |
|       |
| **G. REPORTER’S INFORMATION** |
| 1. Name:       | 2. Health Professional? [ ]  Yes [ ]  No  | 3. Occupation:[ ]  Physician [ ]  Pharmacist [ ]  Consumer[ ]  Others (     ) |
| 4. Telephone:       | 5. Address:       |
| 6. Reporter’s signature:       7. Signed date: (Mmm/DD/YYYY)       |

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| **FOR COMPANY USE ONLY** |
| a. Date this report initially received by Eisai: (Mmm/DD/YYYY)       | b. ARISg No:      | c. Local No:      |

Additional pages may be attached if necessary (e.g. hospital discharge summary, laboratory records, etc.).