**Information sheet and consent form**

**Study title:** A Phase III, Randomized, Double-blinded, Placebo-controlled Clinical Study with A Long-term Extension to Evaluate the Efficacy and Safety of Mavacamten in Chinese Adults with Symptomatic Obstructive Hypertrophic Cardiomyopathy

**Study protocol No.:** LB2001-301

**Study drug:** Mavacamten Capsules, referred throughout the document as the "study drug"

**Sponsor of the study:** Shanghai LianBio Development Co., Ltd.

**Site Name:** <Site Name>

**Investigator:** <Investigator's Name>

**Introduction**

You are invited to take part in a Phase III, randomized, double-blinded, placebo-controlled clinical study with a long-term extension to evaluate the efficacy and safety of Mavacamten in Chinese adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM). "Phase III" means this study is at a late stage of drug development where the safety and efficacy of the drug in human have been preliminarily evaluated in Phase I, Phase II, or other prior Phase III studies. Phase III studies usually serve as the major source of clinical evidence to support the marketing approval of a drug. Randomized means you will be put into a group by chance; like rolling a coin, you do not know which side will face ground. Double-blinded means neither you nor your study doctor will know which group you are in. A placebo is a "dummy treatment", which looks like the genuine medicine but contains no active ingredient. In this you will be assigned to take either the study drug or the placebo, but in addition to this you will still receive standard oHCM therapies as per study protocol regardless of your assignment (so named background treatment, see "What will you have to do?" below. The background treatment is not supplied by the sponsor). To help you decide if you want to take part, you should understand the study and what it will involve for you. To make an informed decision to take part – you should know the purpose of the study, the procedures, the benefits and risks of the study, the discomforts and the precautions taken. This process is called 'informed consent'. Please take the time to read the following information carefully and discuss it with others. Please ask your study doctor if there is anything that is not clear or if you would like more information.

The potential clinical benefit of mavacamten in this study is to provide therapeutic effect in participants with symptomatic oHCM. It cannot be promised the study will help you but in the future the information we get from this study may help improve the future treatment of people with the same condition.

Once you have decided if you want to take part, you will be asked to sign the informed consent form. You will have a copy of the signed form to keep, and the original will stay at the study center.

The study drug, mavacamten, is being developed for the treatment of obstructive hypertrophic cardiomyopathy (oHCM). The oHCM is a condition where the muscular wall of the heart (ventricles) becomes thicker than normal and blocks blood flow out of the heart. The study drug is a novel small-molecule drug. It selectively inhibits the cardiac myosin ("cardiac myosin" is a type of protein in the cardiac muscle building block and plays a critical role in cardiac muscle contraction; "selectively" means this drug mainly target cardiac myosins). A number of clinical studies have been conducted in patients and healthy subjects: as of August 5th 2022, 22 global clinical studies (not including China studies) have been initiated, of which 15 have been completed. Available clinical data observed from these studies have demonstrated the efficacy and safety of the study drug in non-Chinese symptomatic oHCM patients. This study will specifically look at the efficacy and safety of the study drug in Chinese symptomatic oHCM patients. The conduct of this study has been approved by National medical Products Administration (NMPA) and site Ethics Committee. Approximately 81 subjects will take part in this study. According to the information revealed in the Investigators Brochure (Version 10, date October 31st 2022), mavacamten is approved for the treatment of adults with symptomatic New York Heart Association (NYHA) class 2-3 obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms in the United States (US, April 28th 2022) and for the same indication in Australia (September 19th 2022).
Expenses and payment
There will be no cost to you for taking part in this study. You will be provided with all study drugs and examinations related to the study at no cost to you. You will be paid CNY 200 for each visit in total (including required unscheduled visits) as reimbursement for travel costs and other expenses. Nutrition costs will be covered by a fixed allowance of CNY 300 for each PK sample collection. (These blood samples will be used to find out the concentration of study drug in your body by checking how much of the study drug is in your bloodstream at a particular point in time. This type of research is known as “pharmacokinetics” or “PK.”) You will receive your reimbursement [every xx month or at each visit] from [Institution or Investigator] in [Cash or bank transfer] during study conduct.

What will you have to do?
• You will have to go to the study visits and finish study assessments as instructed by the study doctor. You should take study drugs per the instructions the doctors give you. At all onsite visits days you should take the drug at the study center after all relevant assessments are done. You should also return your drug containers to the study center.

• You should comply with the restrictions defined in study protocol. For example, you should refrain from intensive exercise, abstain from blood/plasma donation, and refrain from grapefruit or grapefruit juice-containing products, within specific periods during the study. Your study doctor will give you detailed instruction.

• You must not take part in any other studies while you are taking part in this study.

• If you are a woman of childbearing potential, you and your male partner must use effective methods of birth control or practice true abstinence.

• You must tell your doctor all drugs and treatments you are taking. If you cannot remember drug name, please bring the pill box to your doctor. If at the time of signing the consent form you have been on stable optimal standard HCM therapy as determined by your primary doctor and the standard therapy meets the specific requirements defined in study protocol, you should maintain your standard therapy unchanged during the study. If during the study it is needed to adjust the standard hypertrophic cardiomyopathy (HCM) therapy it should be adjusted by your study doctor. There are some drugs and therapies that you should not take during this study. For example, concomitant use of omeprazole or esomeprazole is prohibited. The study staff will give you more information on this.

• You should not participate in the study if you plan to have implantable cardioverter-defibrillator (ICD) placement or septal reduction therapy over the study periods.

• You should inform your study doctor in a timely manner any symptoms or medical problems you have including any inpatient hospitalization, and should let the study doctor know if you think you and your partner may have become pregnant.

The study will consist of 4 periods:
• A screening period of up to 4 weeks which is to screen eligible subjects for the study. After signing this ICF, you will undergo a variety of general, cardiac and laboratory examinations to assess your eligibility, and only the eligible subjects could enter the treatment period.

• A 30-week double-blinded, placebo-controlled treatment period. Your possibility of being assigned to the active drug group versus placebo group is 2:1. During this period, you will take the treatment (active drug or placebo) orally once a day, and receive examinations and assessments at schedules discussed in below sections. The starting dose is 2.5 mg once daily (or placebo). Based on your results of echocardiography (refer to below for explanations on this examination) and PK tests, your dose may be adjusted according to prespecified rules. But as has been mentioned above, this period treatment is double blinded, so neither you nor your study doctor will know whether you are taking the active drug or the placebo, nor will you know the exact dose you are taking. Although the treatment assignment is not made known to you, the dose will be strictly determined and your safety will be monitored according to the study protocol. In special cases, when the protocol pre-defined safety criteria is met, you will be timely instructed to temporarily or permanently stop the treatment to protect your safety. In case of permanent discontinuation, an
early termination (ET) visit will be scheduled for you as soon as possible, which will include a series of heart function examinations to ensure your safety. If early discontinuation, you will be required for a phone visit at 4 weeks visit and an onsite follow-up visit at 8 weeks (If you are CYP2C19 poor metabolizer, an additional onsite visit will be performed 20 weeks later; please refer to below for explanation of CYP2C19 and its relation with your treatment), and attending the week 30 visit. Please follow your doctor’s instruction so that your safety will be well monitored.

- The 48-week Long-term extension (LTE) period. Subjects who complete the 30-week double-blinded, placebo-controlled treatment period and in the judgment of the investigator have no active safety concerns will roll directly into the LTE period. All subjects will receive active study drug (mavacamten) for a duration of 48 weeks during the LTE period. Subjects who were previously in mavacamten group will continue to receive dose at Week 30. Subjects who were previously in placebo group will receive mavacamten 2.5 mg, once daily as starting dose. Your dose may be adjusted based on your response to the treatment (eg, your echocardiography). The LTE period will first be double-blinded until all subjects complete the 30-week placebo-controlled treatment period, after which it will be open-label. "Open-label" means both you and your study doctor know your treatment and dose, as opposed to “double-blinded”.

- The post treatment follow-up period. After you complete the LTE period (or discontinue the study at an earlier stage) you will be contacted by phone 4 weeks later and return to the study center 8 weeks later. If you are CYP2C19 poor metabolizer, an additional onsite visit will be performed 20 weeks later.

Your study doctor will give you detailed instruction about the study procedures and requirements for you.

You will take below procedures for various purposes during the whole study and the frequency of the procedures can be referred to the tables listed as below as well.

- You will read, review this main informed consent form and if you choose to be considered for this study you need to sign and date on it.
- The study doctor will review the entry criteria with you to find out whether or not you are eligible for this study.
- You will be asked about your personal information, eg., age, sex, and race.
- You will be asked about how you are feeling, your medical history and any medicine you are currently taking.
- Your vital signs (temperature, heart rate, breathing rate, and blood pressure) will be measured. At some visits only the heart rate and blood pressure are required. Blood pressure should be taken after resting for at least 5 minutes.
- You will have a physical examination. A complete physical examination includes assessments of general appearance, skin, head and neck, mouth, lymph nodes, thyroid, abdomen, and muscle and bones, heart, neurological, and breathing systems. A brief physical examination includes heart and breathing systems. Details can be referred to below table annotation.
- Your height and weight will be measured and your body mass index will be calculated.
- You will have an electrocardiogram (ECG). This is a painless, non-invasive test that shows how your heart works (captures the electrical activity of your heart). To have the ECG, you will lie on a bed/couch for few minutes with sensors called electrodes taped to your arms, legs, and chest.
- At certain visits you will be asked to wear a Holter monitor for approximately 24-48 hours. The Holter monitor basically functions like an ECG – it tracks the electric activities in your heart and it is also non-invasive. Different than the ECG, the Holter monitor is a portable device for continuous monitoring for 24-48 hours.
- You will have an echocardiography which is an imaging test to determine your heart function utilizing ultrasound. In this study a modality of echocardiography named “transthoracic echocardiogram” is used, which is non-invasive, painless. The probe is placed on the chest wall.
(or thorax) of the subject, and images are taken through the chest wall. The echocardiography will be taken when you are at rest as well as when you are asked to perform the “Valsalva maneuver”. The Valsalva maneuver is an easily performed maneuver in which you will expel the air out with your best effort as if blowing up a balloon. This maneuver has some physiological effects so it can be used to aid accurate echocardiographic assessment for your oHCM. Since the echocardiography result is critical to blinding maintenance, you and your study doctor will not be informed of post-randomization echocardiography data during the 30-week placebo-controlled treatment period and in double-blind LTE phase. However, core lab will review your echocardiography data. and if pre-defined safety criteria is met, your doctor will be notified. In some case, if needed, an unblinded physician might review your echocardiography data to ensure your safety. In some cases, if needed, you may be asked to take unblinded echocardiography (eg, in case of an adverse event, if needed, an echocardiography will be taken and will inform your doctor of the results to facilitate medical interpretation and treatment).

- The cardiac magnetic resonance (CMR) imaging will be taken. It is a medical imaging technology for non-invasive assessment of the function and structure of the heart. Only suitable subjects will be taken the CMR imaging. Under certain circumstances, for example if you are experiencing atrial fibrillation (a kind of irregular beating of the upper chambers of the heart) or you have a CMR contraindication eg, pacemaker, you will not take this examination. Your study doctor will check your eligibility before the examination.

- If you have an implantable cardioverter-defibrillator (ICD), your data will be downloaded from ICD at specific visits.

- The study doctor will assess how your physical activity is limited by the heart problem according to the New York Heart Association (NYHA) functional classification criteria. You will be classified to 1 of 4 categories based on your symptoms.

- You will be asked to answer a questionnaire, namely the Kansas City Cardiomyopathy Questionnaire (KCCQ). The KCCQ (23-item version) is a patient reported questionnaire that measures the impact of patients’ heart disease or its treatment using a 2-week recall.

- Your blood samples will be collected for the below tests:
  - Test to determine different cell components of your blood (hematology),
  - Test to determine your general health and body function (biochemistry),
  - Tests to measure components that help in blood clotting,
  - Follicle stimulating hormone (FSH) test only in postmenopausal women to confirm postmenopausal status,
  - Pregnancy test in women who are able to have children. Blood pregnancy test will be performed at screening, and urine pregnancy tests will be performed at all other onsite visits. A blood test will be performed if any urine test is positive.
  - Test to check for HIV (a virus that can cause the acquired immune deficiency syndrome [AIDS]), and Hepatitis B and Hepatitis C (viruses that can cause liver damage). Positive results for hepatitis or HIV will be reported to health authorities as per the local requirements,
  - Test to measure how much of the study drug is in your blood (PK blood sample),
  - Test to measure the concentration of molecules in your blood which may reflect how good or bad the heart is working (cardiac troponin and NT-proBNP) and the extent of cardiac muscle impairment,
  - Test to analyze the DNA sequence of your CYP2C19 gene. A gene is a chain of DNA. The sequence of DNA within a gene is like a code that instructs how a corresponding protein is produced. Any alterations in the sequence can have a consequence on the structure and function of the protein. This gene codes the enzyme CYP2C19, which plays a major role in metabolizing the study drug (removing it from the blood by processing it in the liver).
Therefore, the gene sequence of the enzyme may change the time the drug remains in the blood, and thus affect the concentration of the study drug in the body.

Volume of blood collected for each test are described in detail in Section “What will happen to any samples you give?”.

• Your urine samples will be collected during the study for following tests:
  − Routine laboratory examinations,
  − Pregnancy test in women who are able to have children.

• You will also be asked if you have had any illness or injury since your last visit and if there have been any changes in the medications you take.

Following tables show what examinations you will take at each visit. Table 1 outlines the schedule of activities from screening to Week 30 (ie, the end of double-blinded treatment period). Table 2 outlines the schedule for the LTE and post-treatment follow-up period.
Table 1 Schedule of Study Procedures: Screening to Week 30

<table>
<thead>
<tr>
<th>Visit</th>
<th>Screening</th>
<th>Double-blinded, Placebo-controlled Treatment Period</th>
<th>ET</th>
<th>Post-treatment Visits*</th>
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<tr>
<td></td>
<td>V0</td>
<td>V1 V2 V3 V4 V5 V6 V7 V8 V9 V10 V11</td>
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<tr>
<td>Day/Week</td>
<td>Day -28 to Day -1</td>
<td>Day 1 W 4 W 6 W 8 W 12 W 14 W 18 W 20 W 24 W 26 W 30</td>
<td>/ Phone visit</td>
<td>Phone visit Site visit Site visit</td>
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</table>

Assessment:

General procedures:
- Informed consent X
- Medical history X
- Demographics X
- Inclusion/exclusion criteria X X
- Roll into LTE X
- Randomization X
- Physical examination X X X X X X X X X X X X X X X
- Body height, weight X X X X X X X X X X X X X X X
- Prior/concomitant therapy X X X X X X X X X X X X X X X
- AEs/SAEs X X X X X X X X X X X X X X X
- ICD download X X X
- Vital signs X X X X X X X X X X X X X

Cardiac Assessments:
- 12-lead ECG X X X X X X X X X X X X X
- Holter X X X
- Resting and Valsalva TTE X X X X X X X X X X X
- CMR X X X

Laboratory Assessments:
- Hepatitis panel and HIV test X
- PK sampling (pre-dose) X X X X X X X X X X X

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### Screening

**Double-blinded, Placebo-controlled Treatment Period**

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<th>ET</th>
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<td>4 weeks from ET/W 30</td>
<td>8 weeks from ET/W 30</td>
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<td>20 weeks from ET/W 30</td>
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<table>
<thead>
<tr>
<th>Visit</th>
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<td>Day/Week</td>
<td>Day -28 to Day -1</td>
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<tbody>
<tr>
<td>a If a subject does not proceed to the LTE period or ET occurs, the subject will be contacted by phone 4 weeks later and return to the site 8 weeks later for an onsite visit after ET or Week 30 visit. For CYP2C19 poor metabolizer, an additional onsite visit will perform 20 weeks after ET or Week 30 visit.</td>
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<tr>
<td>b At screening, ET and Week 30, a complete physical examination will be conducted. At other visits will be an abbreviated physical examination on cardiopulmonary.</td>
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<tr>
<td>c For all females of childbearing potential, serum pregnancy test will be performed at screening, and urine pregnancy tests will be performed at all other onsite visits shown and serum test will be performed if any urine test is positive.</td>
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Protocol LB2001-301
Table 2 Schedule of Study Procedures: LTE and Post Treatment Follow-up Period

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<th>Week</th>
<th>LTE Period</th>
<th>ET</th>
<th>Post-treatment Visits*</th>
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<td>40&lt;sup&gt;d&lt;/sup&gt;</td>
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<td><strong>General Procedures</strong></td>
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<td>X X X X X X X X X X X X X X X X X X X X X X X X</td>
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<td><strong>Cardiac Assessments</strong></td>
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<td>12-lead ECG</td>
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<td>Holter</td>
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<td>Resting and Valsalva TTE</td>
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<td><strong>Laboratory Assessments</strong></td>
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<td>PK sampling</td>
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<td>Hematology</td>
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<td>Coagulation test</td>
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<td>Chemistry</td>
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<td>Urinalysis</td>
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<td>Urine pregnancy test (β-hCG)</td>
<td>X X</td>
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<td>NT-proBNP</td>
<td>X X</td>
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<td>Cardiac troponin</td>
<td>X X</td>
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<td><strong>Symptom Assessment</strong></td>
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<td>NYHA functional classification</td>
<td>X X</td>
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<td>KCCQ</td>
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<td><strong>Investigational Medical Product</strong></td>
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<td>Dose titration</td>
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| Week  | 34<sup>d</sup> | 36 | 40<sup>d</sup> | 42 | 46<sup>d</sup> | 50 | 52<sup>c</sup> | 54<sup>d</sup> | 58 | 62<sup>e</sup> | 64<sup>c</sup> | 66 | 70<sup>d</sup> | 74 | 78<sup>d</sup> | ET   | 4 weeks from ET/W 78 / Phone visit | 8 weeks from ET/W 78 Site visit | 20 weeks from ET/W 78 Site visit |
|-------|----------------|----|----------------|----|----------------|----|-------------|----------------|----|-------------|----------------|----|-------------|----|----------------|--------------------------|--------------------------|
| IMP QD| X              | X  | X             | X  | X             | X  | X           | X             | X  | X           | X              | X  | X           | X  | X             | X                    | X                        |
| IMP administered at site | X   | X  | X             | X  | X             | X  | X           | X             | X  | X           | X              | X  | X           | X  | X             | X                    | X                        |
| IMP compliance | X   | X  | X             | X  | X             | X  | X           | X             | X  | X           | X              | X  | X           | X  | X             | X                    | X                        |

Note: The onsite visit at 20 weeks after ET/Week 78 visit is only for CYP2C19 poor metabolizer.

<sup>a</sup>The onsite visit at 20 weeks after ET/Week 78 visit is only for CYP2C19 poor metabolizer.

<sup>b</sup>At Week 78/ET, a complete physical examination will be conducted, including neurological examinations. At all other visits, an abbreviated cardiopulmonary physical examination will be conducted, with other systems assessed as directed by interval history.

<sup>c</sup>Week 52 and Week 64: Week 52 and Week 64 visits could be removed for prior placebo participants during the open-label LTE phase.

<sup>d</sup>Week 34, 40, 46, 54, 62, 70, 78: During open-label LTE phase, only these visits are required for prior mvcavamten participants.
What will happen to any samples you give?

In this study, the hematology, blood biochemistry, coagulation, virology screen, FSH, blood/urine pregnancy testing, and urinalysis will be carried out in the local laboratory of each study center. After testing, the samples will be destroyed in accordance with the standard procedure of the study center.

The PK sample analysis, cardiac troponin and NT-proBNP measurements, and CYP2C19 gene analysis will be conducted at central laboratories contracted with the Sponsor so that it can be analyzed with the same standard method. The PK analysis and cardiac troponin and NT-proBNP measurements will be conducted at Q2 Solutions (Beijing) Co., Ltd., and the CYP2C19 gene analysis will be conducted at Beijing Prohealth Clinical Laboratory.

Each central laboratory will transport, store, test your samples, and complete analysis and report in accordance with national regulations, standard procedures, and project requirements. For the cardiac troponin and NT-proBNP tests, remaining sample will be destroyed within 7 days after test is completed. Your samples for PK analysis and the CYP2C19 gene analysis will be stored at center lab until the study is completed and passes the inspection conducted by Health Authority. Your sample(s) will be retained for longer if the Health Authority has active questions about the study, in which case sample(s) will be stored until the Health Authority's questions have been addressed.

The volume of blood sample required for each test is summarized in Table 3. A total of approx. 27 mL blood (about 6 teaspoons) will be required for the screening period. A total of approx. 112 mL blood (about 23 teaspoons) will be required for the 30-week double-blinded placebo-controlled treatment period. For the 48-week LTE period a maximum of 103 mL (21 teaspoons) may be collected. Approx. 17 mL blood (4 teaspoons) will be collected in the ET visit period. Approx. 17 mL blood (4 teaspoons) will be collected in the follow-up period (33 mL (7 teaspoons) for CYP2C19 poor metabolizer). Throughout the whole study collectively, a subject will be drawn a maximum of approx. 276 mL (56 teaspoons) over 90 weeks (292 mL (59 teaspoons) for CYP2C19 poor metabolizer).

<table>
<thead>
<tr>
<th>Test</th>
<th>Volume per test (approximately)</th>
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</thead>
<tbody>
<tr>
<td>Hepatitis panel and HIV</td>
<td>5 mL</td>
</tr>
<tr>
<td>PK sampling</td>
<td>3 mL</td>
</tr>
<tr>
<td>Coagulation test</td>
<td>3 mL</td>
</tr>
<tr>
<td>Chemistry</td>
<td>5 mL</td>
</tr>
<tr>
<td>Hematology</td>
<td>3 mL</td>
</tr>
<tr>
<td>Cardiac troponin and NT-proBNP</td>
<td>2.5 mL</td>
</tr>
<tr>
<td>CYP2C19 genotyping</td>
<td>2 mL</td>
</tr>
<tr>
<td>FSH</td>
<td>4 mL</td>
</tr>
<tr>
<td>Pregnancy test</td>
<td>4 mL</td>
</tr>
</tbody>
</table>

Your samples will only be used for the purpose as defined in this informed consent form, and will not be used for other purpose. For carrying out any new analysis on the samples not connected to this study, your permission will be required – you will be asked to sign a new consent form to allow further use of the samples. You have the right to refuse.

All above blood sample will only be collected after the Human Genetic Resource Administration of China (HGRAC) approval is received. You can check related information via below Reference Link: http://most.gov.cn/bszn/new/rlyc/fwzn/.

What alternative treatments are available?

Taking part in this study is voluntary – you do not have to take part to be treated for your condition. Your study doctor will discuss with you any other treatments or investigational drugs that may be available, and will also discuss their risks and benefits. If you decide not to take part in this study, it will not affect your ability to receive medical care.
What are the possible disadvantages or risks of taking part?

Possible side effect and risk of the study drug

Like all research, the treatment and procedure may lead to unknown risk. Any medication may have temporary, permanent, or unforeseen side effects.

It is possible that the symptoms of your condition will not improve during the study. Treatment with this study drug may also involve risks to your future health that we currently don't know about. Treatment or procedures in this study may or may not induce side effects. The side effects may be mild, moderate, or even severe, and differ in people having such experience. We will monitor closely and carefully for any side effects reported by participants in this study. Below are the information regarding side effects:

Possible side effect of the study drug

The safety of mavacamten was evaluated in two other Phase 3 studies (EXPLORER-HCM and VALOR-HCM). In a total of 179 subjects who received 2.5 mg, 5 mg, 10 mg or 15 mg mavacamten, the most commonly reported adverse drug reaction with mavacamten were dizziness, dyspnoea, systolic dysfunctions, and syncope.

There may be other side effects or risks of taking mavacamten that are not yet known. If you suffer any side effects or you think you are experiencing a side effect, during this study, please tell your study doctor immediately (see 'Who should you contact for more information?'). Any side effects or other health issues occurring during the study will be followed up by the study doctor. Notably, like all other medications, please store your study drug in safety places where children are unable to reach.

Possible risk of the study drug

Based on the previous study of the study drug, heart failure due to systolic dysfunction (defined as symptomatic left ventricular ejection fraction [LVEF] <50%) has been identified as an important risk. Teratogenicity and increased exposure to mavacamten due to drug interactions (with CYP2C19 inhibitors or with moderate to strong CYP3A4 inhibitors) have been identified as potential risks.

- Cardiac Failure and Systolic Dysfunction

  Heart failure due to systolic dysfunction defined as symptomatic LVEF less than 50%: In the mavacamten program, systolic dysfunction associated with mavacamten was observed with LVEF < 50% with or without symptoms of left heart failure.

  As of the data cut of 31-May-2022, a total of 11 mavacamten treated subjects experienced at least one of the following events of interest: SAE of cardiac failure (Standardized MedDRA Queries [SMQ] [narrow]), SAE of systolic dysfunction, and adverse event of special interest (AESI) of LVEF ≤ 30%. Four mavacamten-treated subjects experienced more than one of these events of interest.

  Clinical data has shown that dose-dependent, reductions in LVEF have been monitorable with use of echocardiograms, reversible with temporary or permanent discontinuation of the study drug. Therefore, throughout the study subjects’ cardiac function will be extensively monitored by echocardiograms. Also, since dose adjustment will be made in a gradual manner based on individual response, the possibility of overdose can be minimized.

- Drug interactions

  Possibly increased risk of heart failure due to interaction with CYP2C19 or moderate to strong CYP3A4 inhibitors (such as omeprazole or esomeprazole). Mavacamten is primarily metabolized by CYP2C19 and CYP3A4. Starting or increasing the dose of any CYP2C19 or moderate to strong CYP3A4 inhibitor may increase the risk of systolic dysfunction. Stopping or decreasing dose of a CYP2C19 or moderate to strong CYP3A4 inhibitor may lead to a loss of therapeutic response to mavacamten. To overcome this, study doctor will periodically check the medications you are taking. If you have a condition that requires any medication, please tell the primary doctor about your participation in this clinical study, and inform and inquire the study doctor in advance.
Teratogenicity:

For female subjects, based on pregnant animal studies mavacamten may cause fetal harm. No clinical data exists on the safety of mavacamten during pregnancy, this means the effects of study drug on a pregnancy, fetus or a breast-fed infant are not well established. Female subjects who have childbearing potential and their male spouse must take birth control measures following study doctor’s instructions, see below Contraception requirements section for detail. If you are or become pregnant, please tell your study doctor immediately.

Allergic reaction

Sometimes people have allergic reactions to drugs. You may have an allergic reaction to your study drug. Symptoms of an allergic reaction may include hives, rash, itching, flushing, swelling around the mouth, lips, tongue, throat, or eyes, having a hard time breathing, shortness of breath, wheezing, a sudden drop in blood pressure (making you feel dizzy or lightheaded). You may experience other symptoms. Severe allergic reactions (called anaphylaxis) can be life threatening and may require emergency treatment or hospitalization.

Contact your study doctor (see ‘Who should you contact for more information?’) immediately, if you think you may be having an allergic reaction to study drug.

Contraception requirements

If you are a woman who is able to have children, a pregnancy test will be done at screening, and if the result is positive, you will not be able to continue in the study. Also, If you are a woman who is able to have children, you must practice true abstinence or use highly effective form of birth control consistently from screening visit through 5 months after the study drug is last administered, and your male partners must also use a contraceptive (eg, barrier, condom or vasectomy) during the same period. Highly effective methods of birth control are defined as those that result in a low failure rate (< 1% per year) when used consistently and correctly. The acceptable highly effective birth control methods include the follows. The study doctor will discuss methods of birth control with you if needed.

- Estrogen- and progesterone- (a hormone involved in the menstrual cycle, pregnancy, and embryogenesis) containing hormonal birth control associated with inhibition of ovulation, or progesterone-only hormonal birth-control associated with inhibition of ovulation by oral, implantable, or injectable route of administration. (Both estrogen and progesterone are hormones. The estrogen is the sex hormone responsible for the development and regulation of the female reproductive system and secondary sex characteristics, and progesterone is a hormone involved in the menstrual cycle, pregnancy, and embryogenesis).
- Intrauterine device (IUD).
- Intrauterine hormone-releasing system (IUS).
- Bilateral tubal occlusion.
- Female surgically sterile for 6 months or postmenopausal for 1 year.

If you become pregnant or you think you may be pregnant during the study or within 5 months after the last study drug administration, contact the study doctor’s office immediately. You may be asked to withdraw from the study. You must not be breast feeding an infant during the study.

The study doctor must follow-up and keep a record of the course and the outcome of all pregnancies, even if you withdraw from the study or if the study has finished. If you becomes pregnant during the study, the study doctor or his/her staff will ask to contact you/your partner and your doctor for information about the pregnancy and the child until 6 months after the birth.
Male contraception in study subjects is not required as the risk of teratogenic effects caused by mavacamten transferred by seminal is negligible. However, the pregnancy information of your partner would be necessary to further complete the investigated drug's safety information. If your partner becomes pregnant or thinks she may be pregnant while you are in the study or within 5 months after the last study drug administration, contact the study doctor's office immediately. Your female partner(s) will be invited to sign a consent form to allow medical follow-up. The Sponsor may also request you and your female partner's consent to collect confidential information about her health and that of the baby. The study doctor must follow-up and keep a record of the course and the outcome of all pregnancies.

Possible risks of study procedures and assessments

**Blood samples:** Blood samples will be taken from a vein in your arm during the study. The risks of taking blood via a needle include temporary discomfort from the needle in your arm, bruising, clotting, swelling at the needle site, and, in rare instances, infection. In rare case, you may also experience dizziness, nausea or fainting during blood taking. Please tell the study doctor or study staff if you do not feel well after having your blood taken.

**Blood pressure:** An inflatable cuff will be placed on your arm and a machine will measure your blood pressure after you have rested for 5 minutes. You may experience mild discomfort in your arm while the cuff is inflated.

**Electrocardiogram (ECG):** Small electrodes will be stuck to your chest, arms and legs and a machine will measure the electrical activity of your heart. These electrodes may cause some slightly local uncomfortable.

The **holter** is a safe and painless procedure. The patches that the study staff will stick to your chest and other areas of your body to monitor your heart may irritate your skin and cause itching and/or redness. The study staff might need to shave your body hair so that they can stick the pads to your skin only if necessary. The shaving may cause some irritation. If you are allergic to the material in the patches, a local allergic reaction could occur. When the sticky patches are removed, it might sting for a few seconds. Holter will monitor your heart for approximately 24-48 hours.

**Echocardiography:** Cardiac ultrasound is a non-invasive and painless examination. The medical ultrasonic couplant will be smeared to your chest skin. And then, an ultrasound probe will be used to examine your heart. Medical ultrasonic couplant are gel-like substances that are non-toxic to humans but may cause local irritation and may be uncomfortable. You will be required to perform Valsalva maneuver. The Valsalva maneuver requires you to expel the air out with your best effort as if blowing up a balloon. It is a very safe maneuver, but you may feel transient discomfort. In rare case, Valsalva maneuver might cause fainting due to a low heart rate.

During an **CMR (Cardiac Magnetic Resonance)** scan, you may feel anxious because of the enclosed space (claustrophobia). MRIs cannot be performed in the presence of metal, if you have a pacemaker, artificial heart valve, dental braces, internal hardware, or if you are pregnant, you must tell your doctor. In some cases you are not eligible for the CMR. For the scans, you will receive the magnetic resonance contrast material. This is given in your vein using a indwelling needle. You will not receive the CMR scan if you are known to be allergy to the contrast material or if you have abnormal kidney function. You may feel local warmth/pain in the area where the needle was inserted. You may also have nausea/vomiting or headache. Serious allergic reactions related to MRI contrast material may be life-threatening but are very rare. In rare cases extravasation of contrast medium may occur which can cause skin injury or phlebitis.

**What happens when the research study stops?**

During the study you will receive the study drug free of charge. The study drug may not be available as a prescription paid for by the health care system immediately after the end of the study. There is no guarantee that you will continue to receive this particular drug or treatment when you have finished taking part in the study. The care you receive after the study has ended may involve a different drug or treatment, which the hospital, together with your study doctor, considers to be the most suitable alternative.

If you have a reaction to the study drug, your participation may be stopped at any time by the study doctor or sponsor without your consent.

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If the study is stopped, you will be told, and your study doctor will make suggestions or arrangements for your subsequent therapies.

What if you have a question?
If you have a question, concern or complaint about any part of this study, you should ask to speak to the study doctor or a member of the research team, who will do their best to help (see 'Who should you contact for more information?').

If you have any questions about your rights as part of the research, or any concerns or complaints about the research that you do not want to discuss with the study doctor or research team, see 'Who should you contact for more information?'.

If you suffer a serious illness or injury during this study, please contact your study doctor immediately (see 'Who should you contact for more information?').

Compensation for study related injury
The sponsor should take appropriate measures to ensure the compensation or the payment available to subjects and investigators.

The Sponsor should provide investigators and clinical trial institutions with legal and economic insurance or guarantees related to trials, which should be adaptive to the nature and degree of risk of the trials. The damage caused by the fault of the investigator and the clinical trial institution themselves is not included.

The Sponsor should be responsible for the diagnosis and treatment expenses of the subjects’ damage or death related to the trial, and the corresponding compensation. The sponsor and the investigator should promptly pay the compensation or payment for the subjects.

The compensation approach provided by the sponsor to the subjects shall be complied with relevant laws and regulations.

The Sponsor should provide the investigational product to the subjects free of charge and should pay the medical testing fees related to the trials.

What if new information about the study drug becomes available?
Sometimes new information about the study drug is received. You will be told if any relevant new information becomes available that may affect your willingness to carry on taking part in the study. If this happens, your study doctor will contact you as soon as possible, and will discuss whether you should continue in the study. If you decide not to carry on, your study doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign a new consent form.

Also, if new information becomes available, your study doctor may stop your participation without your consent. If this happens the reasons will be explained, and arrangements made for your care to continue.

What will happen if you don’t want to carry on with the study?
You can stop taking part in the study at any time without giving any reason. This will not affect your future treatment or your relationship with your study doctor. If you stop taking part, please tell your study doctor immediately. When you withdraw from the study, please cooperate with your doctor to finish the Early Termination visit as soon as possible and then you will get a phone visit 4 weeks later and you will be requested to be onsite to get a follow-up visit 8 weeks later (if you are CYP2C19 poor metabolizer, an additional onsite visit will be performed 20 weeks later). In addition, if you withdraw during the double-blind treatment period, your study doctor will schedule the Week 30 assessments for you. We strongly recommend you to follow your doctor’s instruction to finish the follow-up visit required as it aims to make safety assessment and ensure your safety to be protected.

Will your taking part in this study be kept confidential and how will your personal information be used?
The study doctor and research team will collect, record and use personal information about you for the study purposes. Your personal information collected during the study may include sensitive information about your physical or mental health or condition, and health information about you in medical records, and other personal information such as date of birth, sex, nationality. Your privacy and your personal information will be protected using measures which follow the requirements applicable in China for the
protection of your personal information. Any information about you that is collected during this study will remain confidential. To ensure privacy and the scientific integrity of the study, your name and address will not be disclosed outside the hospital and you will only be identified by a code. This code will be attached to records or samples released to the Sponsor and the service providers associated with the study.

Your personal information will be stored and used for medical, statistical, and regulatory purposes related to the research. Representatives of the sponsor and regulatory authorities in China and other countries may use your personal information to verify the research. If your personal information is reviewed by one of these people, then they may need your entire medical record. The information obtained during the study may be published or sent to regulatory authorities or health insurers in China or other countries where regulatory approval or payment for the study drug is required. Your identity will not be released except with your permission, unless necessary for your safety.

Your personal information may be accessed by the Research Ethics Committee, the Sponsor and its affiliates, research partners, other participating study centers, and representatives assisting with the research (such as the contract research organization, study monitors, auditors), central laboratory and regulatory authorities in China or other countries and health insurers.

By signing this consent form, you are giving permission for processing of your personal information in a database and transferring of this information or any part of it to people and organizations in the manner as described above, including transferring to people or organizations outside China, where personal data protection laws may be less strict but your information will be adequately protected.

You may use your rights under your local data protection laws to access and correct your personal information or ask for it to be deleted. You can object to any further processing of your information by contacting the study doctor.

According to legal requirements, your personal data will be stored in the study databases and/or paper files for 15 years after the study ends. In case local regulations or institutional policies require a longer retention period, the data will be stored as required.

All subjects participated in China will be able to search the study related information on the Web site www.chinadrugtrials.org.cn This Web site will not include information that can identify you.

The results of this study will be used to make informed clinical decisions for developing this new drug. If you want the results to be made available to you, please talk to your study doctor.

Who has reviewed the study?
All research studies are reviewed by an independent group of people, called a research ethics committee to protect your safety, rights, well-being and dignity. This study has been reviewed and has been given a favorable opinion by Research Ethics Committee.

The Sponsor, Regulatory Authorities or the Ethics Committee may stop the study at any time where there is good reason, e.g., unsatisfactory participant enrollment with regard to quality or quantity, significant or numerous deviations from study protocol requirements, the incidence or severity of safety findings in this or other studies indicating potential health hazard caused by the study drug.

Who should you contact for more information?
For more information about the study, please contact your study doctor or study staff:

Name: <insert name of Investigator or Study staff>
Address: <insert address>
Phone: <insert number>

If you have any questions about your rights as a research subject please contact here.

Name: <insert name of Ethics Committee>
Address: <insert address>
Phone number: <insert phone number>

Thank you for reading this and considering if you will take part in this study.
Consent form

Study title: A Phase III, Randomized, Double-blinded, Placebo-controlled Clinical Study with A Long-term Extension to Evaluate the Efficacy and Safety of Mavacamten in Chinese Adults with Symptomatic Obstructive Hypertrophic Cardiomyopathy

Study protocol: LB2001-301

Study drug: Mavacamten Capsules, referred throughout the document as the “study drug”

Sponsor of the study: Shanghai LianBio Development Co., Ltd.

Site Name: <Site Name>

Investigator: <Investigator's Name>

I confirm the following:

- I have read and understand the information sheet for the above study, and have had enough time to think about taking part.
- I have had enough time to ask question and I am satisfied with the answers given to all of my questions.
- I voluntarily agree to be part of this research study, to follow the study procedures and to provide the information the study doctor, nurses or other staff members ask from me.
- I understand that I am free to withdraw from this study at any time without giving a reason and without my medical care or rights being affected.
- I have received a signed copy of this information sheet and consent form to keep for myself.
- I agree, if my study doctor is not my doctor, my doctor may be told about my taking part in this study and asked for medical information about me.
- I agree to my samples being taken and used as described in this information sheet.
- I give permission for my personal information collected as part of this clinical study to be:
  - identified only with my subject ID number;
  - reviewed, processed and transferred by and to the Sponsor and its authorized representatives for the purposes described in the study protocol;
  - reviewed and audited by appropriately authorized organizations;
  - published and sent to regulatory authorities or health insurers in China or other countries; and
  - transferred if required to any country, where data protection laws may be less strict.
- I understand I may also be contacted at a later date(s) for my permission in connection with this.
- <The following text is only used for study centers that had previously received ethics committee approval for the informed consent form from Shanghai Jsure Health Technology CO., Ltd. If previously the informed consent form from Shanghai Jsure Health was not approved by ethic committee, the following text will be deleted.>

The personal information collected by Shanghai Jsure Health Technology CO., Ltd. (hereafter referred to as “Jsure Health”), including name, ID number, mobile phone number, and address, will be used by Jsure Health to provide you with reimbursement for additional expenses caused by participating the study. Whether or not to provide personal information to Jsure Health does not impact continuous participation in this study.

At any time while Jsure Health is providing you the services, you have the right to contact Jsure Health to terminate the service and request Jsure Health to delete or withdraw the personal information you provided.

The contact information is stated below:
Shanghai Jsure Health Technology CO., Ltd.
Address: Room 2-A, Building 4, No. 315, Guangyuan West Road, Xuhui District, Shanghai
E-mail: finance@jsure.com
Tel: (86 21) 31229190

Personal information will be deleted immediately after the reimbursement fee is transferred to you via bank card/WeChat payment code (after confirming not rejected or returned).
Please tick "√" in the box below □ to indicate whether you agree or not the personal information to be handled by Jsure Health. If you agree and sign this consent, Jsure Health will consider you agree with their process regarding your personal information. If you do not agree to let Jsure Health handle your personal information, Jsure Health will delete your personal information collected previously and will no longer process any of your personal information after signing this consent.

□ I agree
□ I disagree

By signing this document, I give agree to take part in this study, as set out in the information sheet and consent form.

For Subject

Printed Name of Subject:

_________________________________________   ____________________
Signature of Subject:     Date and time:
For Impartial Witness (If Applicable)

Printed Name of Impartial Witness: ________________________________

Signature of Impartial Witness: __________________________ Date and time: __________________________

Investigator/Authorized Designee:

• I have fully and carefully explained the study to the person named above and confirm that, to the best of my knowledge, they clearly understand the nature, risks and benefits of taking part in this study.

• I confirm that I gave them all opportunities to ask questions about the study, and that I answered all the questions they asked correctly and to the best of my ability.

• I confirm that they have not been forced into giving consent, and that they have given their consent freely and voluntarily.

• I confirm they have been given a copy of this information sheet and consent form.

Printed name of Investigator/Designee: ________________________________

Signature of Investigator/Designee: __________________________ Date and time: __________________________