Volunteer Information Sheet

<table>
<thead>
<tr>
<th>Study Title:</th>
<th>Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Ascending Doses of HBM9161(HL161BKN) in Healthy Chinese Volunteers (Randomized, Single-blinded, Placebo-controlled Trial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Number:</td>
<td>9161.1</td>
</tr>
<tr>
<td>Study Drugs:</td>
<td>HBM9161(HL161BKN)</td>
</tr>
</tbody>
</table>
| Sponsor:             | Harbour BioMed Therapeutics Limited  
                     Suite 2004, 20/F, Tower 5,  
                     China Hong Kong City, 33 Canton Road,  
                     Tsim Sha Tsui, Kowloon, Hong Kong |
| Principal Investigator: | Dr. Desmond Yat Hin YAP  
                       Clinical Associate Professor  
                       Division of Nephrology  
                       Department of Medicine  
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| Study Site:          | Phase 1 Clinical Trials Centre, The University of Hong Kong  
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Introduction

This is a clinical research. The study doctor will explain the details of the captioned study to you. It is important for you to understand the details of the study in order to decide if you want to participate. Please take time to read the following information carefully and discuss with your family members and family doctor, if you wish. If you have any questions, please ask the study doctor for more explanation. Please take time to decide whether or not to take part.

Harbour BioMed Therapeutics Limited (“Harbour BioMed”) is the Sponsor of this study. Harbour BioMed will provide funding, as well as the study drug to the study site for conducting the study.

What is the study drug involved in this study?

The study drug to be used in this study is called HBM9161 (HL161BKN) (abbreviated as HBM9161). It is developed and manufactured by the Sponsor in accordance with Good Manufacturing Practice. HBM9161 that is used in this study is being administered via subcutaneous injection. HBM9161 has not yet been approved by a regulatory authority for use for an indicated disease. Hence, it is available for clinical trial purpose only.

HBM9161 is a human monoclonal antibody. Human monoclonal antibody is a type of human protein made in the laboratory that can locate and bind to one specific substance in human body. Research on HBM9161 has been shown that it could reduce IgG level (a type of human antibody), in the body. Build-up of pathogenic IgG causes abnormal immune response and leads to autoimmune disease (a...
condition in which your immune system mistakenly attacks your body). Therefore, HBM9161 is now being studied for targeting in treatment of autoimmune diseases.

**Why is this study being done?**

This study is called a Phase 1 clinical trial. The phase 1 trial is conducted to test the safety of a study drug. “Study drug” means that the drug is still being studied and the study doctor is trying to find out more about it.

HBM9161 has been tested in the laboratory and in animals. As of 15 Oct 2018, an ongoing phase 1 first-in-human study is being conducted in a limited number of people in Canada. Therefore, the study doctor does not know if the study drug HBM9161 will have any good or bad effects on you.

The main purpose of this study is to evaluate safety of HBM9161 in Chinese healthy volunteers at three dose levels. Once the research team finds out the suitable dose, other study can be done in the future to see if HBM9161 works at treating autoimmune disease.

In addition, the study staff will collect blood samples during your participation in the study for pharmacokinetic (PK) and pharmacodynamics (PD) studies. PK study is the measurement of the level of HBM9161 in your blood and sees what your body does to HBM9161 after you have taken it. PD study is the measurement the effect of HBM9161 on IgG level.

**What is the study plan?**

This study is comprised of 3 cohorts at most. Each volunteer will only be allowed to participate in one cohort and is required to take a single dose of HBM9161 or placebo (a substance that contains no therapeutic value). Volunteers of cohort 1, 2 and 3 are proposed to receive 340mg, 510mg and 680mg of HBM9161 or placebo, respectively. The study doctor will tell you which cohort you are in.

Approximately 8 healthy volunteers will be recruited to each cohort. 6 out of 8 volunteers will be randomly assigned to administer a single dose of HBM9161 while 2 out of 8 volunteers will be randomly assigned to administer a single dose of placebo. This random method for drug administration is commonly used in clinical studies when selection bias has to be minimized for making a scientific comparison.

Each study group will be conducted in a non-overlapping and consecutive manner, starting from cohort 1 and moving up to cohort 3.

The study is designed in a way that you will not know if you receive HBM9161 or placebo during the study. This procedure is called single blinding and is used in clinical trials to eliminate potential bias in study drug effect and/or safety assessment by volunteers.
What will happen if I decide to take part in this study?

All study procedures described below will only be performed on you by the study staff if you have signed the informed consent form. Throughout the study, you will be required to go through the study assessments as described in this information sheet, comply with dietary and activity restrictions and follow the instruction given by the study staff. For sexually active female or male volunteer’s female partner with childbearing potential (including females who are within 12 months of menopause), you will be required to use (or have your partner used) at least one of the acceptable contraceptive method(s) (see section “Reproductive risk associated with the study drugs”), starting from screening until 90 days after dosing. If you do not want these assessments and restrictions, you should not agree to participate in this study.

Screening Visit (Before dosing from Day -40 to Day -2)

Volunteers will be screened up to 40 days prior to study drug administration. You will need to go through the following screening procedures in order to confirm your eligibility for the study. You must answer all questions asked by the study staff honestly and completely. If your conditions change during the screening period, you must inform the study doctor. To complete the screening assessments, you may need to visit the study site more than one time during this period. The screening procedures include:

- You will be asked to provide your personal information (e.g. gender, date of birth and ethnicity);
- You will be asked about your past medical history and current health condition. The study doctor will also access and review your medical records and collect your health information;
- You will be asked about any medications (including over-the-counter drugs, vitamins, herbal and nutritional supplements) that you are currently using or have used within the last 14 days;
- You will be asked about your reproductive status, smoking status and use of alcohol and drugs of abuse, recent diet and exercise habit;
- Body height and weight measurement;
- Physical examination;
- 12-lead electrocardiogram;
- Vital signs measurement including blood pressure, pulse rate and body temperature;
- Alcohol breath test;
- Routine urine test and urine drug abuse test;
- For female volunteers of childbearing potential, a urine or blood sample will be collected for pregnancy test;
- For postmenopausal female volunteers, blood sample will be collected for follicle-stimulating hormone (FSH) test to confirm the postmenopausal status;
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- Blood sample will be collected for complete blood count, biochemistry, coagulation tests, viral serology tests i.e., hepatitis B and C, human immunodeficiency virus (HIV), and tuberculosis test;
- Blood sample will be collected for PD analysis and exploratory biomarkers;
- You will be required to follow the dietary and activity restrictions (see Table 1)

At least 31 ml of blood will be collected during the screening period. You should bear in mind that completing the above-mentioned procedures does not guarantee your entry into the study. Study entry will depend upon the results of your laboratory tests, study-specific guidelines, and the decision made at the discretion of the study doctor.

Even if you are eligible, you may not necessarily be able to participate in this study. The study staff may screen more volunteers than required as backup to ensure that the recruitment target of the study can be met. To ensure a fair enrolment process, the study staff will select the volunteers in chronological order of recruitment during screening. The study doctor will make a decision on whether you can be enrolled in the study before administering study drug. If the target number of volunteers for the study is met, the remaining volunteers will not be able to enrol.

**Day -1 (Pre-dose)**

You will be asked to visit the study site on Day -1. You will need to go through the following procedures:

- Body weight measurement;
- Physical examination;
- 12-lead electrocardiogram;
- Vital signs measurement including blood pressure, pulse rate and body temperature;
- Alcohol breath test;
- Routine urine test and urine drug abuse test;
- For female volunteers of childbearing potential, a urine or blood sample will be collected for pregnancy test;
- Blood sample will be collected for complete blood count, biochemistry and coagulation tests;
- Blood sample will be collected for PD analysis, exploratory biomarkers and anti HBV antibody;
- You will be assessed on any illnesses that you experienced since the last visit;
- You will be asked about any medications that you are taking or have taken since the last visit;
- You are required to follow and be assessed on the compliance of the dietary and activity restrictions (see Table 1);
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At least 56ml of blood will be collected on Day-1 (pre-dose). After completing the procedures, the study doctor will decide if you are eligible for participating in the study. If you deem eligible to the study, you will stay overnight at the study site on Day -1.

Confinement (Day -1 to Day 5)

If you are deemed eligible for the study, you will be asked to stay at the study site for 6 days 5 nights, starting from 1 day prior to dosing (Day-1) until 5 days after dosing (Day 5). You are required to follow the study procedures and comply with the dietary and activity restrictions during your stay at the study site (see Table 1).

Day 1 (Dosing)

Before the administration of HBM9161

You will need to go through the following procedures at the specific time points:

- You will be asked about any medications that you are taking or have taken;
- You will be assessed by the study staff for any illnesses;
- Telemetry (continuous monitoring of heart function e.g. heart rhythm and breathing rate) and pulse oximetry (measurement of oxygen saturation in the blood) will begin 30 to 60 minutes prior to dosing until 4 hours after dosing, then restart at 5 hours for at least half an hour and approximately 6 hours for at least half an hour after dosing;
- Vital signs measurement including blood pressure, pulse rate and body temperature (before breakfast);
- 12-lead electrocardiogram (before breakfast);
- Blood sample will be collected for PK (Pharmacokinetics) analysis at approximately 2 hours before dosing;
- Blood sample will be collected for PD (Pharmacodynamics) analysis;

Administration of HBM9161

You will receive two subcutaneous injections of HBM9161 in equal volume at two separate injection sites (e.g. abdomen or upper thigh). These two injections contain a total volume (approximately 2 to 4 ml) required to make up the dosage of HBM9161.

After administering HBM9161

You will need to go through the following procedures at the specific time points:
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- Physical examination (approximately 3 hours after dosing);
- Skin reaction assessment at approximately 15 minutes after the injections;
- Blood sample will be collected for PK (Pharmacokinetics) analysis at approximately 2, 4, 8, and 12 hours after injection;
- Vital sign measurement at approximately 10 minutes, 60 minutes, 120 minutes, 4 hours after dosing, and before dinner;
- You will be assessed by the study staff for any illnesses;
- You are required to follow the dietary and activity restrictions (see Table 1)

At least 67ml of blood will be collected on Day 1. You will stay overnight at the study site on Day 1.

Day 2 to Day 5 Post-dose (24, 36, 48, 72 and 96 hours after dosing)

You will need to go through the following procedures at the specific time points:

- Physical examination with skin reaction assessment;
- Vital signs measurement including blood pressure, pulse rate and body temperature twice daily (prior to breakfast and dinner);
- 12-lead electrocardiogram at approximately 24, 48, and 72 hours after dosing;
- Routine urine test at approximately 24 and 72 hours after dosing;
- Blood sample will be collected for complete blood count, biochemistry and coagulation tests at approximately 24 and 72 hours after dosing;
- Blood sample will be collected for PK analysis at approximately 24, 36, 48, 72 and 96 hours after dosing;
- Blood sample will be collected for PD analysis at approximately 24, 48, 72 and 96 hours after dosing;
- Blood sample will be collected for exploratory biomarkers at approximately 24 and 72 hours after dosing;
- You will be assessed by the study staff for any illnesses;
- You will be asked about any medications that you are taking or have taken;
- You are required to follow the dietary and activity restrictions (see Table 1);

At least 124ml of blood will be collected from Day 2 to Day 5. You will stay overnight at the study site on Day 2, Day 3 and Day 4. You are allowed to leave the study site on Day 5 after completing the procedures scheduled and after the study staff reviewed your condition. You should continue to comply with the dietary and activity restrictions when you are outside of the study site (see Table 1).
Day 8 to Day 85 Post-dose

You will be asked to return to the study site on Day 8, Day 11, Day 15, Day 22, Day 29, Day 43, Day 57, and Day 85 for follow-up. Day 85 is regarded as the End of Study Visit.

You will need to go through the following procedures:

- Physical examination with skin reaction assessment;
- Vital signs measurement including blood pressure, pulse rate and body temperature;
- 12-lead electrocardiogram on Day 8 and Day 85;
- For female volunteers of childbearing potential, a urine or blood sample will be collected for pregnancy test on Day 43 and Day 85;
- Routine urine test on Day 8, Day 15, Day 43 and Day 85;
- Blood sample will be collected for complete blood count, biochemistry and coagulation tests (except on Day 11 and Day 22);
- Blood sample will be collected for PK analysis (only on Day 8 and Day 11);
- Blood sample will be collected for PD analysis;
- Blood sample will be collected for exploratory biomarker (except on Day 11 and Day 22);
- Blood sample will be collected for anti HBM9161 antibody (except on Day 11, Day 22 and Day 43);
- You will be assessed by the study staff for any illnesses that you experienced since the last visit;
- To provide information about any treatments you are taking or have taken since the last visit;

At least 317ml of blood will be collected from Day 8 to Day 85. In each visit, you are allowed to leave the study site after completing the procedures and after the study staff reviewed your conditions. You should continue to comply with the dietary and activity restrictions when you are outside of the study site (see Table 1) until End of Study Visit.

Extended Follow-up Visit at 6, 9 and 12 months Post-dose (if required)

You will be informed by the study staff if you have been tested to have positive anti-HBM9161 antibodies on Day 85. You will be requested to return to the study site for Extended Follow-up Visit to have you blood sample collected for anti-HBM9161 antibodies test at approximately 6, 9 and 12 months after dosing or until 2 consecutive blood samples have been confirmed to be negative for anti-HBM9161 antibodies, whichever occurs earlier.
What are the dietary and activity restrictions for this study?

Table 1 below lists out all dietary and activities restrictions during screening, during the study and post-study. You are required to follow the restrictions strictly.

<table>
<thead>
<tr>
<th>Restrictions</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td></td>
<td>During Screening Period</td>
</tr>
<tr>
<td>I illicit drugs</td>
<td>X</td>
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<tr>
<td>Clinical trial participation or administration of investigational drug(s)</td>
<td>X</td>
</tr>
<tr>
<td>(except this study)</td>
<td></td>
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<tr>
<td>Blood donation (except for blood samplings in this study)</td>
<td>X</td>
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<tr>
<td></td>
<td>&gt; 450ml whole blood within 3 months and 50 ml whole blood within 1 month prior to dosing</td>
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<tr>
<td>Immunisation</td>
<td>X</td>
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<tr>
<td></td>
<td>within 12 weeks after dosing</td>
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<tr>
<td>Contraceptive measures</td>
<td>☑</td>
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<tr>
<td></td>
<td>from screening until 90 days after dosing</td>
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<tr>
<td>Smoking, using tobacco or nicotine containing product(s)</td>
<td>X</td>
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<tr>
<td>Any prescription or non-prescription drugs including vitamins, dietary and</td>
<td>X</td>
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<tr>
<td>herbal supplements except:</td>
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<tr>
<td>• Topical medications</td>
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<tr>
<td>• Eye drops with no systemic action</td>
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<tr>
<td>• Acetaminophen ≤4 grams/day will be allowed after dosing if permitted by</td>
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<tr>
<td>study doctor</td>
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<tr>
<td>• Injectable or combined oral contraceptives</td>
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<td></td>
<td>X</td>
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<tr>
<td></td>
<td>Within 7 days prior to dosing</td>
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<tr>
<td>Restrictions</td>
<td>Timeframe</td>
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<td>-----------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
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<tr>
<td></td>
<td>During Screening Period</td>
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<tr>
<td></td>
<td>X</td>
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<tr>
<td>Strenuous exercise</td>
<td>Within 7 days prior to dosing</td>
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<tr>
<td></td>
<td>X</td>
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<tr>
<td>Xanthine-containing beverages (e.g. coffee, tea, chocolate, cola, any caffeinated beverages, and high energy drinks)</td>
<td>X</td>
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<tr>
<td></td>
<td>X</td>
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<tr>
<td>Alcoholic beverages</td>
<td>X</td>
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<tr>
<td>Consuming food containing poppy seeds (e.g. breads, muffins, pastries, cake, salad dressing and meals with poppy seeds recipe)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Confinement at study site</td>
<td>✓</td>
</tr>
<tr>
<td>Fasting</td>
<td>✓</td>
</tr>
<tr>
<td>Dosing</td>
<td>✓</td>
</tr>
<tr>
<td>Discharge from study site</td>
<td>✓</td>
</tr>
</tbody>
</table>

X = Not allowed; ✓ = Required
How long will you be in this study?

Your participation in the study will last for:

Screening – approximately 40 days

During study period – a minimum of 85 days

During the study period, you will stay at the study site for 6 days 5 nights and followed by returning to the study site for study visits up to 85 days after dosing. If deemed necessary, you will also be required to visit the study site 6, 9 or 12 months after dosing for follow up.

How many volunteers will take part in this study?

Approximately 24 healthy volunteers will be recruited for 3 study groups. Approximately 8 volunteers will be enrolled in each study group.

What are the risks of being in this study?

Taking part in this study may involve some risks and possible discomfort. Everyone taking part in the study will be monitored closely for any undesirable effects. You should talk to the study doctor about any undesirable effects that you have while taking part in the study.

Foreseeable risks associated with HBM9161

An ongoing Phase 1 first-in-human study is being conducted in Canada. As of 15 Oct 2018, 57 volunteers have been given HBM9161 intravenous infusion or subcutaneous injection in different doses and frequencies. Besides, 16 volunteers have received placebo intravenous infusion and subcutaneous injection. The following treatment-emergent adverse effects were reported:

- Moderate gastroenteritis (stomach flu)
- Chest pain
- Body ache and pain
- Vomiting
- Feeling dizzy
- Headache
- Fatigue
- Sore throat
- Mild erythema, swelling at the injection site
- Mild rash
- Coughing
- Abdominal pain
- Feeling nauseous
- Feeling sleepy and drowsy
- Skin itchiness on the right arm
- Low back pain
- Stuffy nose
- Upper respiratory tract infection
- Mild skin redness at the injection site
Prior to Phase 1 first-in-human study, several studies on HBM9161 have been conducted in animal model for establishing the safety and toxicity profile before human use. In one study, HBM9161 was administered to the cynomolgus monkeys twice weekly at different dose level for 6 weeks. The following adverse effects had been observed in the monkeys:

- Thrombocytopenia (Low platelet count)
- Reticulocytosis (Increase in the number of premature red blood cells) with anaemia (low red blood cell count)
- Increase in triglycerides level
- Changes in the electrolyte level
- Significant decrease in total protein and albumin
- Development of anti-HBM9161 antibodies
- Weight loss
- Increase in serum creatinine and/or blood urea
- Increased size of kidney
- Inflammation on kidney
- Acute systemic reaction to immune complexes (one type of serious allergic reactions)

**Possible serious allergic reaction associated with HBM9161**

No serious allergic reaction was observed in the ongoing phase 1 first-in-human study. But it will not be absolutely ruled out. HBM9161 may possibly cause serious and potentially life-threatening allergic reaction. This may be due to the build-up of immune complexes (production of antibodies, bind to antigens, and activate immune response) in the body. Possible signs and symptoms of serious allergic reactions include:

- Difficulty in breathing or wheezing
- Tightness in the throat or a feeling that the airways are closing
- Swollen lips, tongue, or throat
- Feeling nauseous, stomach pain or vomiting
- Fast heartbeat
- Skin itchiness, tingling sensation
- Swollen skin or hives (raised red skin)
- Feeling anxious and dizzy
- Loss of consciousness

**Skin reactions at the site of injection**

Subcutaneous injection may cause local skin reactions which include pain, redness, swelling, or possibly skin infection at the injection site(s).

**Other unanticipated side effects of HBM9161**

HBM9161 used in this study is still experimental. In addition to the above-mentioned risks, there may be unknown risks or risks that we did not anticipate that are associated with being in this study.

**Reproductive risk associated with the study drug (For female volunteer and male volunteer with partners of childbearing potential)**
HBM9161 may cause unknown risks to you, your unborn baby or nursing infant. For this reason, all female volunteers who have the ability to become pregnant are required to undergo pregnancy testing before entering the study and during the study period when pregnancy is suspected. If you are pregnant, you cannot participate in this study. You should not become pregnant or father a baby while you are participating in this study and within 90 days after dosing. You should not breastfeed a baby or provide breastmilk to other babies while you are in this study.

If you or your partner has childbearing potential, you are required to use (or have your partner used) at least one of the acceptable contraceptive methods from screening visit until 90 days after dosing. Acceptable contraceptive methods include abstinence (for at least 1 month prior to screening), correct use of condom, spermicides, injectables, combined oral contraceptives, intrauterine device with or without local hormone release, cervical cap or diaphragm and vasectomy performed at least 1 year prior to screening. You should check with the study doctor about what kind of contraceptive measures you should adopt.

If you (for female volunteer) miss a period or think you might be pregnant during the study or you (for male volunteer) think your female partner is pregnant during the study, you must tell the study doctor immediately. In case you or your partner become pregnant prior to dosing, you will not be able to receive the study drug. If you are a female, the study doctor will collect information related to pregnancy outcome from you. If you are a male, the study doctor will collect information related to pregnancy outcome from you and your partner upon agreement by your partner.

**Foreseeable risks associated study procedures and assessments**

**Blood sample collection and venepuncture**

A needle/catheter will be inserted into your vein for blood collection. You may experience some discomfort when blood samples are taken and needle/catheter is inserted, such as pain at the site where the blood has been drawn, bruising, occasional light-headedness, fainting (rare) or infection (very rare) at the site of the needle/catheter stick. Repeated blood draws may lead to anaemia or low blood cell counts.

Total blood volume taken in the study:

<table>
<thead>
<tr>
<th>Study Visit</th>
<th>Estimated blood volume (ml)</th>
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</thead>
<tbody>
<tr>
<td>Screening</td>
<td>31564</td>
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<tr>
<td>Study Period</td>
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</table>

For female volunteer of childbearing potential, an additional 24ml blood may be required for serum pregnancy tests. The study doctor may need to take additional blood samples if it is deemed necessary.

**ECG**
An ECG is a painless test that provides information on how your heart is working. When you have an ECG, study staff will apply soft gel tapes to certain parts of your body. If there is excessive hair where the soft gel tapes are placed, shaving of hair may be needed before the procedure. The skin beneath the soft gel tapes may become red or you may feel irritation on the skin after the soft gel tapes were removed.

**Fasting**

You will be asked to fast for at least 8 hours before blood draw for biochemistry tests. There is a chance that you may experience some short-term side effects from fasting. These can include headaches, dizziness, feeling tired, feeling light-headed, low blood pressure and abnormal heartbeat.

**What are my responsibilities during the study?**

- You have to attend every study visits and arrive at the study site on time. If you cannot attend one of your study visits, you should contact the study doctor or the study team as soon as possible;
- You should not participate in other clinical studies and use other investigational medicinal products without the approval from the study doctor;
- You are required to confine in the study site for 6 days 5 nights (Day -1 to Day 5);
- You should strictly comply with the dietary and activity restrictions (Table 1);
- You should contact the study doctor or study staff as soon as you experience any unwell or illnesses, no matter you think the study drugs have caused them or not;
- You are advised to consult the study doctor before you start any medications. This includes any supplements, over-the-counter drugs and alternative medicines, e.g. Chinese herbal medicine;
- You should comply with the study procedures and instructions given by the study doctor or staff.

**Are there benefits in taking part in this study?**

Since this study does not provide treatment, there is no direct benefit to you. Taking part in the study may help in providing important information about HBM9161.

**What other choices do I have if I don’t take part in this study?**

Your participation in this study is voluntary. This study recruits healthy volunteers and does not aim at providing treatment. Therefore, there is no alternative treatment.
Will my personal data be kept confidential?

Your data relevant to this study will be collected during the study. In the study database, your data will only be identified by a volunteer number without personal identity, e.g. name and identification card number. The Sponsor/Sponsor’s designees/collaborators will receive and analyse the data without your identity. The data will be stored and protected for at least 5 years after study completion. The study results will be reported and/or published without disclosure of your identity.

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his office (Tel No. 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By consenting to participate in this study, you expressly authorise:

- the Principal Investigator and his research team, The University of Hong Kong, and the IRB of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) responsible for overseeing this study to get access to, to use, and to retain your personal data including medical record for the purposes and in the manner described in this informed consent process; and

- the Sponsor, the Sponsor’s designees and the relevant government agencies (e.g. the Hong Kong Department of Health and the China National Medical Products Administration) to get access to your personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

Any person who has access to your personal data that identifies you (e.g. medical record) should keep such data confidential. Any data that may identify you will not be removed from the study site.

Any study data to be transferred to the Sponsor, the Sponsor’s designees, relevant government agencies and other parties will remain anonymous and will no longer constitute personal data under the definition of the Personal Data (Privacy) Ordinance of Hong Kong.

What will happen to my study data?

You have the rights of access to your personal data and publicly available study results, if and when needed.

The Sponsor may use the study data (this will not include any information that directly identifies you) for the following purposes:

- Analysing the data to find out what this study is telling us
• Using the data/results to apply for marketing authorisation

• Publishing the results of the study

• Sharing the data/results as part of research with other companies or universities for the purpose of further understanding or developing the study drug

• Using the data/results to plan new studies or other types of research or other medical purposes related to the development of the study drug

What will happen to my biological samples?

The blood and urine samples taken for safety tests will be destroyed after study completion. Each sample will be labelled with a code, so that the laboratory testing the samples will not know your identity. The samples may be kept by the Sponsor or its designees for a minimum of 5 years after study completion. Any remaining samples will be destroyed locally according to the applicable local regulations if the Sponsor/regulatory authority concerned do not require the samples to be tested. If you change your mind and wish to withdraw your biological samples during the study, you should contact the study doctor for the arrangement.

What if new information about the research study becomes available?

Sometimes during the course of a research study, new information about the study drug may become available. If this happens, the study doctor will tell you about it and discuss with you whether you want to continue participating in the study, if applicable.

Will there be any extra cost for taking part in this research study?

The study drug will be given to you at no cost during the study. You will not need to pay for the study assessments or procedures that are performed for this research study.

Will I be paid for taking part in this research study?

You will not be paid for receiving any drug, providing any biological sample, undertaking any procedure, or being examined during your participation in this study. However, you will receive a cash allowance as a subsidy for the time spent, any inconvenience caused or reasonable expenses related to participation in this study, such as transportation or other out-of-pocket expenses.
Volunteer Information Sheet and Informed Consent Form

- HKD 4500 per scheduled overnight stay completed in the study site (i.e. Day -1, Day 1, Day 2, Day 3, and Day 4)
- HKD 500 per scheduled study visit day attended (i.e. screening, Day 8, Day 11, Day 15, Day 22, Day 29, Day 43, Day 57, and Day 85)

**What happens if I am injured because of taking part in this research study?**

If you require immediate medical care to treat an illness or injury that is directly caused by the study drug or study-specific procedure, as determined by the Principal Investigator or the Sponsor, the Sponsor will be responsible for the payment of necessary medical treatment (e.g. by reimbursement) of the illness or injury. The study doctor will follow up your conditions if you are injured.

The Sponsor has secured an insurance coverage for settlement of possible claims which may arise from this study.

If you have any queries related to the insurance coverage from your own insurer(s) for your participation in the study, please discuss with your insurance consultant.

By signing this form, you have not waived any of the legal rights to which you will otherwise be entitled to.
Can I refuse to join the study? Can I be asked to leave the study?

It is up to you to decide whether or not you wish to take part and continue in this study. If you decide to take part, you are still free to withdraw at any time without giving any reason. If you decide not to take part, please tell the study doctor immediately. You will be asked to return to the study site for End of Study Visit assessments including safety assessments.

Although it is not expected, you should be aware that the study doctor may stop your participation in this study for any of the following reasons:

- You are required to take medication which may interfere with the study drug or study results
- You fail to follow the instructions given by the study doctor
- You are not able to complete the study procedures
- Female volunteer who has become pregnant
- As determined by the study doctor, it is in the best interest of your health and welfare to discontinue
- The Sponsor decides to stop the study

Who has reviewed the study?

The ethics committee namely the IRB of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB), the Hong Kong Department of Health and the China National Medical Products Administration have reviewed and approved this study.

Who should I call if I have questions?

For questions about your rights as a study participant, call the Secretary, the IRB of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) at 2255 4086.

For questions about the study or reporting of any illness, call the study doctor, Dr Desmond YAP, other study doctors or study staff at telephone no. 2255 6920 (24-hour).
Informed Consent Form

<table>
<thead>
<tr>
<th>Study Title:</th>
<th>Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Ascending Doses of HBM9161(HL161BKN) in Healthy Chinese Volunteers (Randomized, Single-blinded, Placebo-controlled Trial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Number:</td>
<td>9161.1</td>
</tr>
<tr>
<td>Sponsor:</td>
<td>Harbour BioMed Therapeutics Limited</td>
</tr>
<tr>
<td>Principal Investigator:</td>
<td>Dr. Desmond Yat-Hin YAP</td>
</tr>
<tr>
<td>Study Site:</td>
<td>Phase 1 Clinical Trials Centre, The University of Hong Kong</td>
</tr>
</tbody>
</table>

Statement by the Volunteers:

The information of this informed consent document has been explained to me by the below-named investigator. I have read and understood this informed consent document. I have had chances to ask questions. I have had answers to my satisfaction. I voluntarily consent to participate in this study.

____________________________  ___________________________  ___________________________
Print Name of Volunteer  Signature  Date
(Date by the Volunteer)

Statement by the Investigator who conducted the informed consent discussion:

I confirm that I have conducted this informed consent discussion and explained the study to the above-named Volunteer. I have answered all questions asked by the Volunteer to his/her satisfaction. To the best of my knowledge, the Volunteer understands the nature, risks and benefits of taking part in this study, and gives consent voluntarily.

____________________________  ___________________________  ___________________________
Print Name of Investigator  Signature  Date
(Date by the Investigator who signed)

Statement by Impartial Witness* (where applicable)  ☐ Not applicable

I attest that the information in this informed consent document was clearly explained to and apparently understood by the above-named Volunteer and that informed consent was freely given by the Volunteer.

____________________________  ___________________________  ___________________________
Print Name of Witness  Signature  Date
(Date by the Witness)

* An impartial witness is required when the Volunteer is not able to read the consent document (blind or illiterate)

Signed informed consent should be distributed to (1) Volunteer; (2) Medical Record