TQB2450 with or without anlotinib as maintenance treatment in subjects with locally advanced/unresectable non-small cell lung cancer that have not progressed after prior concurrent/sequential chemoradiotherapy (R-ALPS): a randomized, double-blind, placebo-controlled, multicenter phase III study

Informed Consent Form

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Version Date: **September 16, 2022**

Sponsor: Chia Tai Tianqing Pharmaceutical Group Co., Ltd.
September, 2022

Dear participant,

We sincerely invite you to participate in the "TQB2450 with or without anlotinib as maintenance treatment in subjects with locally advanced/unresectable non-small cell lung cancer (NSCLC) that have not progressed after prior concurrent/sequential chemoradiotherapy (R-ALPS): a randomized, double-blind, placebo-controlled, multicenter phase III study" sponsored by Chia Tai Tianqing Pharmaceutical Group Co., Ltd. This study is led by Zhejiang Cancer Hospital and Sun Yat-sen University Cancer Center, in collaboration with more than fifty hospitals from China. The Ethics Committee of Zhejiang Cancer Hospital and Sun Yat-sen University Cancer Center have reviewed and approved the study protocol, agreeing to conduct this clinical research as planned. The study will strictly adhere to the Declaration of Helsinki and relevant laws and regulations of China.

Before you decide whether to participate in this study, please read the following content carefully, which can help you fully understand the reason of this research being conducted, the procedures and duration of the study, and the potential benefits and risks that may arise from participating in the study. You can discuss with your relatives and friends, and ask the doctor in charge of this study, who will explain any questions about this study to help you make the final decision.

1. Background and Purpose

Lung cancer display high incidence and mortality rates worldwide. Based on the biological characteristics, treatment, and prognosis of lung cancer, the World Health Organization (WHO) classifies it into two major categories: NSCLC and small cell lung cancer (SCLC), with NSCLC accounting for approximately 80-85% of lung cancers. About one-third of patients with NSCLC have locally advanced stage III (locally advanced). For patients with unresectable stage III NSCLC, the standard treatment recommended by clinical guidelines is concurrent chemoradiotherapy (CCRT). According to previous research reports, the median progression-free survival (PFS) for NSCLC patients undergoing CCRT is about 8 months, the 5-year overall survival (OS) rate is about 15% with the median OS less than 28 months.

Anlotinib, an oral multitarget tyrosine kinase inhibitor (TKI) that inhibits angiogenesis, is a Class 1.1 novel drug independently developed in China. The ALTER 0303 study confirmed that anlotinib, significantly prolonged both PFS and OS in patients with advanced

NSCLC in third-line treatment compared to the placebo. To date, anlotinib has also been approved for additional third-line treatment indications include soft tissue sarcoma and SCLC.

Immune checkpoint inhibitors (ICIs) targeting programmed cell death protein 1 (PD-1) and its ligand programmed death-ligand 1 (PD-L1) have revolutionized the treatment of stage III NSCLC. Relevant studies have shown that vascular abnormalities may promote tissue hypoxia and accumulation of lactic acid, thereby activating immunosuppression and inhibition of T cell function. Anlotinib could enhance the infiltration of effector immune cells according to the inhibition of the growth of vascular endothelial cells. Meanwhile, a large body of existing evidence suggests that radiotherapy can enhance the immune function, which could induce tumor cells to release tumor-specific antigens, trigger the body's immune response, or, when combined with specific immunotherapies, enhance the killing ability of immune cells, thereby controlling tumor cells. In February 2018, PD-L1 inhibitor (durvalumab) of AstraZeneca was approved by the U.S. Food and Drug Administration (FDA) for the treatment of patients with unresectable stage III NSCLC who have not progressed after CCRT. The results of the PACIFIC study showed that durvalumab provided significant PFS benefits compared to placebo, with median of 17.2 months vs. 5.6 months, and the safety was controllable.

TQB2450 (benmelstobart) is a novel humanized immunoglobulin G1 (IgG1) monoclonal antibody against PD-L1 developed by Chia Tai Tianqing Pharmaceutical Group Co., Ltd., and received the clinical trial approval from the National Medical Products Administration (NMPA) on October 20, 2017 (Approval No.: 2017L04914). The purpose of this study is to evaluate the efficacy, safety, and immunogenicity of TQB2450 in patients with locally advanced/ unresectable stage III NSCLC who have not progressed after concurrent/sequential chemoradiotherapy.

2. Study Design

This study aims to evaluate the efficacy and safety of TQB2450 with or without anlotinib compared to placebo as consolidation therapy in patients with locally advanced/unresectable (stage III) NSCLC who have not progressed after concurrent/sequential chemoradiotherapy. The study design is a randomized, double-blind, placebo-controlled, multicenter phase III clinical trial, and a total of 534 participants are planned to be enrolled.

All participants will sign the informed consent form, and those who meet the criteria after screening examinations will be randomly (1:1:1) assigned to experimental arm A, experimental arm B, or the placebo control arm. The experimental arm A receives TQB2450 plus anlotinib regimen; The experimental arm B receives TQB2450 injection combined with anlotinib placebo regimen; The placebo control arm receives TQB2450 placebo plus anlotinib placebo regimen.

The current study has entered the second phase, and eligible participants will be randomly (1:1) assigned to experimental arm A or experimental arm B.

Each treatment cycle is 21 days, with the regimen for no more than 36 cycles (108 weeks), unless patients assessed by the investigator to have disease control (CR+PR+SD) and tolerable adverse reactions may continue the regimen until disease progression or intolerance. No other anti-tumor treatments are allowed during the medication period.

3. Study Process

If you meet the following conditions:

1) Age: 18-75 years; ECOG performance status: 0-1; Expected survival period of more than 3 months;
2) Patients with pathologically or cytologically confirmed unresectable stage III NSCLC (according to the Chinese Society of Clinical Oncology [CSCO] Guidelines for the Diagnosis and Treatment of Primary Lung Cancer 2019 Edition);
3) Patients should have at least one measurable lesion before radiotherapy (according to RECIST 1.1 requirements);
4) Patients who have undergone at least one platinum-based concurrent/sequential chemoradiotherapy regimen previously and have not experienced disease progression after the end of treatment:
   a） The first dose of the study must be administered within 42 days after the completion of chemoradiotherapy.
   b） The platinum-based drug must be one of the following: cisplatin, carboplatin, or nedaplatin; Other drugs in the regimen must include one of the following: etoposide, vinorelbine, pemetrexed, paclitaxel, docetaxel, or gemcitabine (the gemcitabine is not allowed in the chemotherapy regimen of concurrent chemoradiotherapy).
   c） For sequential chemoradiotherapy, the interval between the end of the chemotherapy (21st day of the 3-week regimen) and the start of radiotherapy should not exceed 6 weeks.

d） Consolidation chemotherapy is not allowed after radiotherapy, but chemotherapy is allowed before concurrent chemoradiotherapy.

e） The total dose of radiotherapy is 60 Gy ± 10% (54 Gy – 66 Gy). The minimum technical standard for radiotherapy is intensity modulated radiation therapy (IMRT).

5) Laboratory tests must meet the following criteria:

a) Complete blood count: Hemoglobin (Hb) ≥90g/L (no blood transfusion within 14 days); Absolute Neutrophil Count (ANC) $\geq 1.5\times10^9$ /L; Platelets (PLT) $\geq 100\times10^9$ /L;

b) Biochemical examination: Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) ≤ 2.5×ULN; Serum total bilirubin (TBIL) ≤ 1.5×ULN (for patients with Gilbert's syndrome, ≤ 3×ULN); Serum creatinine (Cr) ≤ 1.5×ULN, or creatinine clearance rate (CL) ≥ 60 ml/min;

c) Coagulation function: Activated partial thromboplastin time (APTT), international normalized ratio (INR), prothrombin time (PT) ≤ 1.5×ULN; if the patient is on anticoagulant therapy, PT within the intended range of the anticoagulant is acceptable;

d) CK and CK-MB do not exceed the upper limit of normal; Doppler ultrasound assessment: Left Ventricular Ejection Fraction (LVEF) ≥ 50%;

6) Females must agree to use contraception during the study and for 6 months after the study ends; Serum or urine pregnancy test must be negative within 7 days prior to enrollment, and the patient must be non-lactating; Males must agree to use contraception during the study and for 6 months after the study ends;

7） Voluntarily join this study, sign the informed consent form, and have good compliance.

If you agree to participate in this study after consideration, the doctor will conduct the following for you:

Screening (Day -28 to -1 before administration):

- Demographic information: including gender, date of birth, ethnicity, etc.;
- Medical history and treatment history;
- Collection of genetic test results;
- ECOG score; physical examination; vital signs examination;
- Laboratory tests: including complete blood count, blood biochemistry, urinalysis, routine stool test (including occult blood), thyroid function, coagulation function, virology, tumor markers, lipase, amylase, fasting blood glucose;
- Pulmonary Function Test;

- 12-lead electrocardiogram; Echocardiography;
- Myocardial Enzyme Spectrum, Troponin;
- Pregnancy Test: Women of childbearing age need to undergo a urine (or blood) pregnancy test;
- Imaging Examination, including: enhanced CT or MRI of the neck, chest, and abdomen; during the screening period, a plain + enhanced CT/enhanced MRI scan of the brain is required; Bone scan examination (patients who have not undergone a whole-body bone scan within 3 months before enrollment should undergo a whole-body bone scan). All suspicious lesion sites should undergo imaging examination.
- Quality of Life Questionnaire.

Given that durvalumab has been approved by the FDA and NMPA for the maintenance treatment of patients with unresectable stage III NSCLC after concurrent chemoradiotherapy, we encourage you to receive the standard immunotherapy. If you still decide to decline the maintenance therapy with durvalumab and meet the enrollment criteria of this study after screening, you will be randomly assigned in a 1:1:1 ratio by the randomization system. You may be assigned to the experimental arm A, experimental arm B, or the placebo control arm. The specific medication regimens for each group are as follows:

- **Experimental arm A:** 21 days/cycle.
  TQB2450: 1200 mg iv D1, Q3W;
  Anlotinib: 8 mg po D1–14, Q3W.
- **Experimental arm B:** 21 days/cycle.
  TQB2450: 1200 mg iv D1, Q3W;
  Anlotinib placebo: 8 mg po D1–14, Q3W.
- **Placebo control arm:** 21 days/cycle.
  TQB2450 placebo: 1200 mg iv D1, Q3W;
  Anlotinib placebo: 8 mg po D1–14, Q3W.

During the study and prior the end of the study, the responsible physician will conduct physical and laboratory examinations according to the trial protocol to assess the impact of

the investigational drug on you. In the first 36 cycles of this study, follow-up will be conducted once per cycle (21 days), and after 36 cycles, follow-up will be conducted once every 4 cycles (84 days).

The first cycle visit:

- Vital signs, physical examination;
- 12-lead electrocardiogram;
- Laboratory tests: including blood biochemistry, complete blood count, urinalysis, routine stool test (including occult blood), thyroid function, coagulation function, blood amylase, blood lipase, myocardial enzyme spectrum, and troponin.

The 2nd cycle and subsequent even-numbered cycles (follow-up every 4 cycles after 36 cycles):

- Vital signs, physical examination, ECOG score;
- Laboratory tests: including complete blood count, blood biochemistry, urinalysis, routine stool test (including occult blood), thyroid function, coagulation function, lipase, amylase, myocardial enzyme spectrum, and troponin; (during follow-up, the investigator will decide based on clinical needs);
- 12-lead electrocardiogram monitoring; pulmonary function test; (during follow-up, the investigator will decide based on clinical needs);
- Imaging examinations, including: enhanced CT or MRI of the chest and abdomen (additional neck imaging may be performed if deemed necessary by the investigator) and whole-body bone scan (whole-body bone scan is recommended every 16 cycles, with an interval not exceeding 18 cycles); even if asymptomatic, enhanced MRI of the head should be followed up every 4 cycles.
- Tumor Marker;
- Quality of Life Questionnaire.

The odd-numbered cycles from the 3rd cycle onwards (no odd-numbered cycle examinations after 36 cycles):

- Vital signs, physical examination;
- 12-lead electrocardiogram;
- Laboratory tests: including blood biochemistry, complete blood count, urinalysis, routine stool test (including occult blood), myocardial enzyme spectrum, and troponin.

End-of-study Visit:

- Vital signs, physical examination; ECOG score;

- 12-lead electrocardiogram, pulmonary function test;
- Laboratory tests: including blood biochemistry, complete blood count, urinalysis, routine stool test (including occult blood), thyroid function, coagulation function, tumor markers, amylase, lipase, myocardial enzyme spectrum, and troponin;
- Imaging examination, including: chest and abdominal enhanced CT or MRI (additional neck imaging if deemed necessary by the investigator), all suspicious lesion sites should undergo imaging examination;
- Quality of Life Questionnaire.

End-of-study follow-up:

For participants who have withdrawal, the doctor will continue to conduct long-term follow-up. Follow-up will occur once every 4 cycles (including telephone follow-up). During follow-up, information will be collected on whether you have adopted other treatments. If other treatments are used, please actively cooperate and accurately inform the study doctor of the detailed information of the subsequent treatment plan.

4. Immunogenicity Blood Collection

To evaluate the immunogenicity of TQB2450 in subjects with locally advanced/ unresectable NSCLC who have not progressed after concurrent/sequential chemoradiotherapy, participating subjects will have 5 ml of venous blood collected before administration (-15min) in cycles 1, 2, 5, and 9, and 90 (±7) days after the last administration, totaling 25 ml. The above samples will be sent to the central laboratory for testing, solely for the purpose of biological sample testing by that laboratory and not for any other use. Any remaining samples after testing will be destroyed according to standard destruction procedures.

5. Tissue Sample Collection

During the screening period, your driver gene test report will be collected to determine whether you are a driver gene-negative patient. However, if the reagent kit used in your driver gene test report does not comply with NMPA-approved kits, or if you have not undergone driver gene testing or the test items are incomplete, your driver gene will need to be retested. You may conduct gene testing that meets the protocol requirements on your own and provide the report to us. It is also possible to collect your archived pathological tissue samples within 24 months or freshly obtained pathological tissue samples, and make 10 slices with a thickness of 3–5 μm to be sent to the central laboratory for driver gene testing. The central laboratory is entrusted to Xiamen AIDE Medical Laboratory. The central laboratory will conduct gene testing for EGFR, ALK, and ROS1. Only if your driver gene test is negative can you be enrolled in this clinical trial. The cost of the driver gene test will be borne by the

sponsor. The specimens sent to the central laboratory will be destroyed immediately after the test is completed.

6. Other matters requiring your cooperation

During the study, please take the medication according to the instructions of the responsible physician and come to the hospital for examinations and visits at the scheduled times; Please carefully record your daily medication usage and any adverse reactions in your treatment log.

Timely visits and accurate records are very important. These records can directly reflect your physical condition during the medication period and serve as the basis for the physician to study your illness. The responsible physician will use this information to determine whether the treatment you are receiving is safe and effective, and to decide on the next steps of your treatment.

You may receive other medications deemed medically necessary by the investigator, but you cannot receive non-protocol specified chemotherapy, radiotherapy, immunotherapy, anti-tumor biological therapy, anti-cancer traditional Chinese medicine, or herbal medicine.

Subjects must not receive live vaccines, including measles, mumps, rubella, varicella, yellow fever, seasonal influenza, H1N1 influenza, rabies, BCG, and typhoid vaccines, from 14 days before the first dose of study treatment until 60 days after the last dose. If the investigator believes it does not affect the study endpoints, unconventional therapies (such as herbal medicine or acupuncture) and vitamin/mineral supplementation may be used.

If you are receiving any other medication, please inform your physician before participating in this study.

7. Contraception and Pregnancy

It is currently unclear what effects the study drug may have on the fetus, including whether it may cause genetic material changes, developmental disorders, birth defects, or neurodevelopmental delays. Therefore, for safety reasons, from the time you sign this informed consent form until 6 months after stopping the medication, you must take effective contraceptive measures.

For female subjects, if you become pregnant during the study, please inform the responsible physician immediately. The responsible physician will stop the investigational drug treatment, explain the potential risks to the fetus, and discuss specific measures that can be taken. For male subjects, if your partner becomes pregnant during your participation in the study, please inform the responsible physician, who will provide you with appropriate advice and measures. Medical data related to your (or your partner's) pregnancy will be collected and

reported to Chia Tai Tianqing Pharmaceutical Group Co., Ltd. to help understand the drug's impact on pregnancy.

8. Possible risks

Efficacy Risk:

Although anlotinib, as a new small molecule multi-target TKI, have been marketed for the treatment of advanced NSCLC, the TQB2450 is still in the clinical trial stage and has not been approved for marketing by the relevant national authorities. It cannot be guaranteed that the tumor can be controlled and alleviated.

Computed Tomography (CT) Risk:

X-rays are painless. Enhanced CT uses a contrast agent (or dye) administered via intravenous injection, which may cause a slight burning sensation at the injection site, a metallic taste in the mouth, or a feeling of warmth in the body. These sensations are normal and will disappear within seconds. Rare reactions include life-threatening allergic reactions to the contrast agent in some individuals.

Magnetic Resonance Imaging (MRI) Scan Risk:

Due to the use of strong magnets in MRI scans, you should not undergo an MRI scan if you have any metal objects in your body, such as bone screws, skull plates, or stents. If you have medical devices such as a pacemaker or defibrillator in your body, you should not undergo an MRI scan.

Risk of drug adverse reactions:

Adverse reactions that may be caused by TQB2450 include: pneumonia, gastrointestinal adverse reactions (diarrhea, abdominal pain, etc.), dermatitis (rash, pruritus, etc.), liver function impairment (elevated aspartate aminotransferase, elevated alanine aminotransferase, elevated total bilirubin, etc.), endocrine adverse reactions (hypophysitis, hypothyroidism, hyperthyroidism, etc.), rheumatic/musculoskeletal immune-related adverse reactions (inflammatory arthritis, etc.), anemia, nephritis, infusion site reactions (tenderness or associated fever, erythema, pruritus, edema, etc.), etc.

Infusion reactions may occur after the infusion of TQB2450, manifested as symptoms such as fever, chills, dizziness, or difficulty breathing after infusion. Before each infusion, the study doctor will administer medications to prevent infusion reactions and closely monitor your condition during each infusion, taking appropriate treatment measures immediately if an infusion reaction occurs.

Very common adverse reactions (≥10%) of anlotinib include hand-foot syndrome, proteinuria, hypertriglyceridemia, decreased appetite, hyperglycemia, hyponatremia,

hypothyroidism, liver function impairment, QT interval prolongation, fatigue, hypertension, sinus tachycardia, decreased white blood cell count, diarrhea, etc. Common adverse reactions (1%–10%) include elevated lipase, elevated amylase, elevated creatinine, hyperbilirubinemia, decreased lymphocyte count, dizziness, hyperthyroidism, pulmonary infection, hypokalemia, rash, dry mouth, sinus arrhythmia, joint pain, etc.

As of April 2020, statistical analysis of adverse events in 112 subjects enrolled in 8 phase Ib exploratory studies of TQB2450 combined with anlotinib showed that grade 3 and above adverse reactions were mainly palmar-plantar erythrodysesthesia syndrome, prolonged QT interval on ECG, hypertriglyceridemia, hypertension, diarrhea, etc. In the ongoing phase II-III clinical studies, there have been occurrences of SAE potentially related to the study drugs, including liver function impairment, myocarditis, pulmonary inflammation, pulmonary infection, fever, arthritis, and pericardial effusion.

During the medication process of this study, you may experience the above adverse reactions, and there may also be unforeseen or previously undiscovered adverse reactions, which could be severe and even life-threatening. Throughout the study, any changes and newly identified adverse reactions will be promptly communicated to you by your physician.

9. Potential Benefits

Considering that similar drugs such as durvalumab have already been approved by the FDA and NMPA for the treatment of patients with unresectable stage III NSCLC who have not progressed after CCRT; anlotinib have been approved by the NMPA for the treatment of recurrent or metastatic NSCLC patients who have failed at least two lines of prior chemotherapy. Therefore, you may benefit from participating in this clinical study, but there is still a possibility that the expected results may not be achieved.

During the study, if the efficacy evaluation shows benefit and the adverse reactions are tolerable, you will be allowed to continue using the drug, until the physician determines that you are no longer suitable for the medication or the efficacy evaluation indicates disease progression.

You may not directly benefit from this study, but your participation contributes positively to the research and development of treatments for this disease and related drugs. The study team sincerely thanks you for your contribution.

10. Costs of participating in the study

During the study, the sponsor will provide the study drug free of charge. The sponsor will cover the costs of all study-related examinations during the study, such as complete blood count, urinalysis, routine stool test, blood biochemistry, tumor markers, echocardiography,

electrocardiogram, and imaging examinations. Additionally, the sponsor will provide each participant with a free electronic blood pressure monitor for blood pressure monitoring.

The treatment and examinations required for other diseases you have before participating in the study will not be covered.

In addition, for the visits specified in the protocol, the sponsor will provide a transportation subsidy of 200 RMB per visit. For immunogenicity blood sample collection, a nutritional subsidy of 200 RMB will be provided at each blood draw point. The transportation and nutritional subsidies will be given to you after you complete the study, based on the actual number of visits completed. Even if you withdraw from the study or do not complete the study, you will still receive subsidies for the visits you have completed.

11. Withdrawal from the study

During the study, if it is determined according to the protocol design that you are no longer suitable to continue the medication, the responsible physician will proactively explain the reasons to you and terminate your participation in this drug study.

Your participation in this study is entirely voluntary. You have the right to choose not to participate in this study, and you also have the right to withdraw at any time during the study. Your subsequent treatment will not be affected, and you can continue to receive other treatments. If you decide to withdraw from the study, please inform your responsible physician promptly. For your safety, he will conduct a comprehensive examination.

Once you choose to participate in this study, we hope that you will take the medication on time and attend visits and examinations as scheduled, unless there are special reasons.

12. Compensation for the study

If you experience any discomfort or unexpected situations during the study, whether related to the study or not, please inform your responsible physician immediately. He will make a judgment and provide professional medical treatment. If an adverse event is confirmed to be related to this study and causes injury, the sponsor, Chia Tai Tianqing Pharmaceutical Group Co., Ltd., will bear the cost of treatment and provide corresponding financial compensation in accordance with Chinese laws and regulations. The sponsor has purchased liability insurance for this drug clinical trial.

The treatment and examinations required for other diseases you have before participating in the study will not be covered by the compensation.

13. Confidentiality of personal information

The information collected from this study will be kept confidential. To protect your identity, any information about you in the study documents will use a code number instead of

your name. In all collected and combined subject information, any information that can help identify your identity will be removed to ensure that the relevant information cannot be linked to a specific research subject.

Once you participate in the study, Chia Tai Tianqing Pharmaceutical Group Co., Ltd., the research doctor, and other staff required for the research (including data management, analysis, or research monitoring and quality control personnel designated by the research project) will have the right to examine your medical records and related data. The purpose of this is to analyze the research results and ensure that the research is conducted according to the protocol or regulatory requirements. In addition, representatives from the Institutional Review Board, Ethics Committee, or China Food and Drug Administration may audit these relevant records within the scope specified by relevant Chinese laws or regulations to ensure that the study is conducted correctly and reliable data is collected. All these individuals will have a confidentiality obligation regarding your participation as a research subject. Any information that can identify you will not be disclosed outside the hospital/institution unless required by law.

The study data will be examined and analyzed by an independent department and ultimately stored in a securelocation according to relevant laws or regulations. All medical information collected during the study will be compiled into a written report, which will not mention your name, but may use your initials in pinyin, date of birth, and your personal study number.

The results of this study may be published in medical journals, shared for scientific purposes, or used by Chia Tai Tianqing Pharmaceutical Group Co., Ltd. for product research or improvement, but your identity and personal information will never be disclosed at any time.

14. **Physician Contact information**

If you have any questions about this study or want to know the latest progress and conclusions of the study, you can directly contact the responsible physician, his/her contact information: _____.

15. **Ethics Committee Contact Information**

If you have any questions related to the rights of the participant, or wish to provide opinions and suggestions related to this study, you may also contact to the Ethics Committee, the contact information is: _____.

Informed Consent Signature

I have read the above informed consent form in detail and understand the purpose of the study as well as the potential benefits and risks of participating. The investigator has clearly explained the above medical terms. I have had the opportunity to ask questions and all of my questions have been answered in a way that I can understand. I can choose not to participate in this study, or withdraw at any time after notifying the responsible physician, without affecting any of my medical treatments and rights. If I need other treatments, do not follow the study plan, experience research-related injuries, or for any other reason, the responsible physician may terminate my continued participation in this study.

Confirmation: I have read the above Informed Consent Form and obtained a signed original copy from both parties. My doctor has also provided me with a detailed explanation. I voluntarily participate in this clinical trial. I agree to allow relevant parties to review my original medical records and verify the data collected in the trial study.

Signature: Contact Number:

ID Number: Date (yymmdd):

(Note: For participants with limited civil capacity, the guardian's signature is required)

Guardian Signature: Relationship to Subject:

Contact Number: Date (yymmdd):

Witness Statement: The undersigned witness hereby certifies that the patient has been fully informed about the trial during the entire informed consent process, including the nature of the study, potential benefits, and risks, and has voluntarily signed this consent form.

Witness Signature (if applicable): _____ Contact Number:

Witness ID Number:_____ Date (yymmdd):

Investigator Statement: The undersigned investigator hereby certifies that the subject signing this informed consent form has been fully informed about the study, including its nature, potential risks, and possible benefits.

Investigator Signature: Contact Number:

Date (yymmdd):