Informed consent form

Principal investigator: ☐ ☐ ☐ ☐ Hospital ☐ ☐ Department ☐ ☐

Trial title: A double-blind comparative randomized Japanese trial of triplet standard antiemetic therapies with or without 5 mg olanzapine to prevent chemotherapy-induced nausea and vomiting for patients with breast cancer treated with an anthracycline/cyclophosphamide regimen.

<Explanation items>

Introduction
☐ 1. Name of the specified clinical trial to be implemented, as well as confirmation that approval from the administrator of the implementing medical institution has been obtained for the implementation of the specified clinical trial and that the protocol has been submitted to the Minister of Health, Labour and Welfare
☐ 2. Name of the implementing medical institution, as well as the affiliation, job title, and name of the principal investigator (when specified clinical trial is conducted as a multicenter joint trial, this includes the affiliation, job title, and name of the sponsor investigator as well as the affiliation, job title, and name of the principal investigators of the implementing medical institutions)
☐ 3. Reason why patient was selected as a subject of the specified clinical trial
☐ 4. Expected benefits and disadvantages from implementing the specified clinical trial
☐ 5. Refusal to participate in the specified clinical trial is voluntary
☐ 6. Items concerning withdrawal of consent
☐ 7. Patient will not receive any disadvantageous treatment by refusing to participate in or withdrawing consent from the specified clinical trial
☐ 8. Method of disclosing information relating to the specified clinical trial
☐ 9. Subjects of the specified clinical trial or their substitutes (henceforth, “subjects, etc., of the specified clinical trial”) can obtain or view research protocol and other documents relating to implementation of the specified clinical trial upon request; how to obtain and view documents
☐ 10. Items relating to the protection of personal information of subjects of the specified clinical trial
☐ 11. Method of storing and disposing samples, etc.
☐ 12. Circumstances relating to conflict of interest for the specified clinical trial
☐ 13. System for responding to complaints and inquiries
☐ 14. Items relating to costs of implementing the specified clinical trial
☐ 15. Presence/absence and content of other treatments, and comparison with the expected benefits and disadvantages of other treatments
☐ 16. Items relating to compensation and provision of medical care for health hazards due to implementation of the specified clinical trial
☐ 17. Review items relating to the accredited clinical trial institutional review board that conducts review/opinion work on the specified clinical trial, and other items relating to the accredited clinical trial institutional review board in association with the specified clinical trial
☐ 18. Other necessary items relating to implementation of the specified clinical trial

Conclusion

【Physician’s signature line】
I have provided a sufficient explanation regarding this clinical trial to the abovementioned patient.

Explanatory date: YYYY MM DD Affiliation: __________________________
Explanatory time: AM • PM (Hour) (Minute) Name: __________________________ (signature)

【Patient’s signature line】*Add substitute entry line if trial requires substitute.

For participating in this trial, I have received sufficient explanation regarding the above items, received the consent explanation document, and sufficiently understood its contents; therefore, I consent to participation in this trial.

Consent date: YYYY MM DD Patient ID: __________________________
Consent time: AM • PM (Hour) (Minute) Patient name: __________________________ (signature)