#### PARTICIPANT INFORMATION SHEET and CONSENT DOCUMENT

STUDY TITLE:	A DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP STUDY TO EVALUATE THE SAFETY AND EFFICACY OF BRIQUILIMAB IN PARTICIPANTS WITH ALLERGIC ASTHMA	
PROTOCOL NUMBER:	JSP-CP-012	
SPONSOR:	Jasper Therapeutics Inc.	
INVESTIGATOR (" study	Brianne Philipenko, MD, FRCPC	
doctor"):	Division of Respirology, Critical Care and Sleep Medicine	
	University of Saskatchewan 103 Hospital Drive, Saskatoon, SK S7N 0W8	
	306-380-6777	
SUB-INVESTIGATORS:	Beth Davis, PhD	
("study staff")	Don Cockcroft, MD, FRCPC	
24 hour emergency contact	Beth Davis	
	306-229-8709; beth.davis@usask.ca	

You are being invited to participate in a research study because you have stable, allergic asthma with occasional wheezing and shortness of breath. Please take time to read the following information carefully. You may direct any questions or concerns to the Investigator (study doctor) or study staff at any time during the study. Please feel free to discuss the study and your potential participation with friends, family, and/or your personal healthcare provider. If you choose to participate, you will be asked to sign and date this document. You will receive a copy of the signed and dated document.

Taking part in this study is voluntary. You can choose to participate, or you can choose not to participate. If you choose to participate, you can withdraw from participating in the study at any time, without giving any reason. If you do not wish to participate or if you choose to withdraw from the study, your current health care and/or academic status and/or employment will not be impacted.

Jasper Therapeutics, Inc. is the sponsor of this study and will be referred to as "the Sponsor." This research study is funded by the Sponsor. The study investigators will not receive any personal financial benefit for conducting the study. The University of Saskatchewan will receive some financial compensation to offset research associated costs.

## WHY IS THIS RESEARCH BEING DONE?

Asthma is a condition in which your airways narrow, swell and produce extra mucous which can make breathing difficult. Asthma can also cause symptoms such as coughing, wheezing and shortness of breath. Asthma symptoms can be triggered by infection, environmental exposures, allergens or other stimuli. The many symptoms experienced may be due to genetic and/or environmental factors. We are doing this study to learn more about a potential asthma treatment called briquilimab (the "study drug") and how effective the treatment could be in helping people with asthma, and to better understand asthma.

#### HOW MANY PEOPLE WILL BE IN THIS STUDY?

About 30 people will take part in this study. This study will be conducted at 6-10 sites in Canada and Germany. In Canada approximately 6 sites will participate in the study and approximately 20 people will be enrolled in Canada. We plan to enroll 3-5 participants at this site.

#### WHAT IS THE PURPOSE OF THIS STUDY?

Briquilimab is a medicine undergoing clinical testing, which means it does not have a marketing authorization from Health Canada for the treatment of your disease. To date, it has been tested in 77 healthy volunteers and 68 patients suffering from different disorders (such as, chronic urticaria, immunodeficiency, leukemia, Sickle cell disorder, Fanconi anemia). To date, the study drug has been found to be well tolerated and has not been associated with significant side effects. This study is experimental which means the study drug is not approved by any health authority, including Health Canada, except for use in research studies like this.

The goal of this study is to see how people with allergy induced asthma respond to treatment with briquilimab. The study is also planned to see if briquilimab is safe for people in the study.

The purpose of this study is to investigate if the study drug can reduce allergen-induced asthmatic responses and airway swelling and explore the potential of the study drug as a treatment of asthma. The study drug is a monoclonal antibody. It is a type of protein that is designed to only attach to specific substances in the body. Briquilimab attaches to a protein called c-KIT. c-KIT is found on the surface of various cells in your body, such as mast cells, but also on other cells. Mast cells are a type of white blood cell. They are part of the immune system and play an important role in the development of allergic disorders, such as asthma.

This study is a placebo-controlled and parallel study which means half of the participants will receive the study drug and half will receive a placebo. A placebo is a substance that looks like the actual study drug but has no active ingredient. The purpose of the placebo is to compare the untreated response of allergen exposure in allergic asthmatics to the response after treatment with briquilimab. You will receive either the placebo or the study drug and this will be administered to you once by giving two injections in your abdomen or in your upper arm.

## WHAT WILL HAPPEN DURING THE STUDY?

This is a placebo-controlled study. Before you can start the study drug or placebo you will undergo a series of tests. This is called screening. If you meet the screening criteria, you will be randomly assigned by chance (like the flip of a coin) to receive either the study drug or a placebo.

Since this study is double-blinded, neither you nor the study staff will know which treatment you receive. However, in case of medical emergencies, your study doctor can find out what treatment you were given. If you do not meet the screening criteria, the reasons for this will be explained and the study doctor or other study staff will talk to you about other possible treatments. However, any change in your current asthma treatment would need to be decided between you and the health care provider currently treating your asthma.

You will be in the study for approximately 18 weeks, which includes a screening period up to 30 days (but may be extended if screening tests need to be repeated), a treatment period of approximately 85 days, and a safety follow-up visit at day 99 (129 total days or 18.4 weeks). During the study, three inhaled allergen challenge tests will be performed, one in the screening period and two in the treatment period.

During the study you will have a minimum of 12 visits to the study site and 1 phone call visit. There will be 4 visits during the screening period, 8 visits during the study treatment period (which includes a phone call visit), and 1 safety follow-up visit. You may be required to have additional visits at the discretion of the study doctor.

You will be asked to provide accurate and complete information about your medical history, any medications you are taking, and your present health status. You should come for all scheduled visits and inform study staff if you have a problem with keeping an appointment. You should inform the study staff as soon as possible about any medical treatment you receive outside of your participation in the study. You should report any undesirable, unwanted or unusual symptoms you experience. This includes reporting any worsening of existing conditions.

If you volunteer to participate in this study, we will ask you to do the following things:

## **Screening Period:**

The purpose of the Screening Period is to see if you qualify for this study. The Screening Period will be split into 4 visits: Visit 1 (**Day -30**), Visit 2, Visit 3, and Visit 4, and will include the following:

# Screening Period Visit 1 (Day -30) – approximate time required: 2 hours

- consent to participate will be obtained study staff and/or the study doctor will explain the study to you in detail, will answer all your questions and ask you to provide written informed consent (i.e. sign this document) prior to having any study specific assessments.
- collection of information including age, sex, ethnicity, medical and medication history, vital signs and performance of a physical examination including height and weight.
- measuring/recording your vital signs (sitting blood pressure, heart rate, breathing, and temperature taken by mouth)
- a lung function (**spirometry**) test lung function tests are breathing tests that measure the amount of air you have in your lungs and how well you can move that air by forcefully blowing into a spirometer (a lung function machine). This test will provide information on how your lungs are functioning and help study staff determine if you are eligible for the study.
- an electrocardiogram (ECG) an ECG is a test that measures the electrical activity of your heart at rest and provides information on how your heart is functioning.
- a skin prick test drops of different allergen extracts will be placed on your skin and then your skin will be pricked with a sharp pointed object called a lancet. If the allergen (the substance that causes allergy) causes an allergic reaction, a raised itchy bump (wheal) develops. You must have a response to one of the allergens to participate in the study.
- a pregnancy test a urine pregnancy test will be done for female participants who can become pregnant. If the urine pregnancy test is positive or inconclusive, a serum pregnancy test will be

conducted for confirmation of the result. In this case, a negative serum pregnancy test is required prior to dosing on Day 1.

- blood collection for safety lab tests blood will be collected using a needle and sterile techniques and drawn into tubes. We will test your blood to make sure it safe for you to continue study procedures. We will collect up to 31 mL (approximately 2 tablespoons) of blood at some visits.
- collection of a urine sample for urinalysis
- adverse events collection: We will ask you about how you are feeling and about any changes in your health
- review of current medications information: We will ask you about any changes in the medications you are taking.

If you continue to qualify for this study, you will return for Screening Visits 2-4, performed on 3 consecutive days.

# <u>Screening Period Visit 2 – approximate time required: 2 hours</u>

Study Visit 2 can be scheduled any time after the necessary screening data from Visit 1 are available. At this visit, you will:

- be asked about how you are feeling and about any changes in your health.
- be asked about any changes in the medications you are taking.
- undergo a skin titration test similar to the skin prick test but instead of many allergens, increasing amounts of one of the allergens identified during skin prick testing will be placed on your arm and pricked with a lancet/needle. This test will help us determine the dose of allergen extract to use in the allergen inhalation challenge.
- undergo a methacholine challenge test methacholine challenge tests are used routinely by asthma specialists to assist in diagnosing asthma. Methacholine challenge testing involves the inhalation of aerosolized methacholine, a known bronchoconstrictor that may cause your airways to narrow. After completing spirometry (described above), you will inhale 0.5mL aerosolized saline (i.e. salt water) using normal breathing through a mouthpiece connected to a vibrating mesh nebulizer. You will be required to wear nose clips during the inhalations. You will inhale for approximately 2 minutes, until the nebulizer is empty. Spirometry is performed again at 30 and 90 seconds post-inhalation (additional measurements may be required). Five minutes after the start of the previous inhalation, you will begin to inhale the first dose of methacholine. The process will repeat with increasing doubling doses of methacholine until the amount of air you are able to exhale is reduced by at least 20%.
- undergo sputum induction during this procedure, you will inhale using normal breathing, 3 concentrations (3%, 5% and 7%) of saltwater solution (hypertonic saline) from a nebulizer each for 7 minutes. Inhaling hypertonic saline helps to produce mucus (i.e. sputum) which will be collected by having you huff/cough/spit the mucus into a sterile cup that can be analyzed and provide information about airway inflammation.

# <u>Screening Period Visit 3 – approximate time required: 9 hours</u>

Visit 3 will occur at 24 ( $\pm 2$  hours) after Visit 2.

- we will ask about how you are feeling and about any changes in your health.
- we will review use of current medications
- you will undergo an allergen inhalation challenge test you will perform spirometry as described above and then you will inhale increasing amounts of allergen from a nebulizer with nose clips on until your lung function decreases by at least 20%. Similar to the methacholine challenge test, 0.5mL of each dose of allergen will be inhaled to completion. Once the required decrease in lung function has been achieved, you will continue to perform lung function measurements at pre-defined timepoints until 7 hours after your last allergen inhalation. After the test, 200 mcg of bronchodilator (salbutamol) will be administered to you.
- you will undergo sputum induction

Screening Period Visit 4 – approximate time required: 2 hours

Visit 4 will occur at 24 ( $\pm 2$  hours) after Visit 3.

- we will ask about how you are feeling and about any changes in your health
- we will review your current medications
- you will undergo a methacholine challenge test
- you will undergo sputum induction

Study staff will review the results of all the screening tests, and if you are eligible to participate in the study you will be invited to return for the Study treatment Period starting at Visit 5/Day 1. If you are not eligible, study staff will explain the reason(s) why and advise next steps.

**Study Treatment Period** (Day 1 to Day 85): Participants will begin the Treatment Period at a minimum of 2 weeks and maximum of 6 weeks, after the screening allergen challenge.

Study Treatment Period Visit 5 (Day 1 / Baseline) – approximate time required: 5 hours

The baseline visit will include the following assessments:

- vital signs (sitting blood pressure, heart rate, breathing, and temperature taken by mouth)
- a urine pregnancy test done for female participants who can become pregnant. If the urine pregnancy test is positive or inconclusive, a serum pregnancy test will be conducted for confirmation of the result. In this case, a negative serum pregnancy test is required prior to dosing on Day 1.
- adverse events: we will ask you about how you are feeling and about any changes in your health.
- review of current medications: we will ask you about any changes in the medications you are taking.
- fractional exhaled nitric oxide (FeNO) test this is a test in which you will exhale into a device that measures the quantity of nitric oxide in your breath. The amount of nitric oxide in exhaled air of asthma patients often increases when they are exposed to an allergen. Participants should refrain from eating and drinking for at least 1 hour prior to FeNO measurements when possible.

- Spirometry
- blood collection for safety lab tests and study specific laboratory tests to determine the concentrations of certain proteins (biomarkers) that could be influenced by the study drug and to measure how much active study drug is in your blood (pharmacokinetic (PK) analysis) and to determine concentrations of IgE (an antibody).
- methacholine challenge test
- sputum induction
- administration of study drug or placebo via injection(s) to you in your abdomen or in your upper arm. This is the only administration of study drug or placebo in this study.

After study drug administration, you will be observed at the study site for a minimum of 2 hours. This observation time may be extended if medically necessary. If you have a severe allergic reaction, you will receive immediate medical attention. If you suspect you are having a severe allergic reaction at home, after leaving the study site, please seek emergency medical care immediately (i.e. call 911 or visit an emergency department) and inform the treating healthcare professional about your participation in this study and contact study staff as soon as possible.

# Study Treatment Period Visit 6 (Day 14) – approximate time required: 15 minutes

This visit will occur by telephone. The purpose of the call will be to inquire about adverse events and current medication use.

The next six visits (visits 7, 8 and 9 and visits 10, 11 and 12) are allergen challenge triad visits and these visits are similar to screening visits 2, 3 and 4. The 3 visits in each triad must occur on 3 consecutive days. Procedures performed at Visits 7 and 10 are similar; those at Visits 8 and 11 are similar and those at Visits 9 and 12 are similar. These visits include:

# Study Treatment Period Visits 7 & 10 (Day 41 & Day 83) – approximate time required at each visit: 2.5 hours

- vital signs (sitting blood pressure, heart rate, breathing, and temperature taken by mouth)
- adverse events: We will ask you about how you are feeling and about any changes in your health.
- review of current medications: We will ask you about any changes in the medications you are taking.
- a symptoms-directed physical examination (performed based on symptoms you may have)
- FeNO test
- methacholine challenge test
- sputum induction
- blood collection for safety lab tests and study specific laboratory tests to determine the concentrations of biomarkers, to determine how much active drug is in your body, and to determine concentrations of IgE (an antibody)
- allergen skin titration test

# Study Treatment Period Visits 8 & 11 (Day 42 & Day 84) – approximate time required: 9 hours

- adverse events: we will ask you about how you are feeling and about any changes in your health.
- review of current medications: We will ask you about any changes in the medications you are taking.
- allergen inhalation challenge test
- fractional exhaled nitric oxide test
- sputum induction

# Study Treatment Period Visits 9 & 12 (Day 43 & Day 85) – approximate time required: 2.5 hours

- adverse events: we will ask you about how you are feeling and about any changes in your health.
- review of current medications: we will ask you about any changes in the medications you are taking.
- FeNO test
- methacholine challenge test
- sputum induction
- blood collection for study specific laboratory tests to determine concentrations of biomarkers

# **Safety Follow-up Period** (Day 99) – approximate time required: 30 minutes

Following completion of the Treatment Period, you will be required to return to the study site for one final visit; if safety concerns or an adverse events is ongoing, additional visits may be required.

- adverse events: we will ask you about how you are feeling and about any changes in your health.
- review of current medications: we will ask you about any changes in the medications you are taking.
- a symptoms-directed physical examination (limited to any symptoms you may have)
- vital signs (sitting blood pressure, heart rate, respiratory rate, oral temperature)
- a urine pregnancy test will be done for female participants who can become pregnant. If the urine pregnancy test is positive or inconclusive, a serum pregnancy test will be conducted for confirmation of the result.
- blood collection for safety lab tests
- blood collection for study specific laboratory tests to determine concentrations of biomarkers and to determine concentrations of IgE (an antibody).

## WHAT WILL MY RESPONSIBILITIES BE IF I TAKE PART IN THE STUDY?

- come to all study visits.
- do not take any other medication(s) or remedies unless discussed with study staff first. This includes prescription and over-the-counter medication(s) (including vitamins and herbs).

- agree to withhold use of inhaled short-acting (rescue) inhalers (e.g. a bronchodilator such as Ventolin®) for a minimum of 8 hours before all study visits where spirometry is performed. In the event of an emergency in which use of your rescue inhaler is medically necessary, you should use your inhaler and contact study staff to reschedule your visit.
- agree to refrain from eating or drinking before certain study procedures.
- tell the study staff about any new treatment or medication you take during the study.
- give correct and complete information about your health history and current health.
- tell the study staff about any health problems you have during the study.
- if you are female and if you become pregnant, or if you are male and you get your partner pregnant, tell your study staff as soon as you know (for additional information, please see section on "Are there any reproductive risks?" below).
- contact study staff and tell them if you have a change in your contact information or if you no longer wish to be in the study.

If you choose to take part in this study, you will be told about any new information which might affect your willingness to continue to participate in this research in a timely manner.

## WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

While on the study treatment, you may experience side effects. Risks and discomforts may also be associated with study procedures. There may be side effects that are not known at this time. Most side effects go away when you stop taking the study drug. Side effects may also be long-lasting or permanent.

#### Placebo related risks:

You have a 50:50 chance of being assigned to the group receiving a placebo. A placebo looks identical to the study drug but contains no active ingredients. If you receive placebo, your response to allergen exposure will likely be similar to that experienced in the real world. There is also no guarantee that your response to allergen exposure will improve if you receive study drug. Your asthma and your general health will be carefully monitored throughout the study. If your asthma worsens or if it is in your best interest for some other reason, the study doctor will withdraw you from the study and you will be offered appropriate care.

## Briquilimab (study drug) Risks:

Briquilimab has been administered to a total of 145 study participants to date. The side effects and complaints observed so far for briquilimab include:

- Very common (in more than 1 treated person out of 10):
  - o nausea (23%), tiredness (20%), upper respiratory infection (17%), dizziness (13%), back pain (10%),
- Common (in 1 to 10 treated persons out of 100):
  - O Allergic reactions occurring within 24 to 48 hours after administration of briquilimab such as rash, itching, or hives. Most were mild in nature and resolved. More severe allergic reactions (such as low blood pressure, throat swelling, trouble breathing) might occur, but have not been reported after briquilimab
  - o Mild or moderate altered taste, which resolves over time.
  - o Reduced white blood cells count, platelets or red blood cells. These effects revolved with time.

- Approximately 17% of participants tested positive for anti-briquilimab antibodies after receiving briquilimab. Antibodies are part of the body's defense system and sometimes can be produced against the study drug and may affect how the drug works.
- In addition to the risks above you may experience a previously unknown risk. At this time no long-term risks are known.

## Other potential risks of Briquilimab observed in animal studies:

- Reproductive risks: In animal studies, briquilimab has been associated with a decrease of sperm production that resulted in a complete depletion of sperm. Sperm production recovered to pretreatment levels after an extended treatment-free period. The effect of briquilimab on human sperm has not yet been studied and therefore the risk in humans is currently unknown, including at what doses this effect may occur, how long it could last, or if it may return to what it was initially.
- Changes in hair color: In animal studies, changes in fur color (paleness) were observed that tended to recover after briquilimab was stopped.

## **Procedure Related Risks:**

- **Injection of study treatment:** the injection of study treatment itself might hurt and cause discomfort, pain, or irritation at the injection site such as redness, itching, swelling and/or bruising.
- **Drug Interactions:** all medications can cause side effects. Tell the study staff about every medication, supplement, and vitamin (or changes in them) you take while you are in the research study. It is unknown what interactions may occur if other medications or supplements are taken with the study drug.
- **Electrocardiogram (ECG):** the ECG test is painless. The sticky pads placed on your chest may cause mild skin irritation, slight redness, and itching. You may need to have your chest shaved for this procedure.
- Allergen Challenge Test and Methacholine Challenge Test: during these procedures, you could experience cough, chest tightness, wheezing, and difficulty breathing. The use of allergens through inhalation is an investigational procedure using extracts developed for administration in the skin. Symptoms resolve following the inhalation of a bronchodilator medication which will be provided to you if necessary. The tests are carried out in a way to minimize the development of a severe asthmatic reaction; however, there is still a very small possibility of significant narrowing of your airways. If this occurs, you will be immediately treated with medication to reverse this.
- **Blood Collection:** bruising can occur where the needle was inserted. The risk of infection is very low. The total amount of blood collected will not exceed 120 mL (8 tablespoons) over the entire study. Please note that participants should not donate blood while participating in the study.
- **Skin Prick Test:** this test causes itch and swelling that normally stops within 1 to 2 hours. More prolonged or severe swelling may be treated with an oral antihistamine, topical corticosteroid cream, and an ice pack. Severe allergic reactions from allergy testing are very rare but can result in a decline in blood pressure and difficulty breathing and can be potentially fatal. These reactions usually arise shortly after the test. Study staff will be monitoring you during this time and provide any necessary treatment.

- **Spirometry Test:** sometimes this procedure can cause cough, you may experience chest soreness or shortness of breath, or feel light-headed. You may be asked to repeat some tests if the quality of the test is not adequate.
- **Sputum Induction:** breathing in saltwater mist may cause cough, and in some patients, may cause the narrowing of the airways and wheezing. Cough usually stops shortly after you stop inhaling the saltwater solution and wheezing is reversible with a bronchodilator that is provided. Study staff will stop the procedure if your symptoms become bothersome.
- Fractional Exhaled Nitric Oxide Test: sometimes this procedure can cause you to cough or feel light-headed. You may be asked to repeat some tests if the quality of the test is not adequate.

Please tell study staff about all symptoms, complaints, illnesses, or injuries that occur during the study. If these are serious, please immediately advise study staff.

## **Potential Reproductive Risks:**

It is not known whether briquilimab (the study drug) may cause side effects to pregnant women, to an unborn child (an embryo or a fetus), or to children of breastfeeding women. Because of these unknown risks, if you are pregnant, trying to become pregnant or are currently breastfeeding, you are not eligible to participate in the study.

If you decide to take part in this study, both male and female participants must agree to either avoid heterosexual intercourse or use a highly effective birth control method for the entire study duration and for at least 150 days after you receive the study drug. No one method of contraception is 100% effective.

If you are a woman of child bearing potential (i.e. you are able to become pregnant), you are required to have a negative pregnancy test result before enrolling in the study. You are a woman of child bearing potential if:

- you have not completed menopause
- you have not had a hysterectomy
- you have not had surgery to become sterile (i.e., a tubal ligation)
- you have a male sexual partner who has not had surgery to become sterile (i.e., a vasectomy)

Highly effective methods of birth control for women include:

- combined (estrogen and progestogen containing) hormonal contraception preventing ovulation, administered by mouth, intravaginal, or patch route.
- progestogen-only containing hormonal contraception inhibiting ovulation administered as oral or injectable drug, as well as implant, intrauterine device (IUD), and intrauterine hormone-releasing system (IUS).
- sterilized (vasectomized) partner (provided that it is your sole male sexual partner and that the sterilized partner has received medical assessment of the surgical success).
- sexual abstinence [if in line with your preferred and usual lifestyle and defined as refraining from heterosexual intercourse during the entire period of the study and for 150 days after the last dose of the study drug.

- periodic methods of abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) are not accepted methods of contraception.
- Men who are participating in this study also need to understand the danger of taking the study drug where the effects of the study drug on a fetus are unknown. The effect of study drug on sperm is also not known. If you are a man participating in this study and your partner is able to become pregnant, you and your partner must use effective birth control measures while you are participating in the study and for at least 150 days after study treatment was administered.
- Highly effective methods of birth control for men include:
- Double barrier methods (when having sexual intercourse with a female or partner of child-bearing potential)
- Sexual abstinence with a female partner capable of becoming pregnant

In addition, you must not donate sperm while participating in the study and for 150 days after the study drug was administered. You should inform the study staff if your partner becomes pregnant.

The study staff will talk to you about a suitable birth control method for you at the beginning of the study. Your study doctor is responsible for checking whether you are using suitable birth control in order to be able to take part in the study.

You must accept the risk that pregnancy could still result despite the responsible use of a reliable method of birth control. You must notify the study staff as soon as possible if you become pregnant or think you may be pregnant (i.e. miss a menstrual period), either of which may result in your being withdrawn from study.

If you are a female study participant and you become pregnant, or if the female partner of a male study participant becomes pregnant (i.e. a pregnant partner) during the study, or within 150 days from the administration of study drug, the study staff will ask to follow the outcome of your pregnancy and the health status of your newborn. Should pregnancy occur in a pregnant partner, a separate consent form regarding pregnancy will be provided and discussed with the pregnant partner at that time.

#### WHAT ARE THE POSSIBLE BENEFITS OF BEING IN THE STUDY?

If you choose to participate in this study, there may or may not be direct benefits to you. It is hoped the information gained from this study can be used in the future to benefit other people with a similar condition.

Information from this study, including information from research on your samples, may lead to discoveries, inventions, or development of commercial products. Neither you nor your family will receive any benefits or payment if this happens.

## IF I DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

You do not have to participate in this study to receive treatment for your asthma. If you choose not to participate in this study, the alternative is to continue treating your asthma as directed by your family physician. Other treatments for asthma are available (e.g. inhaled corticosteroids, combination therapies, biologics etc) but the use of these treatments depends on your asthma severity/control. As your asthma is well-controlled requiring only infrequent use of a rescue inhaler other currently available asthma

medications may not be right for you. Study staff will discuss this with you in more detail if you are interested but the way in which you treat your asthma is ultimately a decision made between you and your family physician.

#### WHAT IF NEW INFORMATION BECOMES AVAILABLE?

Your study doctor, study staff and/or the Sponsor may learn new information during the study that might influence your decision to continue participating, make you want to stop taking the study drug or withdrawal from the study. You will be told about the new information in a timely manner. You can then decide if you want to still be in the study. If you leave the study, there will be no penalty and you will not lose any benefits you are entitled to. Leaving the study will not affect the health care you receive, your academic status or your employment.

## WHAT HAPPENS AFTER COMPLETION OF THE STUDY?

You will not be able to receive the study drug after your participation in the study ends. This is a single dose study, no extension or additional investigations in mild allergic asthma are planned at this time.

The results of the study will be available in aggregate form (i.e. you will not be identified) at <a href="http://www.clinicaltrials.gov">http://www.clinicaltrials.gov</a>. Study results will only be available once all participants have completed the study and the data are analyzed. This could take at least one year or more (i.e. available in 2026-2027).

The Investigators and the study Sponsor intend to publish the study results in a reputable scientific journal and may present the aggregate data at future relevant conferences/workshops or meetings but your identity will not be disclosed.

You can indicate how you would like to obtain the study results on the signature page of this document.

#### WHAT HAPPENS IF I DECIDE TO WITHDRAW?

Your participation in this research is voluntary. You may withdraw from this study at any time. You do not have to provide a reason. Your future medical care, employment or academic status will not be affected.

If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment will be retained for analysis.

## CAN I BE ASKED TO LEAVE THE STUDY?

Please note that the study, and your participation in the study, may be stopped earlier than expected for scientific or for safety reasons.

The study doctor may withdraw you from the study for any of the following reasons:

- Staying in the study would be harmful for you.
- You need treatment that is not allowed in the study.
- You did not follow instructions about what to do in the study.
- If female, you became pregnant during the study.
- The study is cancelled.

The study doctor will discuss with you the reason(s) why you should stop participating in the study.

If you leave the study early, the study doctor or study staff will ask you to complete the end of study tests (such as a final health exam and lab tests) for your own safety. If you cannot visit the study site to undergo these final tests, the study doctor or another study staff member will call you by phone. This is done to have complete data about your health and safety at the end of the study.

After withdrawal, no new information will be collected unless follow up on any side effects you may have experienced is required.

#### WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

You will not be charged for the study drug(s) or any research-related procedures. You will not be paid for participating in this study. An honorarium of \$1350 will be provided to cover your time, out-of-pocket expenses such as travel, parking, or meals. The honorarium will be provided at the completion of your participation. If you are withdrawn from the study or decide to withdraw early from the study, your compensation will be proportional to the visits you have completed as follows: \$75 for Visits 1, 2, 4, 5, 6, 7, 9, 10, 12 and 13 and \$200 for Visits 3, 8 and 11. Any personal information collected as a record of compensation payment will be stored separately from the data for 7 years for auditing purposes. The honorarium will be tax reportable; you will need to provide your social insurance number and the University will issue you a T4 for tax purposes.

Your participation in this research project could lead to the creation of commercial products. However, you will not receive any financial benefit should this occur.

# WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?

In the case of a medical emergency related to the study, you should seek immediate medical care. Inform the medical staff treating you that you are participating in this study. Notify the study doctor or other study staff about the emergency as soon as possible. Necessary medical treatment will be made available at no cost to you.

The Sponsor has taken out an insurance policy for the study that complies with current local law. If you suffer an injury from participation in this study, medical care will be made available to you by your study doctor, or you will be referred for appropriate medical care. The Sponsor will pay all necessary medical costs to treat the injury or illness, if the injury was directly caused by the study drug or correctly performed study procedures that you received because you are in the study.

You do not waive any liability rights for personal injury by signing this form, and you are not precluded from seeking compensation for injury related to malpractice, fault, or blame on the part of those involved in the study, nor does it mean that you are releasing the investigator(s), institution(s) and/or Sponsor from their legal and professional responsibilities.

#### HOW WILL MY TISSUE SAMPLES BE USED AND STORED?

Blood (safety samples and exploratory biological samples), urine, and sputum samples will be collected from you in this study. Your samples will be sent to both central and local laboratories to be tested.

Blood samples and sputum will be sent to the following central laboratories:

- Eurofins (15 Research Park Drive, St. Charles, MO 63304) USA (blood samples)
- Jasper Therapeutics (2200 Bridge Parkway Suite 102, Redwood City, CA 94065) USA (blood samples)
- McMaster University (1280 Main Street West, Hamilton, Ontario, Canada L8S 4K1) (blood samples and sputum samples)

Your samples will be labelled using a unique identifier, no information identifying you will be used. Anyone who works with your samples will keep your coded samples and the results private. After the study tests are completed, your samples will be destroyed. Your samples will only be used for research and development purposes related to this study. You may also, at any time request that your samples be destroyed by indicating this to study personnel. However, any information already gathered from the analyses of your samples will not be destroyed.

# Optional sub-study/biobanking for future scientific research

The Sponsor would like to use your de-identified information (discussed in the next section) and any leftover biological samples (e.g. blood and sputum) collected for this study for future scientific research. This is called biobanking. The goal of biobanking is to make more research possible that may improve people's health. Your biological samples will be stored for up to 15 years by the laboratories to which they are sent:

- Eurofins (15 Research Park Drive, St. Charles, MO 63304) USA (blood samples)
- Jasper Therapeutics (2200 Bridge Parkway Suite 102, Redwood City, CA 94065) USA (blood samples)
- McMaster University (1280 Main Street West, Hamilton, Ontario, Canada L8S 4K1) (blood samples and sputum samples)

Agreeing to future use is optional. You can still participate in the main study without participating in the optional sub-study. Your willingness (or not) to participate in this optional sub-study will be captured on the signature page of this document.

Only the study Sponsor and study Investigators will have access to your leftover biological samples (i.e. the Sponsor will not share your samples with any other entity).

Right now, we don't know exactly what research may be done in the future using your de-identified data and leftover biological samples. This means that:

You will not be asked if you agree to take part in the future research studies.

You and the study doctor will not be told when or what type of research will be done.

You will not get reports or other information about any research that is done using your samples.

#### WILL MY PARTICIPATION BE KEPT CONFIDENTIAL?

In Saskatchewan, the Health Information Protection Act (HIPA) defines how the privacy of your personal health information must be maintained so that your privacy will be respected. Your name will not be attached to any information, nor mentioned in any study report, nor be made available to anyone

except the research team. No information that discloses your identity will be released or published without your specific consent to the disclosure, or as required by law.

Your study records and samples will be de-identified by assigning a unique number (e.g. 305-001; site number and participant number) that will link your information and samples to you. They will be kept for 15 years in a secure area such as a locked file cabinet in a locked office at the University of Saskatchewan. Biological samples and results of the study without your name or other information that could identify you will be sent to the study Sponsor and its service providers and combined with information from other participants for analysis.

No information that discloses your identity will be released or published without your specific consent to the disclosure, or as required by law. Rarely, your study documents may be obtained by courts of law. Some authorities have a duty to check your study and medical records to make sure all the information is correct.

Your de-identified study and medical records may be inspected in the presence of the investigator or their qualified designate by representatives of the Sponsor, Jasper Therapeutics, any company the Sponsor is working with to develop the study drug and its employees and representatives, including affiliated companies, such as the contract research organization, PPD (the clinical research business of Thermo Fisher Scientific that is managing the study on behalf of the Sponsor), study monitors, study auditors and/or representatives of Health Canada, the United States Food and Drug Administration and/or The University of Saskatchewan Biomedical Research Ethics Board.

If you decide to withdraw from this study, your study and de-identified medical records will be made available to these agencies. However, they will only look at your records up to the date of your withdrawal, except where the reporting of side effects associated with the study medication is required. You may ask the study doctor to correct any study related information about you that is wrong. In the case of a blinded study, you may have to wait until the end of the study to see your study records to protect the integrity of the study.

Your data may be transferred outside of Canada to the USA and Europe. The Sponsor will respect the confidentiality rules in effect in all countries, however, data protection laws in other countries may not be as stringent as the laws in Canada and absolute confidentiality cannot be guaranteed.

For your own safety, it is recommended that your family physician be informed of your participation in this study. With your permission (see signature page of this document), your family physician will be informed of your participation and consulted regarding your health and treatment.

## IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study, please contact the study doctor - Dr. Philipenko at 306-380-6777 or the Sub-Investigator - Dr. Davis at 306-229-8709. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study and contact the study doctor or other study staff member as soon as possible.

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, contact the Chair of the University of Saskatchewan Biomedical Research Ethics Board at 306-966-2975 (toll free: 1-888-966-2975). The Research Ethics Board is a group of

individuals (scientists, physicians, ethicists, lawyers, and members of the community) that provide an independent review of human research studies. This study has been reviewed and approved on ethical grounds by the University of Saskatchewan Biomedical Research Ethics Board.

#### **CONSENT STATEMENT**

# A DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP STUDY TO EVALUATE THE SAFETY AND EFFICACY OF BRIQUILIMAB IN PARTICIPANTS WITH ALLERGIC ASTHMA

- I have read (or someone has read to me) the information in this consent document
- I understand the purpose and procedures and the possible risks and benefits of the study.
- I understand that this study may not provide any benefit to me.
- I have been informed that the alternative to participating in this study is not to participate.
- I was given sufficient time to consider whether I will participate.
- I have been given the chance to ask any questions that I had about the study, and all questions that I asked were answered to my satisfaction.
- I understand that I am free to withdraw from the study at any time for any reason and that this will not affect my future medical care, academic standing or employment.
- I agree to follow study staff instructions and will tell the study staff as soon as possible if I feel I have had any unexpected or unusual symptoms
- I give permission for the collection, use and disclosure of my personal health information for the research purposes, as described in this consent document
- I understand that by signing this document I do not waive any of my legal rights
- I will be given a signed and dated copy of this consent document

Please inform my family physician of my p	articipation in this study		
Name of family physician:			
Please DO NOT inform my family physicia	n of my participation in this study		
do not have a family physician			
(initial) Please send me a lay summar phone; street address):	ry of the study results when available. Provide conta	act information (e.g. email	
(initial) Please send me a copy of the phone; street address):	journal publication if/when available. Provide conta	act information (e.g. email	
(initial) I will access the study results	by contacting the study site or visiting <a href="http://www.c">http://www.c</a>	linicaltrials.gov.	
Regarding the optional sub-study/biobankir	ng for future scientific research:		
Yes, I consent to the storage of my leftover	biological samples for future scientific research		
No, I DO NOT consent to the storage of my	leftover biological samples for future scientific rese	arch 🗌	
Name of participant (print)	Signature of participant	Date	
Name of person administering consent	Signature of person administering consent	 Date	