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  No  7.(       ) 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 |
| **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). | | | | | | | | |

Version (August 2020) Page 2 of 3

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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: |  |  |  | |  | |  |  |
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| Other drugs: |  |  |  | |  | |  |  |
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Version (August 2020) Page 3 of 3

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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.).