PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO COLLECT, USE AND DISCLOSE MEDICAL INFORMATION FOR ADULTS

Sponsor / Study Title:	**Bluefin Biomedicine, Inc./ "A Phase 2, Dose Ranging, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of BFB759 in Patients with Moderate to Severe Hidradenitis Suppurativa (COMPASS 2 - HS)"**
Protocol Number:	**CL-BFB759-003**
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KEY INFORMATION SUMMARY

Key Information You Should Know Before Agreeing to Participate

The key information that follows can help you learn more about this clinical study. It can also help you decide whether or not to take part in the study. Please read the entire consent form or have someone read it with you. If there is anything that you do not understand, please talk to the study doctor or study staff to have your questions answered before signing and dating the consent form.

Voluntary Participation and Right to Discontinue Participation (see the section titled "VOLUNTARY PARTICIPATION / WITHDRAWAL")

We are asking you to consent to participate in this research study. Your participation is voluntary and should be based on what is important to you. It is your choice to participate in this study. If you agree to participate, you may leave at any time without penalty or loss of benefits to which you are otherwise entitled.

Purpose of the Research

The purpose of the study is to find the safety and efficacy of different dose regimens of BFB759 in treating adults like you who have moderate to severe hidradenitis suppurativa.

Key Reasonably Foreseeable Risks and Discomforts (see the section titled "RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS")

- If you take BFB759, you have a chance of side effects, such as itching, redness, swelling and rash at the injection site. BFB759 may increase a risk of infection or neutropenia (a lower-than-normal level of certain white blood cells that fight infection).
- We do not know if BFB759 will help you. There is a chance that BFB759 could worsen your hidradenitis suppurativa.
- More information on risks is available in the consent form.

Reasonably Expected Benefits (see the section titled "POTENTIAL BENEFITS OF PARTICIPATING IN THE STUDY")

- Prior research suggests that BFB759 may improve hidradenitis suppurativa.
- Researchers are studying BFB759 in this study to learn more about whether BFB759 will improve hidradenitis suppurativa.
- By participating in this study, you will help researchers learn how BFB759 may help people with hidradenitis suppurativa.

Expected Duration and Procedures to Be Followed (see the sections titled "INFORMATION ABOUT THE STUDY", "HOW LONG WILL YOU BE IN THE STUDY?", and "STUDY VISITS")

- To learn if BFB759 makes a difference, it is important for the study to include people who will get a placebo (placebo looks like BFB759 but has no active ingredient). With this information, researchers can compare the effects of BFB759 in different dosage with the placebo on your hidradenitis suppurativa.
- You will be assigned to one of three groups in this study: Study drugs will be assigned randomly (like drawing numbers from a hat) at 1:1:1 ratio. All study participants will receive study drug at some point during the study. Groups 1 and 2 will receive BFB759 and group 3 will initially receive placebo. Participants who received placebo in group 3, at Week 16 will be randomized into 2 groups, called sub-group 1 and sub-group 2, to receive BFB759. Those participants who originally received BFB759, will receive placebo starting at Week 16.
- You and your study doctor cannot choose which group you will be assigned to and neither you nor your doctor will know which group you are assigned to.
- This study will take approximately 40 weeks, and you will be required to come to the study clinic for at least 22 visits. More information on the study visits duration and procedures is available in the consent form.

Appropriate Alternative Procedures (see the section titled "ALTERNATIVES TO PARTICIPATING IN THE STUDY")

- Before joining the study, you should talk to your study doctor about alternative approved treatment options for your condition, and whether or not this study is a good choice for you.
- Before agreeing to join, you should review information in the rest of the consent form.

Compensation and Medical Treatments for Research-Related Injuries (see the section titled "COMPENSATION FOR INJURY")

- If you experience an injury caused by your participation in this study, the medical treatment of your injury will be paid for.
- More information on medical treatments for research-related injuries is available in the consent form.

Costs Related to participant Participation (see the section titled "COMPENSATION")

- The sponsor will pay you for your time participating in the study.
- In addition, the sponsor will reimburse you for any travel costs for mileage, parking, and other expenses.
- More information on costs related to participant participation is available in the consent form.

Additional Information

- Additional information about this study is available in the consent form.

You must be 18-75 years old to participate in this study.

WHAT IS AN INFORMED CONSENT FORM?

This form is called an Informed Consent Form. You are being asked to participate in a medical research study (called the "study" from now on). This study includes only people who volunteer to participate.

- The purpose of this informed consent form is to explain the study and how it may affect you. Then you can decide if taking part in the study is right for you.
- This informed consent form may contain words you do not understand. Please ask the study doctor or study staff to explain anything that you do not clearly understand.
- Ask as many questions as you need before you decide if you want to be in the study.
- Please take your time to make your decision.
- You may take home a copy of this informed consent form to discuss with others, such as family, friends, or your regular doctor.

- If you agree to be in this study, you will be asked to sign and date this informed consent form. You will also get a copy to take home with you.

WHAT DOES IT MEAN TO BE A STUDY PARTICIPANT?

- Your participation in this study is entirely voluntary. You may or may not choose to take part.
- If you decide to be in the study, you will need to follow certain rules about the study procedures. You will be asked to provide information about your medical history and any other drugs (including alcohol) you are taking.
- Your study doctor will speak with you about the ingredients of the study drugs used in this study. You may be allergic to one or more components of the study drugs and it is important to tell your study doctor all of your known allergies.
- You might be told to stop using the study drug or to leave the study. This may be because your condition worsens, you had a side effect or because you didn't follow the study instructions properly. This may also be because new information about the study drug's safety or efficacy (how effective the study drug is at treating your condition) becomes available or because of administrative reasons. You could be removed from the study without your agreement, but the study doctor will tell you why.
- If you leave the study before the last scheduled visit, you will be asked to return for a final study check-up called an early termination approximately 42 days after the last dose of the study treatment. Your study doctor may also contact you afterward to find out how you are doing.
- The study staff will inform you immediately of any important new information that might change your decision to be in this study. You can use this information to decide, with the help of your study doctor, whether or not you want to stay in the study.

INTRODUCTION AND BACKGROUND

This study is being done to evaluate the safety and efficacy of BFB759 in participants with moderate to severe hidradenitis suppurativa (HS).

Hidradenitis suppurativa is a long-term inflammatory skin condition that causes painful bumps under the skin close to hair roots and sweat glands. It can affect areas where the skin rubs together, such as the armpits, groin, and breasts.

BFB759 is an investigational drug which means it is not yet approved by Health Canada or the United States (US) Food and Drug Administration (FDA). It is not approved for use outside of studies like this one.

BFB759 is a human antibody with biological activity that works by blocking proteins that cause inflammation. Blocking the activity of these proteins may reduce and/or help control your HS.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Information on this study will also be posted in a similar format on a European Web site at https://euclinicaltrials.eu.

INFORMATION ABOUT THE STUDY

Bluefin Biomedicine, Inc is sponsoring this study. This study will enroll approximately 210 adult participants with HS in Europe and North America.

The total duration of participation in this study is up to 40 weeks.

The study will consist of the following periods:

- Screening period: up to 30 days
- Study Treatment period: up to 30 weeks
- Follow-up period: 6 weeks after the last dose of study drug. (If study drug is discontinued for any reason, you should continue to attend all study visits through Week 36 and you will be evaluated for safety and efficacy)

In this study, BFB759 and/or placebo will be given by injection under the skin; this is called subcutaneous injection.

The placebo is a dummy drug made from the same base product used to make BFB759, but it does not contain any active ingredient. Please notice that this form refers to both BFB759 and placebo as “study drug.”

There are 3 different study treatment groups in this study. Following a 30-day screening period, you will be assigned to one of the study treatment groups. Neither you nor your study doctor will know which group you have been assigned to.

Note: You will receive 4 injections at Day 1, and 2 injections at all subsequent dosing visits. The injections may contain BFB759 or placebo depending on your group assignment.

- **Group 1:** Participants will receive 1200 mg of BFB759 on Day 1 followed by 600 mg of BFB759 every 2 weeks from Week 2 to Week 14 inclusive. Participants will then receive placebo every 2 weeks from Week 16 to Week 30 inclusive.

- **Group 2**: Participants will receive 600 mg of BFB759 on Day 1, Week 2 and Week 4, followed by 300 mg of BFB759 every 2 weeks, from Week 6 to Week 14 inclusive. Participants will then receive placebo from Week 16 to Week 30 inclusive, every 2 weeks.

- **Group 3:** Participants will receive placebo for 14 weeks. At Week 16, participants will be randomized into 2 sub-groups, called sub-group 1 and sub-group 2, to receive BFB759.

    Sub-group 1: Participants will receive 300 mg of BFB759 at Week 16, 18 and 20 and then 150 mg of BFB759 every 2 weeks from Week 22 to Week 30 inclusive.

    Sub-group 2: Participants will receive 600 mg of BFB759 at Week 16, 18 and 20 and then 300 mg of BFB759 every 2 weeks from Week 22 to Week 30 inclusive.

Group	Study Treatment Assignment			
	At Day 1	**At Weeks 2, 4, 6, 8, 10, 12 and 14**	**At Week 16**	**At Weeks 18, 20, 22, 24, 26, 28 and 30**
1	4 injections of 300 mg BFB759	2 injections of 300 mg BFB759	2 injections of placebo	2 injections of placebo
2	2 injections of 300 mg BFB759 + 2 injections of placebo	2 injections of 300 mg BFB759 + 2 injections of placebo at Weeks 2 and 4. 1 injection of 300 mg BFB759 + 1 injection of placebo from Week 6 to 14.	2 injections of placebo	2 injections of placebo
3 (sub-group 1)	4 injections of placebo	2 injections of placebo	1 injection of 300 mg BFB759 + 1 injection of placebo	1 injection of 300 mg BFB759 + 1 injection of placebo at Weeks 18 and 20. 1 injection of 150 mg BFB759 + 1 injection of placebo from Week 22 to 30
3 (sub-group 2)	4 injections of placebo	2 injections of placebo	2 injections of 300 mg BFB759	2 injections of 300 mg BFB759 at weeks 18 and 20. 2 injections of 150 mg BFB759 from Week 22 to 30.

At Day 1, you will not know which of the 3 groups you will be assigned to. Study drugs will be assigned randomly (like drawing numbers from a hat) at a 1:1:1 ratio. This means that you will have a 1 in 3 (33%) chance of being assigned to one of the groups. The study doctor, you, and the study staff will not know which study drug you are receiving. In the case of an emergency, your study doctor will be able to find this out.

If you are in Group 3, you will be assigned to sub-group 1 or sub-group 2 at Week 16. Study drugs will be re-assigned randomly (like drawing numbers from a hat) at a 1:1 ratio. This means that you will have a 1 in 2 (50%) chance of being assigned to one of the 2 sub-groups.

By comparing the results of these groups of participants, we will be able to see whether BFB759 is safe and effective.

Because this is a research study, the study drug will be given to you only during this study and not after the study is over.

Screening Period:
During the Screening Period, you will read and review this Informed Consent Form, and the study doctor will assess the severity of your HS and also explain the study to you, and if you agree to take part in the study, you will be asked to sign and date this form.

A complete physical examination will be performed during this visit. It will include the assessment of your vital signs and all your body's organs: heart, head, neck, abdomen, neurological, eyes, ears, nose, mouth, throat, lungs, skin, muscle, bone, lymph nodes.

You will have an electrocardiogram (ECG) to monitor your heart during the screening visit.

Photography of your HS lesions will be done at the screening visit. Your identity will not be revealed through these photographs.

A blood sample will be collected for below:

- Presence of HIV and hepatitis B and C antibodies. The study doctor may be required by law to report a positive result to the Public Health Authorities.
- Pregnancy in female participants of childbearing potential and measurement of a menstrual hormone to confirm postmenopausal status in postmenopausal female participants.
- Blood coagulation (how well your blood clots), hematology (measurement of your blood cells and platelets), and chemistry (measurement of the amount of certain substances in the blood like sodium, potassium, proteins, and liver enzymes) and biomarkers (a molecule in your blood that is a sign of a normal or abnormal process, to see how well the body responds to a treatment for a disease or condition).
- Tuberculosis (TB). TB will be screened with a blood test. The results of these tests must be negative for you to be eligible for the study. The study doctor will report positive test results to local public health authorities, as required by law.
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Medical history and demographic data including your sex/gender, race, age, year of birth, concomitant medication and prior medication use (including but not limited to over-the-counter or prescription medicines, investigational therapies, vitamins, vaccines, and/or herbal supplements), will be obtained during the Screening Period.

A urine sample will be taken for drug screening (cocaine, opioids, benzodiazepines, amphetamines, barbiturates, phencyclidine) and urine analysis.

You will have the COVID test using a nasal swab at the screening visit only where required by local regulations.

Study Treatment Period:
The study drugs will be administered by subcutaneous injection, administered by your Study Doctor or one of the study site study staff members, once every 2 weeks at the study visit after all assessments are completed.

During this period, you will have photographs of your skin lesions taken (the same targeted lesions that were photographed at screening visit). Your identity will not be revealed through these photographs.

Safety follow-up visit:
You will attend a safety follow-up visit at Week 36 or an Early Termination (ET) Visit for participants who do not complete the study. The follow-up period is planned to be approximately 42 days after the last dose of study drug. If you decide to stop taking the study drug early, we will still ask you to come to the clinic for follow-up visits until Week 36. This is important so we can check on your health, even after you've stopped the study drug. These visits help us understand how the study drug affects people over time and ensure your well-being.

SPECIAL INSTRUCTIONS

Throughout the study duration, these special instructions must be followed:

- You should fast (nothing to eat or drink except water) for at least 8 hours before coming for Day 1 and Week 16 and Week 32 visits.
- You cannot participate in the study if you received an investigational product or device within 4 weeks or 5 half-lives (whichever is longer) prior to Day 1.
- Illicit drug use is prohibited (excluding marijuana).
- Opioid analgesics (pain medications) except tramadol specifically for HS must be discontinued at least 14 days before Day 1. Non-opioid (including tramadol) analgesics for non-HS conditions must be at a stable dose for at least 14 days before Day 1 and be anticipated to remain stable during the study participation. You will be encouraged not to take analgesics 12 hours prior to a study visit.
- You should not have had a major surgery or inpatient hospitalization within 2 months prior to the screening visit or planned major surgery and hospitalizations and any major dental work during your participation in this study (between screening and last study visit).
- You should not receive any live vaccines within 6 weeks before Day 1 and during the study within 6 weeks after end of study treatment. Speak with the study doctor about vaccines you plan to receive.
- You cannot participate in this study if you have a weakened immune system disorder, including human immunodeficiency virus infection (HIV) or Hepatitis B or C.
- You will not be able to participate in this study if you have active tuberculosis (TB) or latent TB (latent means that your blood TB test is positive, but you do not have TB disease).
- You should not have received systemic non biologic treatments that could affect HS (If you're taking this medication for something other than HS, that's okay, as long as you've been on it for more than for 4 weeks and plan to keep using the same medication at the same dose throughout the study) including but not limited to anti-androgens, antibiotics within 4 weeks prior to Day 1.
- You should not have used topical treatment (prescription or non-prescription) affecting HS within 2 weeks prior to Day 1 (e.g., Resorcinol, topical corticosteroids). Topical cleansers or daily antiseptic wash (soap and water, a topical antiseptic wash containing chlorhexidine gluconate, benzoyl peroxide, or a dilute bleach bath) on the HS lesions are allowed.
- You should not have used oral/injectable corticosteroids, methotrexate, cyclosporine, azathioprine, phosphodiesterase type 4 (PDE4) inhibitors, or mycophenolate mofetil within 4 weeks prior to Day 1.

- You cannot participate if you have had prior exposure to any antibody therapy and surgical, laser or pulsed light intervention in areas with HS lesions or received an investigational product or device within 12 weeks prior to Day 1.
- You cannot participate if you have had exposure to phototherapy (including tanning beds or excimer laser) or psoralen and ultraviolet light A (PUVA) treatment within 4 weeks prior to Day 1.
- Rescue therapy for management of your HS may start at the study doctor's discretion:

  The two types of intervention that are permitted are:

  1. Injection with intralesional triamcinolone acetonide suspension
  2. Incision and drainage of the lesion

  You are not allowed to start any new oral or skin treatments, including antibiotics, after the incision and drainage procedure.

  An intervention can occur maximally on 2 different lesions at the same visit or on the same lesion at 2 different study visits, for a maximum of 4 interventions up to Week 32. The same lesion cannot be treated 2 times at the same visit. If you require more than two interventions within the first 16 weeks, you will be discontinued from the study interventions but will continue to be followed up for the remainder of the study.
- You can use wound care dressings during the study, but only certain types are allowed, specifically alginates, hydrocolloids, and hydrogels. If you're already using any oral or topical treatments that aren't restricted, you should continue using them throughout the study.
- If you qualify, you may start treatment with either minocycline or doxycycline, up to 100 mg twice a day. Once you begin, the dose should stay the same throughout the study. If you've had trouble with or cannot take either of these medications due to a medical reason, the study team will look into whether a different backup treatment would be more suitable for you.
- You cannot participate if you have had a heart attack or stroke within the 6 months prior to the screening visit.
- You cannot take part in this study if you have had a malignant tumor in the last 5 years before screening visit, except for some types of skin cancer or cervical cancer that has been treated without recurrence.
- If you have any serious illness or medical, physical, or psychiatric condition that, in the opinion of the study doctor, would interfere with full participation in the study, pose a significant risk to you, or interfere with the interpretation of the study data, you should not participate in this study.
- If you have any evidence of an active infection that requires systemic or topical treatment within 4 weeks prior to Day 1 you should not participate in this study. You may be able to participate in the study if you have a herpes simplex virus (HSV) infection, unless HSV is disseminated (non-localized) or if local herpes lesions have not fully healed by Day 1.
- You may not participate in this study if you have any other skin diseases or conditions that, at the study doctor's discretion, may interfere with the assessment of HS. Examples include bacterial cellulitis, candida intertrigo, and extensive condyloma.)
- If you have a condition that weakens your immune system, such as taking medications to suppress your immune system after an organ transplant, or if you've had your spleen removed, you should not take part in this study.

- If you are breastfeeding, lactating, or planning to become pregnant during this study, you should not participate. Also, you should not be pregnant during this study. Please refer to the “Birth Control Restrictions” section.

HOW LONG WILL YOU BE IN THE STUDY?

Your participation in the study may last up to approximately 40 weeks, including the screening and the follow-up period. However, the study may be terminated earlier in case of major safety concerns or other reasons. If this is the case, you may not receive the study drug for the full 30 weeks. During the study, you will come to the clinic at least 22 occasions. Please refer to the Study Visits section below for more details on study duration and the number and frequency of the study visits.

STUDY VISITS

This section will describe the visits you will have at the clinic and the details of the procedures to be performed at each visit. The following table summarizes your participation in the research study and all the study visits.

During your Screening Period the study staff will verify your eligibility to participate in the study. Further participation in the study depends on the results of the screening tests.

If you do not meet the eligibility criteria you may be re-screened once at the discretion of the study doctor.

If you decide to withdraw from the study early, you should inform the study staff as soon as possible. In this case, we will ask you to come for a final visit. At the end of this final visit, your participation in the study will be discontinued.

If you decide to stop taking the study drug but to not withdraw consent, then you will be expected to return to the clinic for remaining study visits and procedures, without receiving study drug.

STUDY VISITS

	Screening	Study treatment period																		SFU/ET
Study visit (Week=w, Day =d)	Screening d-30 to d-1	d1	w1 d4	w2	w4	w6	w8	w10	w12	w14	w16	w18	w20	w22	w24	w26	w28	w30	w32	w36
Duration (hours)	3	3	3	2.5	2.5	2	2	2	2.5	2	2.5	2	2	2.5	2	2	2	2	2	2
Signing this consent form	X																			
Review of study requirements	X	X																		
Collection of demographic information (name, sex, age, year of birth, race/ethnicity), smoking status	X																			
Collection of medical history	X																			
Drug screen (urine sample)	X																			
Physical examination[1]	X	X									X								X	X
Urine Pregnancy test and Blood[2]	X	X			X		X		X		X		X		X		X		X	X
Vital signs (blood pressure, pulse, temperature, weight, height)[3]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Electrocardiogram (ECG) to monitor your heart	X				X						X									X
Safety Blood tests (69.3 ml = 14 teaspoons total) and urine safety tests	X	X			X		X		X		X			X		X		X	X	X

	Screening	Study treatment period																		SFU/ET
Study visit (Week=w, Day =d)	Screening d-30 to d-1	d1	w1 d4	w2	w4	w6	w8	w10	w12	w14	w16	w18	w20	w22	w24	w26	w28	w30	w32	w36
Duration (hours)	3	3	3	2.5	2.5	2	2	2	2.5	2	2.5	2	2	2.5	2	2	2	2	2	2
Infectious disease screening: COVID test and HIV, Hepatitis B, and Hepatitis C and Tuberculosis screening (17 mL blood sample = 3.5 teaspoons total)[4]	X																			
Blood test for level of menstrual hormone-Postmenopausal Women only (2.5 mL = 0.5 teaspoon total)	X																			
Blood sampling for BFB759 concentration Pre and post-dose (84 mL =17 teaspoons total)[5]		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood sampling for BFB759 anti-drug antibody (24 mL = 5 teaspoons total)	X	X			X						X			X					X	X
Blood sample for biomarkers (154 mL = 31 teaspoons total)	X	X	X	X	X				X		X	X	X				X		X	X
Assessment of the severity of your HS by study doctor and lesion count	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Randomization (Assignment to study treatment group)		X									X[6]									

	Screening	Study treatment period																		SFU/ET
Study visit (Week=w, Day =d)	Screening d-30 to d-1	d1	w1 d4	w2	w4	w6	w8	w10	w12	w14	w16	w18	w20	w22	w24	w26	w28	w30	w32	w36
Duration (hours)	3	3	3	2.5	2.5	2	2	2	2.5	2	2.5	2	2	2.5	2	2	2	2	2	2
Injection of study drug		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Medical photographs of skin lesions	X	X			X						X			X					X	X[7]
Answer questions related to the drainage level of your HS lesions and the impact of HS on your quality of life and skin pain severity		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
List of all the medications you are taking and procedures you have undergone	X----------X																			
Evaluation of any unwanted effects or health problems evaluation	X----------X																			

SFU= safety Follow-up, ET = early termination vis it.

[1] Complete physical examination at Screening. Physical examination may be performed at the discretion of the study doctor at all other visits, based on signs and symptoms.

[2]The amount of blood taken for the pregnancy test has been included in the blood volume for the safety test. Blood pregnancy test at Screening, urine pregnancy test at all other visits.

[3]·Height at Screening only and weight at Screening, Day 1, Week 16 and 36.

[4] You will have the COVID test using a nasal swab at the screening visit only where required by local regulations.

[5]Also you will have 2 additional blood draws for BFB759 concentration (after dosing), one will be 4 ±1 days after dosing on one of either Weeks 8, 10, 12, or 14, and the other will be 4 ±1 days after dosing at one of either Weeks 24, 26, 28, or 30.

[6]At this visit, participants assigned to Group 3 will be reassigned to one of the sub-groups (1 or 2).

[7]Skin photographs should be completed only for ET visits, not for Week 36 visits.

EXPECTATIONS

If you participate in this study, you will be expected to:

- Follow the instructions of the study doctor and the study staff and the special instructions listed above.
- Provide the study doctor and study staff with a complete list of all the medications (prescribed or not) you are taking. This includes vaccines, herbal or "natural" remedies, vitamins, antacids and over-the-counter medications. Talk to your study doctor before changing any of your medicines or starting new medicines or vaccinations.
- Come to all the planned study visits. If you cannot come to a visit, contact the study staff to reschedule as soon as you know that you will miss the appointment.
- Promptly report any side effects or health problems to the study staff or study doctor even if you don't think they are important or related to the study procedures.
- Not participate in another study with a treatment while you are in this study.

If you feel that this study would take too much time or that you cannot comply with the requirements of the study, you should not agree to participate.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

While you are in the study, you may have side effects from the study drug. During the study, if you have any change in your health, you should contact the study doctor as soon as possible.

The safety of BFB759 has been previously evaluated in 3 controlled clinical studies. These clinical studies involved receiving BFB759 subcutaneously (by injection just below the skin, as being done in this study) and included 44 healthy participants, 61 participants with HS, and 30 participants with a skin disease called moderate to severe atopic dermatitis. BFB759 was reported to be well tolerated in these clinical studies.

We do not know all the possible side effects of the study drug. Like all drugs, the study drug can cause side effects, although not everybody gets them. Most side effects are mild to moderate. There may also be side effects that are not expected or are not known that may be serious. If you have any new or worsening symptoms, or are worried about side effects, notify your study doctor immediately. Your study doctor will discuss the best way of managing any side effects with you. Your study doctor and study staff will also be watching you closely for side effects. If a severe side effect or reaction occurs, your study doctor may need to stop your involvement in the study. The following are the most common side effects reported by greater than or equal to 10% of people who received BFB759. It is not known if all these side effects were caused by the study drug:

- Itchiness at the injection site
- Redness at the injection site
- Swelling/Induration and pain at the injection site
- Urticaria at the injection site (skin reaction that caused itch, redness, swelling)
- Rash

BFB759 is an investigational study drug which acts by inhibiting interleukin-1 (IL-1), a group of proteins that are involved in inflammatory responses. Several other medications that work by modulating one or more IL-1 signaling pathways have been associated with serious side effects. Given the shared mechanism of action, the risks observed with these other therapies might also pose a risk for BFB759 and will be monitored in the clinical study. These side effects include:

- Increased risk of infection
- Neutropenia (a lower-than-normal level of certain white blood cells that fight infection)

As with any drug, there may be a risk of allergic reactions. Symptoms of an allergic reaction include hives, or swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing. This could become life-threatening if it is not treated promptly. Please seek immediate medical assistance if you experience the symptoms of severe allergic reaction. Then, contact the study doctor at the numbers given on the first page.

Although unlikely, a serious or lasting research-related injury may in rare cases impact your insurability or employment. This risk is not specific to this study and applies broadly to clinical research participation.

Placebo Risk
If you receive placebo, which does not contain any active ingredients, it may delay the treatment of your condition, and your symptoms of HS may not improve or may get worse.

RISKS OF OTHER STUDY PROCEDURES

- Blood samples: Possible side effects from blood drawing include temporary discomfort from the needle in your arm, faintness, inflammation of the vein, or pain, bruising, swelling, or bleeding at the site of puncture. In rare instances, there is also a slight possibility of infection at the site of the needle stick.
- Electrocardiogram (ECG): The sticky pads placed on your chest may cause skin irritation. The hair on your chest may need to be shaved to allow the sticky pads to properly adhere to your skin.
- Blood Pressure Measurement: Temporary discomfort may occur from the repeated inflation of the blood pressure cuff. Your blood pressure may be required to be taken while you are lying down. You may experience lightheadedness upon sitting up.
- Questionnaires: The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.
- Fasting: Fasting for an extended period of time may cause you to experience symptoms such as hunger, irritability, and upset stomach.
- Subcutaneous injection: You might experience: pain at the site of the needle stick; the needle may break in your skin or hit a nerve; lump, swelling, bruising or scarring that may not go away; dizziness or fainting; or infection at the site of the needle stick.

If you are currently taking medications for HS, you will be asked to stop taking these medications within a specific period prior to your first dose of study drug. Your study doctor will explain how long you need to stay off these medications to you in detail. The specific time periods are explained above under “Special Instructions”. During this time, your symptoms may not improve or may get worse. If your symptoms get worse, tell the study doctor immediately.

UNFORESEEN RISKS

Since the study drug is investigational, there may be other risks that are unknown.

One of the reasons for doing this study is to see how safe BFB759 is to use in people. If any new information about this study becomes available that might affect your decision to continue your participation, you will be informed as soon as possible. At every visit, your study doctor and study staff will ask you about any side effects you may have experienced. If you have any problems, you should let your study doctor know right away.

Additionally, there may be unknown risks to a pregnancy, embryo, or fetus (unborn baby) if you or your female partner become pregnant.

Similarly, it is unknown whether BFB759 is found in the semen of men.

BIRTH CONTROL RESTRICTIONS

Taking the study drug may involve risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant, planning to father a child, or are breastfeeding a child, you cannot participate in this study.

Women Only:
If you are a woman who is able to become pregnant, you must have a negative blood pregnancy test at screening and negative urine pregnancy test at Day 1. You will also have multiple urine pregnancy tests during the study.

You must agree to avoid getting pregnant for the duration of the study in order to participate in the study. If you are engaging in sexual intercourse that could lead to pregnancy with a male partner, you must use a method of birth control that is acceptable to you, the study doctor, and the sponsor from 4 weeks prior to Day 1 and until at least 3 months after the last study drug administration. Acceptable methods of birth control for use in this study are listed below. The study doctor or study staff will discuss this with you:

- Hormonal contraceptives [oral contraceptive (“the pill”), patch (e.g., Evra), vaginal ring (e.g., NuvaRing), injectable (e.g., Depo-Provera), or implant]
- Intrauterine devices or intrauterine systems (IUD or IUS)
- Vasectomized partner; performed at least 4 months before screening visit and you can confirm surgical success
- Tubal ligation (tube tied)
- Two barrier methods of contraception (male condom with cervical cap, male condom with diaphragm, or male condom with contraceptive sponge) used with spermicide

You can practice abstinence if it is your preferred and usual lifestyle, but you must be abstinent for at least 4 weeks before Day 1. You must agree to use one of the bulleted contraception methods listed above if you start engaging in sexual activity that could lead to pregnancy during the study.

Please note that using only a male condom is not considered an acceptable method of contraception for this study. If you do not use any of the acceptable methods of birth control listed above, you must be considered of nonchildbearing potential:

- You had surgical sterilization with one or more of the following:
  - Surgical removal of your uterus
  - Surgical removal of both ovaries
  - Surgical removal of your Fallopian tubes
- You have had no menses for at least 12 months prior screening visit without an alternative medical cause. A blood test will be performed at the screening visit to confirm the nonchildbearing status.

You must agree to not donate ova (eggs) from Screening until 3 months following the last injection of the study drug.

If you become pregnant while you are participating in this study and up to 3 months after the last dose of the study drug, you must tell the study doctor or study staff immediately. The study drug will be stopped and your participation in this study will be ended. The study doctor will ask your permission to follow your pregnancy and collect information about the pregnancy, its outcome and the health of the child up to 1 month after delivery, if applicable.

Men Only:
If you are sexually active and have a female partner who can get pregnant, you agree to use an acceptable method of birth control (such as a condom with spermicide) and agree to encourage your female partner also agrees to use an acceptable birth control method as mentioned in the section for women above, from 4 weeks before Day 1 throughout the study and for at least 3 months after the last dose of study drug.

If you are not using a method of birth control, you should be sexually abstinent or surgically sterilized (vasectomy at least 4 months prior to screening, and you can confirm surgical success).

If your female partner uses any of the hormonal contraceptive methods, this contraceptive method should be used by the female partner from 4 weeks before Day 1 until at least 3 months after the last study drug administration.

If your female partner becomes pregnant while you are participating in this study or within 3 months after your last injection of study drug, you must tell your study doctor or study staff immediately. The study doctor may ask your partner's permission to follow the pregnancy after participation in this study.

In addition, you should not donate sperm during this study from screening and for at least 3 months after the end of study.

ADDITIONAL QUESTIONS?

You should talk with the study doctor or study staff if you have any questions.

BLOOD SAMPLE

After they have been analyzed, your blood samples collected will be stored by a laboratory called ThermoFisher Scientific/PPD Laboratories in a secure storage space. The storage space will have adequate measures to protect your confidentiality. Information sent from the study site will contain an identification number, but it won't contain your name.

Your deidentified samples may be used for possible future analysis to learn more about how BFB759 works. Samples will be stored for up to, but no longer than, 10 years from the end of the main study. Bluefin Biomedicine, Inc. will not use your samples or data generated from those samples for any purpose other than what is described in this form. Your samples and the accompanying data will only be used by researchers at Bluefin Biomedicine, Inc. or people, universities, or companies that Bluefin Biomedicine, Inc. works with. Your samples will not be sold to other people or companies. Bluefin Biomedicine, Inc. does not plan to share any profits with you.

No genetic testing will be done on your samples. You may request destruction of your samples at any time by telling your study doctor.

MEDICAL PHOTOGRAPHS

Photographs of the skin lesions will be taken for all participants at the screening visit, Day 1, Week 4, Week 16, Week 22, Week 32, and at early termination visit. The same skin lesions will be photographed at each time point to allow for consistent documentation of any changes over time.

Bluefin Biomedicine, Inc. requests your permission to use non-identifying photographs of your skin lesions taken during the study. These images may be used for the purposes of: (1) inclusion in scientific reports of the study results; (2) presentation at medical or scientific conferences; and/or (3) publication in scientific or medical journals.

All reasonable efforts will be made to protect your privacy; however absolute privacy cannot be guaranteed. Your name or any other identifying information will not be included. You will only be identified by a unique study number. If you have identifying birth marks or tattoos, the photographs may be recognizable.

POTENTIAL BENEFITS OF PARTICIPATING IN THE STUDY

You should not expect any benefit from taking part in this study. Your condition may get better, stay the same, or get worse. The information from this study may help our understanding of the safety of BFB759 and its potential effectiveness in participants with moderate to severe hidradenitis suppurativa. This may contribute to the advancement of knowledge in the field of dermatology. Your participation in this research may not benefit you but may benefit future patients with your disease or condition.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

You do not have to participate in this study to seek treatment for your HS. There are several other treatment options available. These include:

- Topical antiseptic washes, such as chlorhexidine and, benzoyl peroxide
- Topical antimicrobials (for example, Dalacin T)

- Oral antibiotics (for example, minocycline, doxycycline, clindamycin)
- Hormone therapy (for example, Diane 35, finasteride)
- Antidiabetic agent (metformin)
- **Corticosteroids**: Can be split into:
    - Intralesional corticosteroids
    - Oral corticosteroids
- **Immunosuppressants (IS)**: cyclosporine, methotrexate (MTX), and others.
- **Biologics:**
    - **Approved**: adalimumab, secukinumab, bimekizumab
    - **Off-label use**: infliximab, ustekinumab.
    - **In development**: guselkumab, risankizumab, and others (including JAK inhibitors).
- Surgical procedures can be performed in severe and refractory cases

Treatments applied to the skin are usually used for mild HS, whereas oral treatments like antibiotics, hormone therapy, acitretin and immunosuppressive medications are generally used for moderate to severe hidradenitis suppurativa.

Each option has benefits and possible side effects:

- Topical antiseptic washes can help reduce new lesions, but it may not be very effective to control active lesions.
- Topical and oral antimicrobials can help reduce discomfort related to inflammation and controlling bacterial infections, but they can be less effective in moderate to severe cases and the risk of bacterial resistance can be increased.
- Hormone therapy can be useful in selected patients, but it is not always effective, and it cannot be used during pregnancy and breastfeeding.
- Antidiabetic agent (metformin) can be useful in mild cases in some patients, but it can be poorly tolerated by the digestive system.
- Corticoids:
    - Corticoid creams are easy to use and work well to reduce inflammation. But long-term use can cause skin thinning or easy bruising.
    - Corticoid pills reduce inflammation, but they can raise the risk of infections, high blood pressure, diabetes or bone loss.
- Immunosuppressants can help reduce inflammation by reducing immune response from the body, but they have risks depending on each drug (e.g. Cyclosporine can affect kidney function, Colchicine can cause digestive problems).
- Biologic treatments as adalimumab and secukinumab can be useful in patients with moderate to severe HS by reducing systemic inflammation, but they require strict follow-up and the risk of infections can be higher. Within this group a new type of medicine is being explore - the JAK inhibitor family - which may reduce the number and severity of lesions. However, it also carries a risk of common side effects such as fatigue and headache, as well as rare but serious risks of blood clots and changes in liver enzyme changes.

- Surgical procedures can cure specific lesions, but the recovery time is long and there are risks as in other type of surgeries (scars, infections, pain…).

Your study doctor will review alternative treatment options that are appropriate for you and their important potential risks and benefits. You can decide with your study doctor if this study is appropriate for you or if another drug or treatment would be better.

CONFIDENTIALITY:

Your identity will be kept confidential at all times, except when disclosure is required by law. As part of this study, the study doctor will collect the results of your study-related tests and procedures. He/she may also access your personal medical records for health information, such as past medical history and test results. Information from this study will be submitted to the sponsor. It could also be submitted to governmental agencies (e.g., Health Canada and the US Food and Drug Administration). Information sent from the study site will contain a code number and may contain your initials, but it won't contain your name. A summation of the results of this study may be presented at meetings or in publications, but your identity won't be disclosed.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your medical records. Some persons may need to see these records to monitor the study and verify the accuracy of the study data. These persons are:

- A limited number of representatives from the drug company sponsoring the study including authorized study monitors, other companies within its group, its service providers, its contractors, and business collaborators.
- The research ethics review board, which is Advarra IRB, an independent ethics committee that will review the ethical aspects of this study to ensure the rights and welfare of every study participant is protected.
- Government regulatory authorities, including Health Canada, the US Food and Drug Administration, and other foreign regulatory agencies.

The study doctor is required by law to protect your health information. By signing this document, you authorize the study doctor to use and disclose your health information, in order to conduct this study.

You do not have to sign this consent form, but if you do not, you will not be able to take part in this study.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing this consent form, you consent to the collection, access, use, and disclosure of your information as described above.

WHO IS ORGANIZING AND FUNDING THE STUDY?

This study is being sponsored by Bluefin Biomedicine, Inc. and is under the direction of the study doctor and the study staff. The sponsor is paying your study doctor for his or her time, effort, and expenses to conduct this study.

WHAT ARE YOUR LEGAL RIGHTS?

You do not lose any legal rights by signing this consent form. Your signing does not release the study doctor or sponsor from their legal and professional obligations.

COMPENSATION FOR INJURY

If you become ill or are injured as a result of the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured, then they will help you get the care that you need.

If you are injured as a result of taking the study drug or from procedures done for the purpose of this study, the sponsor will pay for those reasonable medical expenses necessary to treat your injury as long as the study procedures have been followed. The Sponsor may not pay if the Sponsor and the study doctor do not agree that your injury resulted from you taking part in the study. Unless you are covered by Medicare, this payment by the Sponsor applies only to costs that are not covered by your health insurance policy or by any other third party. If you are covered by Medicare, the Sponsor will pay for the costs of the medical care related to these injuries.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

There are no plans for payment for lost wages or other expenses. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

COSTS AND COMPENSATION

All study drugs, study tests, examinations, and medical care required as part of this study are provided at no cost to you, or your private medical insurance (if any).

If you meet all requirements and are enrolled in the study until the final follow-up visit, financial compensation up to $ 2,900 will be given to you for your time and incurred expenses (traveling, parking, etc.). If you leave the study before the end, you will receive $100 to $150 per completed visit attended, depending on the activities completed during each visit. The compensation will be prorated to the number of study visits you completed and the activities you completed on each study visit. See the details below:

- $150 for completion of study visits at Screening and Weeks 0, 4, 16, 20, 32 and Early Termination (if applicable), as these are longer visits requiring photography.
- $100 for completion of study visits at Weeks 2, 6, 8, 10, 12, 14, 18, 22, 24, 26, 28, 30, 36 and Additional PK Collection Timepoints.

If you are asked to come back to the clinic for an unplanned visit, you may receive an additional $100.00 per visit.

You will receive an additional $400 for completing your participation in this study.

Additional compensation may be available for participants traveling a further than average distance:

If you require to travel more than 62.1 miles (100 Km), additional travel expenses incurred for travel will be made based on the following rates:

- If you are traveling by car, standard mileage reimbursement rate of $0.70 /Mile (or Km, as applicable), up to $105.00 for each study visit. Again, this is if your travel is greater than 62.1 miles (100 km).
- Costs for other modes of transportation and/or accommodation may be reimbursed by the sponsor, upon prior approval by the sponsor. Prior to booking your trip, you may be asked to provide booking references for the sponsor's pre-approval. In order to be reimbursed, you will need to provide your receipts to the study staff for sponsor approval. The study staff will ensure that the receipts refer to the pre-approved expenses and will present the receipts to the sponsor for reimbursement, making sure all personal information contained in it has been redacted.

You will be paid following each completed visit.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as;

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact**:**

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00089953.

Do not sign this informed consent form unless you have had a chance to think about it and ask questions, and unless you have received satisfactory answers to all of your questions.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate, or you may withdraw from the study, at any time, for any reason, without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. If you decide to withdraw from the study, please talk to your study doctor to make sure this is done safely. Please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the Sponsor can stop your participation without your consent for any reason. For example, your participation may be stopped:

- If it appears to be medically harmful to you;
- If you fail to follow instructions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

CONSENT

By signing this Informed Consent Form, I acknowledge the following:

- ✓ I have read all pages of this Informed Consent Form and understand the information in all pages of this informed consent document.
- ✓ I had a chance to ask questions, and all of my questions were answered to my satisfaction.
- ✓ I voluntarily agree to participate in this study until I decide otherwise.
- ✓ I give my permission to the study doctor to use and disclose my protected health information as described in this consent form.
- ✓ I do not give up any of my legal rights by signing this consent document.
- ✓ I will receive a signed copy of this form
- ✓ If a positive result for tuberculosis, HIV, hepatitis B, or hepatitis C is found, my study doctor will inform the local public health authorities, as required by law.
- ✓ For male participants; I will inform my female partner that I am in a research study and will ensure that we use acceptable contraception.

A Spanish version of this Information and Consent Form is available.
Una versión en español de este formulario de información y consentimiento es disponible.

The study doctor has my permission to tell my family doctor about my being in this study:
Yes ☐ No ☐ I do not have a family doctor ☐ Initials: _____

Date (dd-mmm-yyyy)	Printed Name of Participant	Signature of Participant

Date (dd-mmm-yyyy)	Printed Name of Person Conducting the Consent	Signature of Person Conducting the Consent

Impartial witness (If participant is unable to read)

The study participant has indicated that he/she is unable to read. The consent document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

I attest that:

- the information in the consent form and any other written information was accurately explained to and apparently understood by the participant; and
- informed consent was freely given by the participant

Date (dd-mmm-yyyy)	Printed Name of Impartial Witness	Signature of Impartial Witness

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study doctor must obtain your authorization (permission) to use or release any health information that might identify you.

What information may be used and shared?

The study doctor and study staff will use and share your health information as part of this research study.

Examples of the information that may be used are:

- Your name
- Address
- Phone number
- Date of birth
- Medical records (from any doctor, hospital or other healthcare provider)
- Information created or collected during the research. This could include your medical history, and dates or results from any physical exams, laboratory tests or other tests

Who will receive information about you?

The study doctor and study staff will share your protected health information with:

- The Sponsor, including persons or companies working for or with the Sponsor
- The Institutional Review Board (IRB)
- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Other regulatory agencies
- Home healthcare support

Why will this information be used and/or given to others?
The Sponsor and the groups above will use your health information:

- To complete this research
- To evaluate the results of the study
- To check that the study is being done properly
- To obtain marketing approval for new products resulting from this research

Is my health information protected after it has been given to others?
Your health information may be further shared by the groups above. If shared by them, the information may no longer be covered by federal privacy law. These groups are committed to keeping your health information confidential.

What if I decide not to allow the use of my health information?
You do not have to sign and date this form. If you do not sign and date this form, you cannot take part in this research study.

May I withdraw or revoke (cancel) my permission?
YES. You may withdraw your permission to use and disclose your health information at any time. You can do this by sending written notice to the study doctor at the address listed on the first page of this form. If you withdraw your permission, you will not be able to continue being in the research study.

What happens if I want to withdraw my authorization?
Information that has already been gathered may still be used and given to others. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

Will my authorization expire?
This Authorization will expire December 31, 2070, unless you withdraw it in writing before then.

May I review or copy the information obtained or created about me?
YES. You have the right to review and copy your health information. However, your access to this information may be delayed until the study is complete.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

AUTHORIZATION

By signing and dating this form, I allow the use or disclosure of my health information. I will receive a signed and dated copy of this Authorization.

Printed Name of Participant

Signature of Participant **Date**

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ (If applicable)

The study participant has indicated that he/she is unable to read. This Authorization document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

Printed Name of Impartial Witness

Signature of Impartial Witness **Date**