

LB=Laboratory Test Results

LBCAT=COAGULATION FUNCTION

QVAL when
SUPPLB.QNAM=LBCLSIG

LBORRES

| No. | Laboratory test item | Measured value | Unit | Determination of clinical significance | Note |
|--------|---|----------------|----------|--|--------------------------------|
| LBSPID | | | LBORRESU | | QVAL when SUPPLB.QNAM=LBTXT |
| 5 | International normalized ratio (INR) | | | <div><div>○ Normal</div><div>○ Abnormal without clinical significance</div><div>○ Abnormal with clinical significance</div><div>○ Not tested</div></div> | |
| | LBTESTCD=INR | | | | |
| | LBTEST=Phothrombin Intl. Normalized Ratio | | | | |

Name of PI:_____

Account:_____

Date of Signature:_____

EG=ECG Test Results

2.12 12-Lead ECG

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: screening period (D-7 to D-1) | Visit No.: 2 |
| 12-lead ECG | EGSTAT=NOT DONE when EGTESTCD=EGALL and EGTEST=All ECG Tests |
| 12-lead ECG: <input type="radio"/> Not performed | |
| Examination date: _____ (DD-MM-YYYY) | EGDTC |

| No. | Examination item | Result | Unit |
|-----------------|------------------|---------------------------------|------|
| EGTESTCD=EGHRMN | Heart rate | EGTEST=ECG Mean Heart Rate | bpm |
| EGTESTCD=PRAG | PR | EGTEST=PR Interval, Aggregate | ms |
| EGTESTCD=QTAG | QT | EGTEST=QT Interval, Aggregate | ms |
| EGTESTCD=QTCFAG | QTc | EGTEST=QTcF Interval, Aggregate | ms |

| | | |
|---|------------------------------|-----------------------|
| 12-lead ECG result: <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance | EGORRES when EGTESTCD=INTP | EGTEST=Interpretation |
| If abnormal, please describe: _____ | QVAL when SUPPEG.QNAM=EGDESP | |

Name of PI: _____

Account: _____

Date of Signature: _____

CV=Cardiovascular System Findings

2.13 Echocardiography

| | | | |
|---|---|---|--|
| Subject ID: _____ | | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI | |
| Study site name: _____ | | Study site No.: _____ | |
| Investigator name: _____ | | Investigator ID: _____ | |
| Visit: screening period (D-7 to D-1) | | Visit No.: 2 | |
| Echocardiography | CVSTAT=NOT DONE when CVTESTCD=CVALL and CVTEST=All CV Tests | | |
| Echocardiography: <input type="radio"/> Not performed | | | |
| Examination date: _____ (DD-MM-YYYY) | | CVDTC | |
| LVEF (%): | CVORRES when CVTESTCD=LVEF | CVTEST=Left Ventricular Ejection Fraction | |
| Result: <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance | | CVORRES when CVTESTCD=INTP CVTEST=Interpretation | |
| If abnormal, please describe: | | QVAL when SUPPCV.QNAM=CVDESP | |

CVORRESU=% when CVTESTCD=LVEF

Name of PI: _____

Account: _____

Date of Signature: _____

LB=Laboratory Test Results

2.14 Blood Pregnancy Test

LBCAT=BLOOD PREGNANCY TEST

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: screening period (D-7 to D-1) | LBTEST=Choriogonadotropin Beta |
| Blood pregnancy test LBTESTCD=HCG | LBSTAT=NOT DONE when LBTESTCD=HCG and LBTEST=Choriogonadotropin Beta |
| Blood pregnancy test: <input type="radio"/> Not performed | |
| Reason for not performing: <input type="radio"/> Menopause <input type="radio"/> Male <input type="radio"/> Others | LBREASND |
| Other reasons: QVAL when SUPPLB.QNAM=LBREASOT | |
| Test date: LBDBC (DD-MM-YYYY) | |
| Result: <input type="radio"/> Negative <input type="radio"/> Positive | LBORRES when LBTESTCD=HCG and LBTEST=Choriogonadotropin Beta |

Name of PI: _____

Account: _____

Date of Signature: _____

IE=Inclusion/Exclusion Criteria Not Met

2.15 Inclusion/Exclusion Criteria

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: screening period (D-7 to D-1) | Visit No.: 2 |
| Inclusion/Exclusion criteria | |
| Did the subject meet all inclusion criteria and not meet any of the exclusion criteria? <input type="radio"/> No <input type="radio"/> Yes | |

[NOT SUBMITTED]

IECAT=Inclusion

IETEST

| No. | Inclusion criteria | Met or not? |
|---------------|--|--|
| IESPID | IETESTCD | IEORRES |
| 1 | With pathologically or cytologically confirmed gastric cancer (GC) or gastroesophageal junction carcinoma (GEJ) with evidence of being unresectable, locally advanced, or metastatic, and was histologically confirmed adenocarcinoma | <input type="radio"/> No <input type="radio"/> Yes |
| 2 | Aged 18 or above, male or female | <input type="radio"/> No <input type="radio"/> Yes |
| 3 | Patients who have not received systemic treatment (including HER-2 inhibitors) for advanced or metastatic GC / GEJ. Subjects who once received adjuvant or neoadjuvant therapy (including chemotherapy, radiotherapy, or radiochemotherapy) for GC/GEJ must have completed the last treatment at least 6 months prior to the first study treatment. Palliative radiotherapy is permitted, but it must be completed 2 weeks prior to the start of study treatment | <input type="radio"/> No <input type="radio"/> Yes |
| 4 | With an Eastern Cooperative Oncology Group (ECOG) PS score of 0-1 | <input type="radio"/> No <input type="radio"/> Yes |
| 5 | With measurable lesion as per RECIST v1.1 | <input type="radio"/> No <input type="radio"/> Yes |
| 6 | With a life expectancy of > 12 weeks | <input type="radio"/> No <input type="radio"/> Yes |
| 7 | All acute toxicities due to previous anti-cancer treatments or surgeries have resolved to Grade 0-1 (as per NCI CTCAE v4.03) or to the level specified in the inclusion/exclusion criteria, except for other toxicities such as alopecia that do not pose a safety risk on the patient as assessed by the investigator | <input type="radio"/> No <input type="radio"/> Yes |

IE=Inclusion/Exclusion Criteria Not Met

IECAT=Inclusion

IETEST

| No. | Inclusion criteria | Met or not? |
|---------------|--|--|
| IESPID | IETESTCD | IEORRES |
| 8a | With adequate organ and bone marrow functions, as defined below: a) Absolute neutrophil count (ANC) $\geq 1,500/\text{mm}^3$ ($1.5 \times 10^9/\text{L}$) | <input type="radio"/> No <input type="radio"/> Yes |
| 8b | With adequate organ and bone marrow functions, as defined below: b) Platelet count (PLT) $\geq 100,000/\text{mm}^3$ ($100 \times 10^9/\text{L}$) | <input type="radio"/> No <input type="radio"/> Yes |
| 8c | With adequate organ and bone marrow functions, as defined below: c) Hemoglobin (Hb) ≥ 9 g/dL (90 g/L) | <input type="radio"/> No <input type="radio"/> Yes |
| 8d | With adequate organ and bone marrow functions, as defined below: d) Serum creatinine $\leq 1.5 \times$ the upper limit of normal (ULN) or creatinine clearance ≥ 60 mL/min | <input type="radio"/> No <input type="radio"/> Yes |
| 8e | With adequate organ and bone marrow functions, as defined below: e) Total bilirubin (BIL) $\leq 1.5 \times$ ULN | <input type="radio"/> No <input type="radio"/> Yes |
| 8f | With adequate organ and bone marrow functions, as defined below: f) Aspartate aminotransferase (AST/SGOT) or alanine aminotransferase (ALT/SGPT) $\leq 2.5 \times$ ULN; ALT and AST $\leq 5 \times$ ULN in case of liver metastasis | <input type="radio"/> No <input type="radio"/> Yes |
| 8g | With adequate organ and bone marrow functions, as defined below: g) International normalized ratio (INR) ≤ 1.5 , and prothrombin time (PT) and activated partial thromboplastin time (APTT) $\leq 1.5 \times$ ULN | <input type="radio"/> No <input type="radio"/> Yes |
| 8 h | Adequate organ and bone marrow functions, as defined below: h) Urine protein $< 2+$; If urine protein is $\geq 2+$, then the 24-hour urine protein must be ≤ 1 g | <input type="radio"/> No <input type="radio"/> Yes |
| 8i | With adequate organ and bone marrow functions, as defined below: i) Thyroid stimulating hormone (TSH) \leq ULN; in case of abnormalities, T3 and T4 levels should be normal | <input type="radio"/> No <input type="radio"/> Yes |

IE=Inclusion/Exclusion Criteria Not Met

IECAT=Inclusion

| No. | IESPID | Inclusion criteria | ETESTCD | ETEST | Met or not? | IEORRES |
|-----|--------|---|---------|-------|--|---------|
| 9 | | Woman of childbearing potential must have a negative serum pregnancy test within 3 days prior to the first dose, and be willing to use a recognized effective contraceptive measure (such as: intra-uterine contraceptive devices, contraceptive pills, or condoms) during the study and within 3 months after the last dose of study drug; male subjects with partners of childbearing potential must either be surgically sterilized or agree to take effective contraceptive measures during the study and within 3 months after the last dose of study drug | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 10 | | Subjects must agree and have signed the informed consent form, be willing and able to follow the scheduled visits, study treatment, laboratory test, and other study procedures | | | <input type="radio"/> No <input type="radio"/> Yes | |

Only subjects who met all inclusion criteria (all "Yes" for inclusion criteria) can be enrolled

IECAT=Exclusion

| No. | IESPID | Exclusion criteria | ETESTCD | ETEST | Met or not? | IEORRES |
|-----|--------|--|---------|-------|--|---------|
| 1 | | Known HER2-positive | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 2 | | Previously received PD-1/PD-L1 antibodies, CTLA-4 antibodies, or other treatments targeting PD-1/PD-L1 and/or VEGFR inhibitors | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 3 | | With known history of allergies to the study drugs or their excipients; with serious allergic reactions to other monoclonal antibodies | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 4 | | Having been treated by immunosuppressive drugs within 14 days prior to the first dose of SHR-1210, excluding intranasal and inhaled corticosteroids or systemic steroids of physiological doses (i.e., no more than 10 mg/d of prednisolone or equivalent physiological doses of other corticosteroids | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 5 | | Having received live, attenuated vaccines within 4 weeks before the first dose or having such vaccination plan during the study. | | | <input type="radio"/> No <input type="radio"/> Yes | |

IE=Inclusion/Exclusion Criteria Not Met

IECAT=Exclusion

| No. | IESPID | Exclusion criteria | IE TESTCD | IE TEST | Met or not? | IEORRES |
|-----|--------|--|-----------|---------|--|---------|
| 6 | | Presence of known uncontrolled or symptomatic active central nervous system (CNS) metastases, manifested as clinical symptoms, cerebral edema, spinal cord compression, carcinomatous meningitis, leptomeningeal disease, and/or progressive growth. With a history of central nervous system metastases or spinal cord compression, unless they were clearly treated and clinically stable 4 weeks after discontinuation of anticonvulsants and steroids before the first dose of study treatment | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 7 | | Presence of > grade 1 peripheral neuropathy | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 8 | | With advanced diseases that were symptomatic, disseminated to viscera, and at risk of life-threatening complications in the short term (including uncontrollable massive [pleural, pericardial, and abdominal] exudate, pulmonary lymphangitis, and more than 30% hepatic involvement) | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 9 | | Presence of any active autoimmune diseases or a history of autoimmune diseases (including but not limited to: autoimmune hepatitis, interstitial pneumonia, uveitis, enteritis, hepatitis, hypophysitis, vasculitis, nephritis, hyperthyroidism, hypothyroidism; adult patient with vitiligo or completely relieved childhood asthma may be enrolled if they did not require any intervention; patient with asthma requiring medical intervention with bronchodilators must not be enrolled) | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 10 | | Have been diagnosed with any other malignancies within 3 years before the enrollment, excluding adequately treated basal cell carcinoma or squamous cell skin cancer, or cervical carcinoma <i>in situ</i> | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 11 | | Infected with human immunodeficiency virus (HIV) or with known acquired immunodeficiency syndrome (AIDS), active hepatitis B (HBV DNA \geq 500 IU/mL), hepatitis C (hepatitis C antibody being positive and HCV-RNA being above the lower limit of detection of the assay), or co-infection of hepatitis B and C | | | <input type="radio"/> No <input type="radio"/> Yes | |

IE=Inclusion/Exclusion Criteria Not Met

IECAT=Exclusion

| No. | IESPID | Exclusion criteria | IE TEST CD | IE TEST | Met or not? | IE OR RES |
|-----|--------|---|------------|---------|--|-----------|
| 12 | | With any of the following conditions observed within 6 months prior to enrollment: myocardial infarction, severe/unstable angina, NYHA Class > II cardiac insufficiency, poorly controlled arrhythmia (including males with QTcF > 450 ms and females with QTcF > 470 ms, QTcF interval calculated with the Fridericia's formula), symptomatic congestive cardiac failure, or cerebrovascular accident (including transient ischemic attack or symptomatic pulmonary embolism) | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 13 | | Had hypertension uncontrolled by antihypertensives (systolic blood pressure > 140 mmHg or diastolic blood pressure > 90 mmHg) | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 14 | | Had abnormal coagulation function (INR > 1.5 or APTT > 1.5 × ULN), bleeding tendency, or was receiving thrombolytics or anticoagulant therapy | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 15 | | With known hereditary or acquired hemorrhage and thrombophilia (such as hemophilia, coagulopathy, thrombocytopenia, and hypersplenism) | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 16 | | With obvious hemoptysis or a daily amount of hemoptysis of half a teaspoon (2.5 mL) or more within 2 months before the enrollment | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 17 | | With clinically significant hemorrhage symptoms or clear bleeding tendency within 3 months prior to participation in this study, such as GI bleeding, hemorrhagic gastric ulcer, baseline fecal occult blood++ and above, or vasculitis | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 18 | | Had events of arterial/venous thrombosis within 6 months prior to participation in this study, such as cerebrovascular accidents (including transient ischemic attacks, cerebral hemorrhage, cerebral infarction), deep vein thrombosis, and pulmonary embolism | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 19 | | With known hereditary or acquired hemorrhage and thrombophilia (such as hemophilia, coagulopathy, thrombocytopenia, and hypersplenism) | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 20 | | Required long-term anticoagulant therapy with warfarin or heparin; or requiring long-term antiplatelet therapy (aspirin ≥ 300 mg/day or clopidogrel ≥ 75 mg/day) | | | <input type="radio"/> No <input type="radio"/> Yes | |

IE=Inclusion/Exclusion Criteria Not Met

IECAT=Exclusion

| No. | IESPID | Exclusion criteria | IETESTCD | IETEST | Met or not? | IEORRES |
|-----|--------|--|----------|--------|--|---------|
| 21 | | Had concurrent severe infection (such as one requiring intravenous infusion of antibiotics, antifungals, or antivirals) within 4 weeks prior to the first dose, or any unexplained fever of > 38.5 °C observed during screening period/prior to the first dose | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 22 | | With known history of allogeneic organ transplantation or allogeneic hematopoietic stem cell transplantation | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 23 | | Have participated in clinical trials concerning any other drugs within 4 weeks prior to the first dose, or less than 5 half-lives from the last dose of study drug | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 24 | | With a known history of psychotropic substance abuse or drug abuse | | | <input type="radio"/> No <input type="radio"/> Yes | |
| 25 | | Had other severe physical or psychiatric disorders or laboratory abnormalities that may increase the risk of participation in the study or interfere with the study results, or was deemed unsuitable by the investigator | | | <input type="radio"/> No <input type="radio"/> Yes | |

Only subjects who did not meet any of the exclusion criteria (all "No" for exclusion criteria) could be enrolled

Name of PI: _____

Account: _____

Date of Signature: _____

DS=Disposition

2.16 Enrollment Information

DSCAT=PROTOCOL MILESTONE
when DSDECOD=ENROLLED or DSDECOD=RANDOMIZED

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: screening period (D-7 to D-1) | Visit No.: _____ |
| Enrollment information | |
| Passed the screening or not? <input type="radio"/> Passed <input type="radio"/> Failed | DSDECOD=SCREEN FAILURE |
| Main reason for exclusion: <input type="radio"/> Adverse event <input type="radio"/> Failed to meet inclusion criteria/met exclusion criteria <input type="radio"/> Lost to follow-up <input type="radio"/> Withdrawn by subject <input type="radio"/> Others | |
| Description of other reasons: _____ | |
| Date of randomization/enrollment: _____ (DD-MM-YYYY) | DSSTDTC when DSDECOD=RANDOMIZED |
| Randomization No.: _____ | QVAL when SUPPDM.QNAM=RANDBUM |
| Group: <input type="radio"/> Sequential therapy of SHR-1210 + capecitabine + oxaliplatin <input type="radio"/> SHR-1210 + apatinib | ARM |

DSTERM

DSDECOD/DSTERM=ENROLLED

DSCAT=DISPOSITION EVENT

DSTERM when DSDECOD=OTHER

DSSCAT=End of Study when Adverse event or Loss to follow-up or Withdrawn by subject or Others

Name of PI: _____

Account: _____

Date of Signature: _____

SV=Subject Visits

Same as Page 3

3 C1_D1

3.1 Date of Visit

| | |
|----------------------------------|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 | Visit No.: 3 |
| Date of visit | |
| Date of visit: _____(DD-MM-YYYY) | |

Name of PI: _____

Account: _____

Date of Signature: _____

3.2 ECOG PS Score

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 | Visit No.: 3 |
| ECOG PS score | |
| ECOG PS scoring: <input type="radio"/> Not performed | |
| Scoring date: _____ (DD-MM-YYYY) | |
| <p>ECOG PS score: <input type="radio"/> 0 point: Fully active, able to carry on all pre-disease performance without restriction <input type="radio"/> 1 point: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work <input type="radio"/> 2 points: Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours <input type="radio"/> 3 points: Capable of only limited selfcare, confined to bed or chair for more than 50% of waking hours <input type="radio"/> 4 points: Completely disabled, cannot carry on any selfcare, totally confined to bed or chair</p> | |

Name of PI: _____

Account: _____

Date of Signature: _____

3.3 Vital Signs

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 | Visit No.: 3 |
| Vital signs | |
| Vital signs measurement: <input type="radio"/> Not performed | |
| Measurement date: _____(DD-MM-YYYY) | |

| No. | Measurement item | Result | Note |
|-----|---------------------------------|--------|------|
| 1 | Temperature (°C) | | |
| 2 | Pulse rate (beats/min) | | |
| 3 | Respiratory rate (resp/min) | | |
| 4 | Diastolic blood pressure (mmHg) | | |
| 5 | Systolic blood pressure (mmHg) | | |

Name of PI: _____

Account: _____

Date of Signature: _____

3.4 Physical Examination

| | |
|---|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 | Visit No.: 3 |
| Physical examination | |
| Physical examination: <input type="radio"/> Not performed | |
| Examination date: _____(DD-MM-YYYY) | |

| No. | Physical examination item | Result | If abnormal, please describe |
|-----|-----------------------------|--|------------------------------|
| 1 | General status | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 2 | Head and face | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 3 | Skin | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 4 | Lymph nodes | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 5 | Eyes | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 6 | Ears, nose, and throat | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 7 | Oral cavity | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 8 | Respiratory system | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 9 | Cardiovascular system | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 10 | Abdomen | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 11 | Reproductive-urinary system | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 12 | Musculoskeletal system | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |

PE=Physical Examination

Same as Page 19

| No. | Physical examination item | Result | If abnormal, please describe |
|-----|---------------------------|--|------------------------------|
| 13 | Nervous system | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 14 | Mental state | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |
| 15 | Others | <input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> Not examined | |

Name of PI: _____

Account: _____

Date of Signature: _____

3.5 Hematology

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 | Visit No.: 3 |
| Laboratory test | |
| Laboratory test category: hematology | |
| This test: <input type="radio"/> Not performed | |
| Sampling date: _____ (DD-MM-YYYY) | |
| LAB name: <input type="radio"/> Central laboratory 1 <input type="radio"/> Central laboratory 2 <input type="radio"/> Central laboratory 3 <input type="radio"/> Central laboratory 4 <input type="radio"/> Central laboratory 5 <input type="radio"/> Others | |
| Others, please specify: _____ | |

| No. | Laboratory test item | Measured value | Unit | Determination of clinical significance | Note |
|-----|---------------------------------|----------------|-------------------|---|------|
| 1 | Red blood cell count (RBC) | | $\circ 10^{12}/L$ | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 2 | Hemoglobin (Hb) | | $\circ g/L$ | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 3 | Platelet count (PLT) | | $\circ 10^9/L$ | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 4 | White blood cell count (WBC) | | $\circ 10^9/L$ | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 5 | Absolute neutrophil count (ANC) | | $\circ 10^9/L$ | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |

| No. | Laboratory test item | Measured value | Unit | Determination of clinical significance | Note |
|-----|------------------------|----------------|-----------------|--|------|
| 6 | Lymphocyte count (LYM) | | $\times 10^9/L$ | <ul style="list-style-type: none">○ Normal○ Abnormal without clinical significance○ Abnormal with clinical significance○ Not tested | |

Name of PI: _____

Account: _____

Date of Signature: _____

3.6 Urinalysis

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 | Visit No.: 3 |
| Laboratory test | |
| Laboratory test category: urinalysis | |
| This test: <input type="radio"/> Not performed | |
| Sampling date: _____ (DD-MM-YYYY) | |
| LAB name: <input type="radio"/> Central laboratory 1 <input type="radio"/> Central laboratory 2 <input type="radio"/> Central laboratory 3 <input type="radio"/> Central laboratory 4 <input type="radio"/> Central laboratory 5 <input type="radio"/> Others | |
| Others, please specify: _____ | |

| No. | Laboratory test item | Measured value | Unit | Determination of clinical significance | Note |
|-----|-------------------------------|----------------|--|---|------|
| 1 | Urine white blood cells (WBC) | | <input type="radio"/> cells/ μ L <input type="radio"/> /HP | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 2 | Urine red blood cells (RBC) | | <input type="radio"/> cells/ μ L <input type="radio"/> /HP | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 3 | Urine protein (PRO) | | <input type="radio"/> mg/L <input type="radio"/> Qualitative <input type="radio"/> g/L | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |

Name of PI: _____

Account: _____

Date of Signature: _____

3.7 24-h Urine Protein Quantitation

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 | Visit No.: 3 |
| Laboratory test | |
| Laboratory test category: 24-h urine protein quantitation | |
| This test: <input type="radio"/> Not performed | |
| Sampling date: _____ (DD-MM-YYYY) | |
| LAB name: <input type="radio"/> Central laboratory 1 <input type="radio"/> Central laboratory 2 <input type="radio"/> Central laboratory 3 <input type="radio"/> Central laboratory 4 <input type="radio"/> Central laboratory 5 <input type="radio"/> Others | |
| Others, please specify: _____ | |

| No. | Laboratory test item | Measured value | Unit | Determination of clinical significance | Note |
|-----|--------------------------------|----------------|---|---|------|
| 1 | 24-h urine protein measurement | | <input type="radio"/> mg/24 h <input type="radio"/> g/24 h | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |

Name of PI: _____

Account: _____

Date of Signature: _____

3.8 Clinical Chemistry

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 | Visit No.: 3 |
| Laboratory test | |
| Laboratory test category: clinical chemistry | |
| This test: <input type="radio"/> Not performed | |
| Sampling date: _____ (DD-MM-YYYY) | |
| LAB name: <input type="radio"/> Central laboratory 1 <input type="radio"/> Central laboratory 2 <input type="radio"/> Central laboratory 3 <input type="radio"/> Central laboratory 4 <input type="radio"/> Central laboratory 5 <input type="radio"/> Others | |
| Others, please specify: _____ | |

| No. | Laboratory test item | Measured value | Unit | Determination of clinical significance | Note |
|-----|-------------------------------------|----------------|--|---|------|
| 1 | Alanine aminotransferase (ALT) | | <input type="radio"/> U/L <input type="radio"/> IU/L | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 2 | Aspartate aminotransferase (AST) | | <input type="radio"/> U/L <input type="radio"/> IU/L | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 3 | Gamma glutamyl transpeptidase (GGT) | | <input type="radio"/> U/L <input type="radio"/> IU/L | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 4 | Total bilirubin (TBIL) | | <input type="radio"/> $\mu\text{mol/L}$ | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 5 | Direct bilirubin (DBIL) | | <input type="radio"/> $\mu\text{mol/L}$ | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |

| No. | Laboratory test item | Measured value | Unit | Determination of clinical significance | Note |
|-----|----------------------------|----------------|--------------|---|------|
| 6 | Alkaline phosphatase (AKP) | | ○ U/L ○ IU/L | ○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested | |
| 7 | Blood urea nitrogen (BUN) | | ○ mmol/L | ○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested | |
| 8 | Urea | | ○ mmol/L | ○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested | |
| 9 | Total protein (TP) | | ○ g/L | ○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested | |
| 10 | Albumin (ALB) | | ○ g/L | ○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested | |
| 11 | Creatinine (Cr) | | ○ μmol/L | ○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested | |
| 12 | Blood glucose (GLU) | | ○ mmol/L | ○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested | |
| 13 | Potassium (K) | | ○ mmol/L | ○ Normal ○ Abnormal without clinical significance ○ Abnormal with clinical significance ○ Not tested | |

LB=Laboratory Test Results

Same as Page 27

| No. | Laboratory test item | Measured value | Unit | Determination of clinical significance | Note |
|-----|----------------------|----------------|----------|---|------|
| 14 | Sodium (Na) | | ○ mmol/L | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 15 | Calcium (Ca) | | ○ mmol/L | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 16 | Magnesium (Mg) | | ○ mmol/L | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 17 | Chlorine (Cl) | | ○ mmol/L | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |

Name of PI: _____

Account: _____

Date of Signature: _____

3.9 Thyroid function

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 | Visit No.: 3 |
| Laboratory test | |
| Laboratory test category: thyroid function | |
| This test: <input type="radio"/> Not performed | |
| Sampling date: _____ (DD-MM-YYYY) | |
| LAB name: <input type="radio"/> Central laboratory 1 <input type="radio"/> Central laboratory 2 <input type="radio"/> Central laboratory 3 <input type="radio"/> Central laboratory 4 <input type="radio"/> Central laboratory 5 <input type="radio"/> Others | |
| Others, please specify: _____ | |

| No. | Laboratory test item | Measured value | Unit | Determination of clinical significance | Note |
|-----|-----------------------------------|----------------|--|---|------|
| 1 | Thyroid stimulating hormone (TSH) | | <input type="radio"/> mIU/L <input type="radio"/> µIU/mL | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 2 | Free triiodothyronine (FT3) | | <input type="radio"/> pmol/L <input type="radio"/> ng/dL <input type="radio"/> pg/mL | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 3 | Free thyroxine (FT4) | | <input type="radio"/> pmol/L <input type="radio"/> ng/dL <input type="radio"/> pg/mL | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 4 | Triiodothyronine (T3) | | <input type="radio"/> nmol/L <input type="radio"/> ng/mL <input type="radio"/> pg/mL | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |

LB=Laboratory Test Results

Same as Page 29

| No. | Laboratory test item | Measured value | Unit | Determination of clinical significance | Note |
|-----|----------------------|----------------|--|--|------|
| 5 | Thyroxine (T4) | | <ul style="list-style-type: none">○ nmol/L○ ug/dL○ pg/mL | <ul style="list-style-type: none">○ Normal○ Abnormal without clinical significance○ Abnormal with clinical significance○ Not tested | |

Name of PI: _____

Account: _____

Date of Signature: _____

3.10 Coagulation function

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 | Visit No.: 3 |
| Laboratory test | |
| Laboratory test category: coagulation function | |
| This test: <input type="radio"/> Not performed | |
| Sampling date: _____ (DD-MM-YYYY) | |
| LAB name: <input type="radio"/> Central laboratory 1 <input type="radio"/> Central laboratory 2 <input type="radio"/> Central laboratory 3 <input type="radio"/> Central laboratory 4 <input type="radio"/> Central laboratory 5 <input type="radio"/> Others | |
| Others, please specify: _____ | |

| No. | Laboratory test item | Measured value | Unit | Determination of clinical significance | Note |
|-----|--|----------------|--|---|------|
| 1 | Activated partial thromboplastin time (APTT) | | <input type="radio"/> sec | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 2 | Prothrombin time (PT) | | <input type="radio"/> sec | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 3 | Thrombin time (TT) | | <input type="radio"/> sec | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |
| 4 | Fibrinogen (FIB) | | <input type="radio"/> g/L <input type="radio"/> mg/dL | <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance <input type="radio"/> Not tested | |

| No. | Laboratory test item | Measured value | Unit | Determination of clinical significance | Note |
|-----|--------------------------------------|----------------|------|--|------|
| 5 | International normalized ratio (INR) | | | <ul style="list-style-type: none">○ Normal○ Abnormal without clinical significance○ Abnormal with clinical significance○ Not tested | |

Name of PI: _____

Account: _____

Date of Signature: _____

3.11 12-Lead ECG

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 | Visit No.: 3 |
| 12-lead ECG | |
| 12-lead ECG: <input type="radio"/> Not performed | |
| Examination date: _____ (DD-MM-YYYY) | |

| No. | Examination item | Result | Unit |
|-----|------------------|--------|---------------------------|
| 1 | Heart rate | | <input type="radio"/> bpm |
| 2 | PR | | <input type="radio"/> ms |
| 3 | QT | | <input type="radio"/> ms |
| 4 | QTc | | <input type="radio"/> ms |

| |
|---|
| 12-lead ECG result: <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance |
| If abnormal, please describe: _____ |

Name of PI: _____

Account: _____

Date of Signature: _____

EX=Exposure

EXTRT=SHR-1210

3.12 SHR1210 Administration Record

ECTRT=SHR-1210

| | |
|--|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 VISIT | Visit No.: 3 |
| SHR1210 administration record | |
| SHR-1210 intravenous drip infusion: <input type="radio"/> Not administered | ECSTAT |
| Initiation date of administration: _____(DD-MM-YYYY) | date of EXSTDTC date of ECSTDTC |
| Start time: _____(hh: mm) | time of EXSTDTC time of ECSTDTC |
| Completion date of administration: _____(DD-MM-YYYY) | date of EXENDTC date of ECENDTC |
| End time: _____(hh: mm) | time of EXENDTC time of ECENDTC |
| Did administration duration exceed 60 min? <input type="radio"/> No <input type="radio"/> Yes | QVAL when SUPPEC.QNAM=ECEXCE |
| Reason for exceeding: <input type="radio"/> AE <input type="radio"/> Management factors <input type="radio"/> Others | QVAL when SUPPEC.QNAM=ECEXCRES |
| Please specify for other reasons: _____ | QVAL when SUPPEC.QNAM=ECEXCREO |
| Was the 200 mg administration completed? <input type="radio"/> No <input type="radio"/> Yes | QVAL when SUPPEC.QNAM=ECCOMP |
| Reason for incompleteness: <input type="radio"/> AE <input type="radio"/> Others | QVAL when SUPPEC.QNAM=ECICOMRE |
| Please specify for other reasons: _____ | QVAL when SUPPEC.QNAM=ECICOMRO |
| Percentage of actual dose (%): _____ | QVAL when SUPPEC.QNAM=ECPACT |
| Note: _____ | QVAL when SUPPEC.QNAM=ECNOTE |

SVSTDTC

Name of PI: _____

Account: _____

Date of Signature: _____

DA=Drug Accountability

EXTRT=Capecitabine

DACAT=Capecitabine

ECTRT=Capecitabine

3.13 Capecitabine Dispensation/Return

| | |
|---|---|
| Subject ID: _____ | CRF status: <input type="radio"/> Not submitted <input type="radio"/> In review <input type="radio"/> Locked <input type="radio"/> Frozen <input type="radio"/> Signed by PI |
| Study site name: _____ | Study site No.: _____ |
| Investigator name: _____ | Investigator ID: _____ |
| Visit: C1_D1 | Visit No.: 3 |
| Capecitabine dispensation/return | |
| Drug dispensation: <input type="radio"/> None | [NOT SUBMITTED] |
| Date of dispensation: _____ (DD-MM-YYYY) | DADTC when DATESTCD=DISPAMT |
| Amount dispensed (0.5 g/tablet): _____ | DAORRES when DATESTCD=DISPAMT |
| Amount dispensed (0.15 g/tablet): _____ | DASCAT when DATESTCD=DISPAMT |
| Date of first dose: _____ (DD-MM-YYYY) | EXSTDTC ECSTDTC |
| Note: _____ | OVAL when SUPPDA.QNAM=DANOTE |

Name of PI: _____

Account: _____

Date of Signature: _____