

**INFORMED CONSENT FORM ADDENDUM
FOR STUDY DRUGS**

Sponsor / Study Title: National Institute of Allergy and Infectious Diseases /
“Adaptive Platform Treatment Trial for Outpatients with
COVID-19 (Adapt Out COVID)”

Protocol Number: ACTIV-2/A5401

Principal Investigator: [REDACTED]
(Study Doctor)

Telephone: [REDACTED]
[REDACTED]

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]

Everything in the main study consent form you signed and dated before still applies to your participation unless otherwise noted in this form.

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns “you” and “your” should be read as referring to the participant rather than the person (legally authorized representative) who is signing and dating this form for the participant. In cases where the participant’s representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

FOR STUDY DRUGS BR11-196 and BR11-198

One of the study drugs that you might be assigned to in this study is the combination of BR11-196 and BR11-198 or the placebos for these study drugs.

BR11-196 and BR11-198 are both study drugs called a monoclonal antibody (mAb). Many antibodies are naturally made by your body and help fight diseases. BR11-196 and BR11-198 are made in a laboratory. “Monoclonal” means that BR11-196 and BR11-198 are made up of many copies of just two antibodies.

Your assignment is random, like the flip of a coin. You will be told about all the study drugs you may be assigned to in this study. If only one study drug is available, you will have an equal chance of receiving the study drug or placebo. If two study drugs are available, you will have a 2:1 chance of receiving a study drug or placebo. If three study drugs are available, you will have a 3:1 change of receiving a study drug or placebo, and so forth. You will not be able to choose your group (study drug), and neither you, your study doctor, nor the study staff at your study site will know whether you are receiving the study drug or placebo. However, your study doctor can find out which group you are in if there is an emergency.

[REDACTED]

The United States Food and Drug Administration (FDA) has not approved BR11-196 or BR11-198 for general use by the public; therefore, for this study they are considered investigational.

An investigational drug is one that is not approved by the United States Food and Drug Administration (FDA). However, we have told the FDA about this study and they have given us permission to conduct this study.

ARE THERE ANY ADDITIONAL STUDY PROCEDURES IF I RECEIVE BR11-196 and BR11-198 OR PLACEBO?

Screening Visit

- At your screening visit, if you can become pregnant, you will be asked to give blood (1 teaspoon) or a urine sample for a pregnancy test. You cannot receive BR11-196, BR11-198, or placebo if you are pregnant.

Entry Visit

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts)
 - Levels of antibodies to the study drug (your body's immune response to the study drug)
- You will have the infusion of BR11-196 and BR11-198 or placebos for each. The infusions will be given back to back and (first one and then the other) will be given through a small plastic tube that will be placed into a vein in your arm. This is called an intravenous (IV) infusion. The infusions will take approximately 60 minutes. You will be monitored in the clinic for 2 hours after the end of the infusions.
- You will have blood drawn to check the levels of study drug in your blood. The blood sample will be collected before the study infusion and 30 minutes after the study infusion in the opposite limb as the study infusion.

Study Visits

After the Entry visit, your study visits and evaluations will be different depending on whether you are in the first part of the study or the second part of the study.

IF YOU ARE IN THE FIRST PART OF THE STUDY:

Study Visits on Days 3, 14, and 28

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts)
 - On days 14 and 28, levels of the study drug and levels of antibodies to the study drug (your body's immune response to the study drug)

Study Visits on Week 12 and Week 24

- You will have blood drawn. This blood will be used for the following tests:
 - Levels of the study drug
 - Levels of antibodies to the study drug (your body's immune response to the study drug)
- You will be asked whether you have had any new symptoms or clinical events since your last visit.

Study Visits on Weeks 36, 48, and 72

- You will be contacted by phone by the study team to assess whether you have had any new symptoms or clinical events since your last visit
- You will answer questions about any potential COVID-19 related symptoms or conditions you have experienced.

IF YOU ARE IN THE SECOND PART OF THE STUDY:

Study Visit on Day 28

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts)
 - Levels of the study drug
 - Levels of antibodies to the study drug (your body's immune response to the study drug)

Study Visits on Week 12 and 24

- You will have blood drawn. This blood will be used for the following tests:
 - Levels of the study drug
 - Levels of antibodies to the study drug (your body's immune response to the study drug)
- You will be asked whether you have had any new symptoms or clinical events since your last visit.

Study Visits on Weeks 36, 48, and 72

- You will be contacted by phone by the study team to assess whether you have had any new symptoms or clinical events since your last visit
- You will answer questions about any potential COVID-19 related symptoms or conditions you have experienced.

HOW LONG WILL I BE IN THIS STUDY?

If you are assigned to BR11-196+BR11-198 or placebo for BR11-196+BR11-198, you will be in this study for 72 weeks.

WHAT ARE THE RISKS OF BR11-196 and BR11-198?

There is a risk of serious and/or life-threatening side effects when non-study medications are taken with the study drugs. For your safety, you must tell the study doctor or study nurse about all medications you are taking before you start the study.

Another risk is that the study drugs used in this study may have side effects, some of which are listed below. Additionally, the study drug tested in the study may have unknown side effects in persons with SARS-CoV-2 infection. In a research study, all of the risks or side effects may not be known before you start the study. You need to tell your study doctor or a member of the study team immediately if you experience any side effects.

Please note that these lists do not include all the side effects seen with this study drug. These lists include the more serious or common side effects with a known or possible relationship to the study drug. If you have questions concerning the additional side effects, please ask the study staff at your study site.



Risks Associated with BR11-196 and BR11-198

There is limited safety data on BR11-196 and BR11-198 since they have not been given to a lot of people. As of August 2020, healthy volunteers in studies of BR11-196 and BR11-198 have not reported any infusion-related reactions, allergic reactions, moderate to severe adverse events (negative effects), or any adverse events requiring discontinuation of therapy.

BR11-196 and BR11-198 are being administered together for the first time to hospitalized persons with COVID-19 in a separate study, but they have not yet been given to persons who have tested positive for COVID-19 and are at a higher risk for developing severe COVID-19.

Administration of mAbs, such as BR11-196 and BR11-198 can result in allergic reactions. Signs and symptoms of these reactions include:

- Chills
- Skin rash
- Itching
- Hives
- Swelling of the face or other soft tissues
- Low blood pressure
- Rapid heart rate
- Throat irritation or tightness
- Tightening of the muscles that line the airways
- Shortness of breath
- Loose stools

Administration of mAbs, such as BR11-196 and BR11-198 may induce release of chemicals called cytokines in the body. These chemicals may induce allergic reactions listed above as well as:

- Fever
- Muscle aches
- Nausea
- Vomiting
- Headache
- Dizziness

Some of these reactions may be serious or life-threatening including:

- Skin rash
- Swelling of the face or other soft tissues
- Low blood pressure
- Rapid heart rate
- Throat irritation or tightness
- Tightening of the muscles that line the airways
- Shortness of breath

You will be monitored closely during administration of study drug. Medical personnel, equipment, and medication will be available to manage these reactions appropriately if they occur.

Administration of mAbs, such as BR11-196 and BR11-198 can cause the following risks and discomforts:

- Development of proteins (antibodies) against BR11-196 and/or BR11-198. This may cause your body to get rid of BR11-196 and/or BR11-198 more quickly or change the effect of these study drugs on the body. Your blood will be tested to find out whether your body made antibodies to BR11-196 and/or BR11-198. The anticipated risk of this is low because BR11-196 and BR11-198 are fully human antibodies. Therefore, it is less likely to be seen as “foreign” by your body’s immune system and your body is less likely to form antibodies against them.
- Mixture of antibody and other chemicals in the body that may be deposited in tissues such as blood vessels and kidneys.
- Unexpected increase in virus reproduction in your body. Although this has been observed with some viruses, this has not been observed with COVID-19 or with the use of serum-containing antibodies given to people with COVID-19. This risk of increased viral growth is perhaps greater when there are lower levels of antibodies in the blood in the presence of virus. To avoid this, BR11-196 and BR11-198 will be given at a dose that is felt to be high enough to keep this from occurring.

Effect on Future Vaccination

The US Centers for Disease Control and Prevention (CDC) currently recommends that people wait at least 90 days after receiving antibody treatment before receiving a COVID-19 vaccine, because some antibodies remain in the body for about 90 days, and there is a chance that these antibodies could interfere with how your body responds to the vaccine during those 90 days. Some of the antibodies in this study including BR11-196 and BR11-198 are designed to remain in the body for longer than 90 days. Although there is no further guidance available, there is a chance that these longer-lasting monoclonal antibodies could interfere with how your body responds to the vaccine even if you wait at least 90 days for the vaccine.

ARE THERE RISKS RELATED TO PREGNANCY AND BREASTFEEDING?

Pregnancy

Since there are no data regarding the use of this study drug in people who are pregnant, you are not eligible to receive this study drug if you are pregnant.

The study drug may involve risks to you (or to the embryo or fetus, if you or your partner become pregnant), which are currently unforeseen.

If you are engaging in sexual activity that could lead to pregnancy, you must agree to use effective contraception for 24 weeks after the study drugs are administered. This would include oral contraceptives, implanted contraceptives, intrauterine devices, and/or barrier methods.

If you are engaging in sexual activity that may lead to pregnancy in your partner, you must agree to either remain abstinent or use male contraceptives. You are also advised to inform your non-pregnant sexual partners that can become pregnant to use effective contraceptives for 24 weeks after the study drugs are administered to you.

If you have a pregnant partner you should use condoms during vaginal intercourse through 24 weeks after the study drugs administered.

If applicable, you should refrain from sperm donation for 24 weeks after study drug administration.

If at any point during the study you think you may be pregnant, you should let the study staff at your study site know so that a pregnancy test can be done.

Let your study doctor know immediately if you become pregnant. If you become pregnant while on the study, you will be asked to continue to have study visits and the study staff would like to obtain information from you about the outcome of the pregnancy (even if it is after your participation in the study ends).

Breastfeeding

It is not known if this study drug is safe to use in people who are breastfeeding. You are not eligible to receive this study drug if you are breastfeeding.

FOR STUDY DRUG AZD7442

ADMINISTERED VIA INTRAVENOUS INFUSION

One of the study drugs that you might be assigned to in this study is AZD7442 or the placebo for AZD7442.

AZD7442 is a type of study drug called a monoclonal antibody. Many antibodies are naturally made by your body and help fight diseases. AZD7442 is made in a laboratory. It is a combination of two monoclonal antibodies, meaning many copies each of two antibodies designed to prevent SARS-CoV-2, the virus that causes COVID-19, from entering cells.

Your assignment is random, like the flip of a coin. You will be told about all of the study drugs you may be assigned to in this study. If only one study drug is available, you will have an equal chance of receiving the study drug or placebo. If two study drugs are available, you will have a 2:1 chance of receiving a study drug or placebo. If three study drugs are available, you will have a 3:1 chance of receiving a study drug or placebo, and so forth. You will not be able to choose your group (study drug), and neither you, your study doctor, nor the study staff at your site will know whether you are receiving the study drug or placebo. However, your study doctor can find out which group you are in if there is an emergency.

The United States Food and Drug Administration (FDA) has not approved AZD7442 for general use by the public, therefore, for this study it is considered investigational. An investigational drug is one that is not approved by the United States Food and Drug Administration (FDA). However, we have told the FDA about this study and they have given us permission to conduct this study.

ARE THERE ANY ADDITIONAL STUDY PROCEDURES IF I RECEIVE AZD7442 OR PLACEBO?

Screening Visit

- At your screening visit, if you can become pregnant, you will be asked to give blood (1 teaspoon) or a urine sample for a pregnancy test. You cannot receive AZD7442 or placebo if you are pregnant.

Entry Visit

- You will have blood drawn. This blood may be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts)
 - Levels of the study drug in your blood (you will have blood drawn before you receive the study drug and again after)
 - Levels of antibodies to the study drug (your body's immune response to the study drug)
- You will have the infusion of each component of AZD7442 or placebo. The infusion will be given through a small plastic tube that will be placed into a vein in your arm. This is called an intravenous (IV) infusion. The infusion itself will take approximately 15 minutes. You will then be monitored for another 2 hours.

Study Visits

After the Entry visit, your study visits and evaluations will be different depending on whether you are in the first part of the study or the second part of the study.

IF YOU ARE IN THE FIRST PART OF THE STUDY:

Study Visits on Days 3, 7, 14, and 28

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts) (days 3, 14, and 28)
 - Levels of the study drug and/or levels of antibodies to the study drug (your body's immune response to the study drug) (days 3, 7, 14 and 28)

Study Visits on Week 12 and 24

- You will have blood drawn. This blood will be used for the following tests:
 - Levels of the study drug and levels of antibodies to the study drug (your body's immune response to the study drug)
- You will be asked whether you have had any new symptoms or clinical events since your last visit.

Study Visits on Weeks 36, 48, and 72

- You will be contacted by phone by the study team to assess whether you have had any new symptoms or clinical events since your last visit
- You will answer questions about any potential COVID-19 related symptoms or conditions you have experienced

IF YOU ARE IN THE SECOND PART OF THE STUDY:

Study Visit on Day 28

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts)
 - Levels of the study drug
 - Levels of antibodies to the study drug (your body's immune response to the study drug)

Study Visit on Weeks 12 and 24

- You will have blood drawn. This blood will be used for the following tests:
 - Levels of the study drug
 - Levels of antibodies to the study drug (your body's immune response to the study drug)

- You will be asked whether you have had any new symptoms or clinical events since your last visit.

Study Visits on Weeks 36, 48, and 72

- You will be contacted by phone by the study team to assess whether you have had any new symptoms or clinical events since your last visit
- You will answer questions about any potential COVID-19 related symptoms or conditions you have experienced

HOW LONG WILL I BE IN THIS STUDY?

If you are assigned to AZD7442 or placebo for AZD7442, you will be in this study for 72 weeks.

WHAT ARE THE RISKS OF AZD7442?

There is a risk of serious and/or life-threatening side effects when non-study drugs are taken with the study drugs. For your safety, you must tell the study doctor or study nurse about all drugs you are taking before you start the study.

Another risk is that the study drug used in this study may have side effects, some of which are listed below.

Additionally, the study drug tested in the study may have unknown side effects in persons with SARS-CoV-2 infection. In a research study, all of the risks or side effects may not be known before you start the study. You need to tell your study doctor or a member of the study team immediately if you experience any side effects.

Please note that these lists do not include all of the side effects seen with this study drug. These lists include the more serious or common side effects with a known or possible relationship to the study drug. If you have questions concerning the additional side effects, please ask the study staff at your study site.

Risks Associated with AZD7442

There is limited safety data on AZD7442 since it has not been given to a lot of people. As of December 8, 2020, there have been no serious unexpected effects reported by greater than 100 healthy people taking AZD7442 or placebo to date. Most effects after taking AZD7442 or placebo have been mild or moderate and have either all gone away or are getting better. This study is likely to be the first study where this study drug is given to people with COVID-19 disease.

Administration of AZD7442 may result in allergic reactions. Signs and symptoms of these reactions include:

- Chills
- Skin rash
- Itching
- Hives
- Swelling of the face or other soft tissues
- Low blood pressure
- Rapid heart rate
- Throat irritation or tightness
- Tightening of the muscles that line the airways

- Shortness of breath
- Loose stools

Administration of AZD7442 may induce release of chemicals called cytokines in the body. These chemicals may induce allergic reactions listed above as well as:

- Fever
- Muscle aches
- Nausea
- Vomiting
- Headache
- Dizziness

Some of these reactions may be serious or life-threatening including:

- Skin rash
- Swelling of the face or other soft tissues
- Low blood pressure
- Rapid heart rate
- Throat irritation or tightness
- Tightening of the muscles that line the airways
- Shortness of breath

You will be monitored closely during administration of study drug. Medical personnel, equipment, and medication will be available to manage these reactions appropriately if they occur.

Administration of study drug may also cause the following risks and discomforts:

- Development of proteins (antibodies) against AZD7442. This may cause your body to get rid of AZD7442 more quickly or change the effect of AZD7442 on the body. Your blood will be tested to find out whether your body made antibodies to AZD7442. The anticipated risk of this is low because AZD7442 is a fully human antibody. Therefore, it is less likely to be seen as “foreign” by your body’s immune system and your body is less likely to form antibodies against AZD7442.
- Mixture of antibody and other chemicals in the body that may be deposited in tissues such as blood vessels and kidneys.
- Unexpected increase in virus reproduction in your body. Although this has been observed with some viruses, this has not been observed with COVID-19 or with the use of serum-containing antibodies given to people with COVID-19. This risk of increased viral growth is perhaps greater when there are lower levels of antibodies in the blood in the presence of virus. To avoid this, AZD7442 will be given at a dose that is felt to be high enough to keep this from occurring.

Effect on Future Vaccination

The US Centers for Disease Control and Prevention (CDC) currently recommends that people wait at least 90 days after receiving antibody treatment before receiving a COVID-19 vaccine, because some antibodies remain in the body for about 90 days, and there is a chance that these antibodies could interfere with how your body responds to the vaccine during those 90 days. Some of the antibodies in this study including AZD7442 are designed to remain in the body for longer than 90 days. Although there is no further guidance available, there is a chance

that these longer-lasting monoclonal antibodies could interfere with how your body responds to the vaccine even if you wait at least 90 days for the vaccine.

ARE THERE RISKS RELATED TO PREGNANCY AND BREASTFEEDING?

Pregnancy

Since there are no data regarding the use of this study drug in people who are pregnant, you are not eligible to receive this study drug if you are pregnant.

The study drug may involve risks to you (or to the embryo or fetus, if you or your partner become pregnant), which are currently unforeseen.

If you are engaging in sexual activity that could lead to pregnancy, you must agree to use effective contraception for 24 weeks after the study drugs are administered. Effective contraception includes oral contraceptives, implanted contraceptives, and intrauterine devices (IUDs).

If you are engaging in sexual activity that may lead to pregnancy in your partner, you must agree to either remain abstinent or use male contraceptives. You are also advised to inform your non-pregnant sexual partners that can become pregnant to use effective contraceptives for 24 weeks after the study drugs are administered to you.

If you have a pregnant partner you should use condoms during vaginal intercourse through 24 weeks after the study drugs administered.

If applicable, you should refrain from sperm donation for 24 weeks after study drug administration.

If at any point during the study you think you may be pregnant, you should let the study staff at your study site know so that a pregnancy test can be done.

Let your study doctor know immediately if you become pregnant. If you become pregnant while on the study, you will be asked to continue to have study visits and the study staff would like to obtain information from you about the outcome of the pregnancy (even if it is after your participation in the study ends).

Breastfeeding

It is not known if this study drug is safe to use in people who are breastfeeding. You are not eligible to receive this study drug if you are breastfeeding.

FOR STUDY DRUG AZD7442

ADMINISTERED AS AN INTERMUSCULAR INJECTION

One of the study drugs that you might be assigned to in this study is AZD7442 or the placebo for AZD7442.

AZD7442 is a type of drug called a monoclonal antibody. Many antibodies are naturally made by your body and help fight diseases.



AZD7442 is made in a laboratory. It is a combination of two monoclonal antibodies, meaning many copies of two antibodies designed to prevent SARS-CoV-2, the virus that causes COVID-19, from entering cells.

Your assignment is random, like the flip of a coin. You will be told about all the study drugs you may be assigned to in this study. If only one study drug is available, you will have an equal chance of receiving the study drug or placebo. If two study drugs are available, you will have a 2:1 chance of receiving a study drug or placebo. If three study drugs are available, you will have a 3:1 chance of receiving a study drug or placebo, and so forth. You will not be able to choose your group (study drug), and neither you, your study doctor, nor the study staff at your site will know whether you are receiving the study drug or placebo. However, your study doctor can find out which group you are in if there is an emergency.

The US Food and Drug Administration (FDA) has not approved AZD7442 for general use by the public, therefore, for this study it is considered investigational. An investigational drug is one that is not approved by the United States Food and Drug Administration (FDA). However, we have told the FDA about this study and they have given us permission to conduct this study.

At this time, participants assigned to this study drug will be in the first part of the study (phase II), as described in the main consent.

ARE THERE ANY ADDITIONAL STUDY PROCEDURES IF I RECEIVE AZD7442 OR PLACEBO?

Screening Visit

- At your screening visit, if you can become pregnant, you will be asked to give blood (1 teaspoon) or a urine sample for a pregnancy test. You cannot receive AZD7442 or placebo if you are pregnant.

Entry Visit

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts)
 - Levels of the study drug in your blood (you will have blood drawn before you receive the study drug and again 1 hour after)
 - Levels of antibodies to the study drug (your body's immune response to the study drug)
- You will receive two intramuscular injections of AZD7442 or placebo. The administration will consist of one injection into the outside of the thigh, one in each thigh. You will be monitored for 2 hours after the injection.

Study Visits

Study Visits on Days 3, 7, 14, and 28

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts) (days 3, 14, and 28)
 - Levels of the study drug and/or levels of antibodies to the study drug (your body's immune response to the drug)

Study Visits on Weeks 12 and 24

- You will have blood drawn. This blood will be used for the following tests:
 - Levels of the study drug and levels of antibodies to the drug (your body's immune response to the study drug)
- You will be asked whether you have had any new symptoms or clinical events since your last visit

Study Visits on Weeks 36, 48, and 72

- You will be contacted by phone by the study team to assess whether you have had any new symptoms or clinical events since your last visit.
- You will answer questions about any potential COVID-19 related symptoms or conditions you have experienced

Extra Visits

Approximately 40 participants will be asked to return about 24 hours (1 day) after the Entry visit for an additional blood draw to test levels of the study drug. The site staff will tell you if you may be one of these 40 participants.

HOW LONG WILL I BE IN THIS STUDY?

If you are assigned to AZD7442 or placebo for AZD7442, you will be in this study for 72 weeks.

WHAT ARE THE RISKS OF AZD7442?

There is a risk of serious and/or life-threatening side effects when non-study drugs medications are taken with the study drugs. For your safety, you must tell the study doctor or study nurse about all drugs you are taking before you start the study.

Another risk is that the study drug used in this study may have side effects, some of which are listed below. Additionally, the study drug tested in the study may have unknown side effects in persons with SARS-CoV-2 infection. In a research study, all of the risks or side effects may not be known before you start the study. You need to tell your study doctor or a member of the study team immediately if you experience any side effects.

Please note that these lists do not include all the side effects seen with this study drug. These lists include the more serious or common side effects with a known or possible relationship to the study drug. If you have questions concerning the additional side effects, please ask the study staff at your study site.

Risks Associated with AZD7442

There is limited safety data on AZD7442 since it has not been given to a lot of people. As of December 8, 2020, there have been no serious unexpected effects reported by greater than 100 healthy people taking AZD7442 or placebo to date. Most effects after taking AZD7442 or placebo have been mild or moderate and have either all gone away or are getting better.

This study is likely to be the first study where this study drug is given to people with COVID-19 disease.

Administration of AZD7442 may result in allergic reactions. Signs and symptoms of these reactions include:

- Chills
- Skin rash

████████████████████

- Itching
- Hives
- Swelling of the face or other soft tissues
- Low blood pressure
- Rapid heart rate
- Throat irritation or tightness
- Tightening of the muscles that line the airways
- Shortness of breath
- Loose stools

Administration of AZD7442 may induce release of chemicals called cytokines in the body. These chemicals may induce allergic reactions listed above as well as:

- Fever
- Muscle aches
- Nausea
- Vomiting
- Headache
- Dizziness

Intramuscular injections of any chemical can cause:

- Redness, pain, and/or swelling at the injection site
- Tenderness of the muscle group or soreness with movement
- Ulceration
- Infection

Some of these reactions may be serious or life-threatening including:

- Skin rash
- Swelling of the face or other soft tissues
- Low blood pressure
- Rapid heart rate
- Throat irritation or tightness
- Tightening of the muscles that line the airways
- Shortness of breath

You will be monitored closely during and after administration of study drug. Medical personnel, equipment, and medication will be available to manage these reactions appropriately if they occur.

Administration of study drug may also cause the following risks and discomforts:

- Development of proteins (antibodies) against AZD7442. This may cause your body to get rid of AZD7442 more quickly or change the effect of AZD7442 on the body. Your blood will be tested to find out whether your body made antibodies to AZD7442. The anticipated risk of this is low because AZD7442 is a fully human antibody. Therefore, it is less likely to be seen as “foreign” by your body’s immune system and your body is less likely to form antibodies against AZD7442.
- Mixture of antibody and other chemicals in the body that may be deposited in tissues such as blood vessels and kidneys.
- Unexpected increase in virus reproduction in your body. Although this has been observed with some viruses, this has not been observed with COVID-19 or with the use of serum or

plasma containing antibodies given to people with COVID-19. This risk of increased viral growth is perhaps greater when there is lower levels of antibodies in the blood in the presence of virus. To avoid this, AZD7442 will be given at a dose that is felt to be high enough to keep this from occurring.

Effect on Future Vaccination

The US Centers for Disease Control and Prevention (CDC) currently recommends that people wait at least 90 days after receiving antibody treatment before receiving a COVID-19 vaccine, because some antibodies remain in the body for about 90 days, and there is a chance that these antibodies could interfere with how your body responds to the vaccine during those 90 days. Some of the antibodies in this study including AZD7442 are designed to remain in the body for longer than 90 days. Although there is no further guidance available, there is a chance that these longer-lasting monoclonal antibodies could interfere with how your body responds to the vaccine even if you wait at least 90 days for the vaccine.

ARE THERE RISKS RELATED TO PREGNANCY AND BREASTFEEDING?

Pregnancy

Since there are no data regarding the use of this study drug in people who are pregnant, you are not eligible to receive this study drug if you are pregnant.

The study drug may involve risks to you (or to the embryo or fetus, if you or your partner become pregnant), which are currently unforeseen.

If you are engaging in sexual activity that could lead to pregnancy, you must agree to use effective contraception for 24 weeks after the study drugs are administered. This would include oral contraceptives, implanted contraceptives, or intrauterine devices (IUDs).

If you are engaging in sexual activity that may lead to pregnancy in your partner, you must agree to either remain abstinent or use male contraceptives. You are also advised to inform your non-pregnant sexual partners that can become pregnant to use effective contraceptives for 24 weeks after the study drugs are administered to you.

If you have a pregnant partner you should use condoms during vaginal intercourse through 24 weeks after the study drugs administered.

If applicable, you should refrain from sperm donation for 24 weeks after study drug administration.

If at any point during the study you think you may be pregnant, you should let the staff at your study site know so that a pregnancy test can be done.

Let your study doctor know immediately if you become pregnant. If you become pregnant while on the study, you will be asked to continue to have study visits and the study staff would like to obtain information from you about the outcome of the pregnancy (even if it is after your participation in the study ends).

Breastfeeding

It is not known if this study drug is safe to use in people who are breastfeeding. You are not eligible to receive this study drug if you are breastfeeding.

FOR STUDY DRUG SNG001

One of the study drugs that you might be assigned to in this study is SNG001 or the placebo for SNG001.

SNG001 is an inhalational form of IFN- β -1a. (IFN-b1a) is a class of study drug called an immunomodulator. IFN-b1a are naturally made by your body and help fight diseases. SNG001 is made in a laboratory. It is designed to stimulate an immune response against SARS-CoV-2, the virus that causes COVID-19.

Your assignment is random, like the flip of a coin. You will be told about all the study drugs you may be assigned to in this study. If only one study drug is available, you will have an equal chance of receiving the study drug or placebo. If two study drugs are available, you will have a 2:1 chance of receiving a study drug or placebo. If three study drugs are available, you will have a 3:1 chance of receiving a study drug or placebo, and so forth. You will not be able to choose your group (study drug), and neither you, your study doctor, nor the study staff at your study site will know whether you are receiving the study drug or placebo. However, your study doctor can find out which group you are in if there is an emergency.

At this time, only the first part of this study (as described in the main consent) is enrolling participants.

The United States Food and Drug Administration (FDA) has not approved SNG001 for general use by the public, therefore, for this study it is considered investigational. An investigational drug is one that is not approved by the United States Food and Drug Administration (FDA). However, we have told the FDA about this study and they have given us permission to conduct this study.

At this time, participants assigned to this study drug will be in the first part of the study (phase II), as described in the main consent.

ARE THERE ANY ADDITIONAL STUDY PROCEDURES IF I RECEIVE SNG001 OR PLACEBO FOR SNG001?

Screening Visit

- If you can become pregnant, you will be asked to give blood (1 teaspoon) or a urine sample for a pregnancy test. You cannot receive SNG001 or placebo if you are pregnant.

Entry Visit (Day 0)

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts)
 - Testing if your body has made an immune response against interferons
- Study site staff will show you how to administer SNG001 or placebo to yourself at home using the Aerogen nebulizer.

Study Events and Evaluations Days 0-13

- You will administer SNG001/placebo to yourself by inhalation using a nebulizer once a day for 14 days, at home. The site staff will discuss with you if the first dose may be taken in the

clinic. Each nebulizer study treatment will take approximately 2 minutes. You should administer your SNG001/placebo at about the same time every day.

- You will record whether or not you gave yourself inhaled SNG001/placebo each day for 14 days.

Study Visits on Day 7, 14, 28

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts) (Day 7, 28)
 - Testing if your body has made an immune response against interferons including SNG001
 - Future study-specified testing

Study Visit on Day 14

- You will return the controller cable, wall charger, and sharps container to the study clinic.

Study Visits on Weeks 12 and 24

You will be asked whether you have had any new symptoms or clinical events since your last visit

Study Visits on Weeks 36, 48, and 72

- You will be contacted by phone by the study team to assess whether you have had any new symptoms or clinical events since your last visit.
- You will answer questions about any potential COVID-19 related symptoms or conditions you have experienced

HOW LONG WILL I BE IN THIS STUDY?

If you are assigned to SNG001 or placebo for SNG001, you will be in this study for 72 weeks.

WHAT ARE THE RISKS OF SNG001?

There is a risk of serious and/or life-threatening side effects when non-study drugs medications are taken with the study drugs. For your safety, you must tell the study doctor or study nurse about all drugs you are taking before you start the study.

Risks Associated with Inhaled SNG001

There is limited safety data on inhaled SNG001 since it has not been given to a lot of people. This study will be one of the first studies to give inhaled SNG001 to non-hospitalized participants with COVID-19.

A study of inhaled SNG001 in COVID-19 outpatients was recently started in the UK. As of December 4, 2020, there have been no serious unwanted effects reported by greater than 300 healthy participants with asthma, as well as 100 COVID-19 participants, taking inhaled SNG001. Most effects after taking inhaled SNG001 or placebo for SNG001 have been mild or moderate and have either all gone away or are getting better.

Based on previous studies, administration of inhaled SNG001 may result in

- Fast heart rate
- Coughing
- Deposits of study drug product on the top and back of mouth and throat
- Dry throat

- Hoarseness of voice
- Sneezing
- Tremors
- Headache

There is extensive experience from individuals who have received intravenous injections of IFN- β -1, as this is has been approved for treatment of multiple sclerosis in the United States since 1996. The most common side effects from intravenous injections of IFN- β -1 are mild and short-lived, including flu-like symptoms such as headache, fever, muscle aches, and chills. Rare side effects that have been reported from intravenous injections of IFN- β -1 include severe allergic reactions, low white blood cell counts, liver injury, kidney injury, seizures, depression, and suicidal thoughts. Importantly, since inhaled SNG001 does not result in elevated levels of IFN- β -1 in the blood, systemic side effects seen with intravenous injections of IFN- β -1 are not anticipated with inhaled SNG001.

ARE THERE RISKS RELATED TO PREGNANCY AND BREASTFEEDING?

Pregnancy

There is limited information regarding the use of this study drug in people who are pregnant. More than 1,000 pregnancy outcomes have been reported from individuals who received injections of IFN- β -1 suggest there are no increased risk to you or the embryo or fetus during the first trimester of pregnancy. Experience in the second and third trimester is very limited. Based on information from animal studies, there is possibly an increased risk for loss of pregnancy. You cannot receive SNG001 or placebo if you are pregnant.

The study drug may involve risks to you (or to the embryo or fetus, if you or your partner become pregnant), which are currently unforeseen.

If you are engaging in sexual activity that could lead to pregnancy, you must agree to use effective contraception for 30 days after taking the study drug. This would include oral contraceptives, implanted contraceptives, intrauterine devices (IUDs), and/or barrier methods.

If you are engaging in sexual activity that may lead to pregnancy in your partner, you must agree to either remain abstinent or use male contraceptives. You are also advised to inform your non-pregnant sexual partners that can become pregnant to use effective contraceptives for 30 days after you take the study drug.

If you have a pregnant partner you should use condoms during vaginal intercourse through 30 days after taking the last dose of study drug.

If applicable, you should refrain from sperm donation for 30 days after taking the study drug.

If at any point during the study you think you may be pregnant, you should let the study staff at your study site know so that a pregnancy test can be done.

Let your study doctor know immediately if you become pregnant. If you become pregnant while on the study, the study staff would like to obtain information from you about the outcome of the pregnancy (even if it is after your participation in the study ends).

Breastfeeding

It is not known if this study drug is safe to use in people who are breastfeeding. You are not eligible to receive this study drug if you are breastfeeding.

FOR STUDY DRUG CAMOSTAT

One of the study drugs that you might be assigned to in this study is camostat for 7 days or the placebo for camostat for 7 days.

Camostat is a type of study drug called a protease inhibitor. It blocks certain enzymes, including an enzyme (called TMPRSS2) that sits on human cells and that the novel coronavirus that causes COVID-19 uses to enter the cells. We want to see if camostat will prevent coronavirus from entering cells and thereby reduce the risk of progression to serious disease and death.

Camostat is made in a laboratory.

Your assignment is random, like the flip of a coin. You will be told about all of the study drugs you may be assigned to in this study. If only one study drug is available, you will have an equal chance of receiving the study drug or placebo. If two study drugs are available, you will have a 2:1 chance of receiving a study drug or placebo. If three study drugs are available, you will have a 3:1 chance of receiving a study drug or placebo, and so forth. You will not be able to choose your group (study drug), and neither you, your study doctor, nor the study staff at your study site will know whether you are receiving the study drug or placebo.

The United States Food and Drug Administration (FDA) has not approved camostat for general use by the public, therefore, for this study they are considered investigational. An investigational drug is one that is not approved by the United States Food and Drug Administration (FDA). We have told the FDA about this study and they have given us permission to conduct this study.

At this time, only the first part of this study (as described in the main consent) is enrolling participants.

ARE THERE ANY ADDITIONAL STUDY PROCEDURES IF I RECEIVE CAMOSTAT OR PLACEBO?

Screening

- If you can become pregnant, you will be asked to give blood (1 teaspoon) or a urine sample for a pregnancy test. You cannot receive camostat or placebo if you are pregnant.

Entry Visit

- You will have blood drawn. The blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts)
- You will take the first dose of camostat/placebo. Camostat/placebo is in the form of tablets. Each dose consists of 2 tablets taken at the same time. After the visit, you will continue to take 2 tablets every 6 hours, by mouth, on your own.

Study Drug Dosing and Requirements Days 0-6

- You will take camostat/placebo every 6 hours for 7 days. Camostat/placebo can be taken with food but this is not required. The doses must be separated by at least 2 hours. The study site staff will discuss the timing of doses in detail with you.
- You will record whether or not you took all doses of the study drug (camostat/placebo) each day for 7 days in a Study Drug Log.
- The study staff will review your Study Drug Log with you.

Study Visit Day 3

- The study staff will review your Study Medication Log with you.

Study Visits on Days 7 and 28

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts)
- The study staff will review your Study Drug Log with you and collect the log (Day 7)

Study Visits on Weeks 12 and 24

You will be asked whether you have had any new symptoms or clinical events since your last visit.

Study Visits on Weeks 36, 48, and 72

- You will be contacted by phone by the study team to assess whether you have had any new symptoms or clinical events since your last visit.
- You will answer questions about any potential COVID-19 related symptoms or conditions you have experienced

HOW LONG WILL I BE IN THIS STUDY?

If you are assigned to camostat or placebo for camostat, you will be in this study for 72 weeks.

WHAT ARE THE RISKS OF CAMOSTAT?

It is not known if this study drug will help your disease or if it will make it worse. We do not know all of the possible risks from study treatment with camostat. Camostat is an approved drug for pancreatitis and postoperative reflux esophagitis in Japan and is generally considered safe for these indications. The dosage of camostat for COVID-19 is higher than that used for pancreatitis (800 mg per day for COVID-19 compared to 600 mg per day for pancreatitis and 300 mg per day for postoperative reflux disease). In another study, a daily dose of 900 mg of camostat was well-tolerated.

Common side effects (reported in 1-4 per 1000 patients) include:

- Rash
- Itching
- Nausea
- Abdominal (stomach) bloating
- Abdominal discomfort
- Diarrhea
- Abnormal liver function tests

- Headache

While rare side effects include:

- Allergic reactions
- Decreased platelets (a component of blood that helps with clotting)
- Increased potassium levels in blood

Although data from studies in animals suggest that camostat could be beneficial for patients with COVID-19, the risks and potential benefits to these patients are unknown.

There is a risk of serious and/or life-threatening side effects when non-study drugs are taken with the study drugs. For your safety, you must tell the study doctor or study nurse about all medications you are taking before you start the study.

ARE THERE RISKS RELATED TO PREGNANCY AND BREASTFEEDING?

Pregnancy

Since there are no data regarding the use of this study drug in people who are pregnant, you are not eligible to receive this study drug if you are pregnant.

The study drug may involve risks to you (or to the embryo or fetus, if you or your partner become pregnant), which are currently unforeseen.

If you are engaging in sexual activity that could lead to pregnancy, you must agree to use effective contraception from the time you start the study through 90 days after the study drugs are last taken. This would include oral contraceptives, implanted contraceptives, intrauterine devices (IUDs), and/or barrier methods.

If you are engaging in sexual activity that may lead to pregnancy in your partner, you must agree to either remain abstinent or use male contraceptives. You are also advised to inform your non-pregnant sexual partners that can become pregnant to use effective contraceptives from the time you start the study through 90 days after you last take the study drug.

If you have a pregnant partner you should use condoms during vaginal intercourse from the time you start the study through 90 days after you last take the study drug.

If applicable, you should refrain from sperm donation from the time you start the study through 90 days after you last take the study drug.

If at any point during the study you think you may be pregnant, you should let the study staff at your study site know so that a pregnancy test can be done.

Let your study doctor know immediately if you become pregnant. If you become pregnant while on the study, you will be asked to stop the study drug, but you will continue to have study visits and the study staff would like to obtain information from you about the outcome of the pregnancy (even if it is after your participation in the study ends).

Breastfeeding

It is not known if this study drug is safe to use in people who are breastfeeding. You are not eligible to receive this study drug if you are breastfeeding.

FOR STUDY DRUG SAB-185

One of the study drugs that you might be assigned to in this study is the SAB-185 or the placebo.

SAB-185 is a type of drug called a polyclonal antibody. Many antibodies are naturally made by your body and help fight diseases. SAB-185 is made by cows that are genetically engineered to make human antibodies. Blood is collected from these cows and the antibodies are separated out and purified so they can be given to humans. “Polyclonal” means that SAB-185 is made up of several different antibodies.

Your assignment is random, like the flip of a coin. You will be told about all the study drugs you may be assigned to in this study. If only one study drug is available, you will have an equal chance of receiving the study drug or placebo. If two study drugs are available, you will have a 2:1 chance of receiving a study drug or placebo. If three study drugs are available, you will have a 3:1 chance of receiving a study drug or placebo, and so forth. You will not be able to choose your group (study drug), and neither you, your study doctor, nor the study staff at your site will know whether you are receiving the study drug or placebo.

The United States Food and Drug Administration (FDA) has not approved SAB-185 for general use by the public. However, we have told the FDA about this study and they have given us permission to conduct this study.

Screening Visit

- At your screening visit, if you can become pregnant, you will be asked to give blood (1 teaspoon) or a urine sample for a pregnancy test. You cannot receive SAB-185 or placebo if you are pregnant.

Entry Visit

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts)
 - Levels of the study drug in your blood
 - Levels of antibodies to the study drug (your body’s immune response to the study drug)
- You will have the infusion of SAB-185 or placebo for SAB-185. The infusion will be given through a small plastic tube that will be placed into a vein in your arm. This is called an intravenous (IV) infusion. The infusions will take approximately 50 minutes. You will be monitored in the clinic for 2 hours after the end of the infusions.

Study Visits

After the Entry visit, your study visits and evaluations will be different depending on whether you are in the first part of the study or the second part of the study.



IF YOU ARE IN THE FIRST PART OF THE STUDY:

Study Visits on Days 3, 7, 14, 28, and 45, Week 12, and Week 24

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts) (Day 3, 14, and 28)
 - Levels of the study drug
 - Levels of antibodies (your body's immune response to the study drug)
- You will be asked whether you have had any new symptoms or clinical events since your last visit (Week 12 and 24)

Study Visits on Weeks 36, 48, and 72

- You will be contacted by phone by the study team to assess whether you have had any new symptoms or clinical events since your last visit
- You will answer questions about any potential COVID-19 related symptoms or conditions you have experienced

IF YOU ARE IN THE SECOND PART OF THE STUDY:

Study Visit on Day 28

- You will have blood drawn. This blood will be used for the following tests:
 - Routine safety tests (liver and kidney tests and blood counts)
 - Levels of the study drug
 - Levels of antibodies (your body's immune response to the study drug)

Study Visits on Week 12 and Week 24

- You will have blood drawn. This blood will be used for the following tests:
 - For future study-required testing
 - Levels of the study drug
 - Levels of antibodies to the study drug (your body's immune response to the study drug)
- You will be asked whether you have had any new symptoms or clinical events since your last visit.

Study Visits on Weeks 36, 48, and 72

- You will be contacted by phone by the study team to assess whether you have had any new symptoms or clinical events since your last visit.
- You will answer questions about any potential COVID-19 related symptoms or conditions you have experienced.

HOW LONG WILL I BE IN THIS STUDY?

If you are assigned to SAB-185 or placebo for SAB-185, you will be in this study for 72 weeks.

WHAT ARE THE RISKS OF SAB-185?

There is a risk of serious and/or life-threatening side effects when non-study medications are taken with the study drugs. For your safety, you must tell the study doctor or study nurse about all medications you are taking before you start the study.



Another risk is that the study drugs used in this study may have side effects, some of which are listed below. Additionally, the study drug tested in the study may have unknown side effects in persons with SARS-CoV-2 infection. In a research study, all of the risks or side effects may not be known before you start the study. You need to tell your study doctor or a member of the study team immediately if you experience any side effects.

Please note that these lists do not include all the side effects seen with this study drug.

These lists include the more serious or common side effects with a known or possible relationship to the study drug. If you have questions concerning the additional side effects, please ask the study staff at your site.

Risks Associated with SAB-185

There is limited safety data on SAB-185 since it has not been given to a lot of people. To date, 28 healthy volunteers and 21 participants positive for COVID-19 have received infusions of SAB-185 in a separate study. There have been no reports so far of serious infusion-related reactions, allergic reactions, moderate to severe adverse events, or any adverse events requiring discontinuation of study therapy.

SAB-185 is produced in the same way as another product known as SAB-301. It is believed that SAB-185 and SAB-301 will have a similar safety profile. In a study of SAB-301, the most common adverse events were headache, increased levels of albumin in urine (may be a sign of kidney damage), increased levels of creatine kinase in blood (may be a sign of muscle damage), and common cold. These adverse events were reported at approximately the same frequency in persons who received SAB-301 as in persons who received a placebo.

Administration of antibodies, such as SAB-185 can result in allergic reactions. Signs and symptoms of these reactions include:

- Chills
- Skin rash
- Itching
- Hives
- Swelling of the face or other soft tissues
- Low blood pressure
- Rapid heart rate
- Throat irritation or tightness
- Tightening of the muscles that line the airways
- Shortness of breath
- Loose stools

Administration of antibodies, such as SAB-185 may induce release of chemicals called cytokines in the body. These chemicals may induce allergic reactions listed above as well as:

- Fever
- Muscle aches
- Nausea
- Vomiting
- Headache
- Dizziness

Some of these reactions may be serious or life-threatening including:

- Skin rash
- Swelling of the face or other soft tissues
- Low blood pressure
- Rapid heart rate
- Throat irritation or tightness
- Tightening of the muscles that line the airways
- Shortness of breath

You will be monitored closely during administration of study drug. Medical personnel, equipment, and medication will be available to manage these reactions appropriately if they occur.

Administration of antibodies, such as SAB-185 can cause the following risks and discomforts:

- Development of proteins (antibodies) against SAB-185. This may cause your body to get rid of SAB-185 more quickly or change the effect of these agents on the body. Your blood will be tested to find out whether your body made antibodies to SAB-185. The anticipated risk of this is low because SAB-185 is a fully human antibody. Therefore, it is less likely to be seen as “foreign” by your body’s immune system and your body is less likely to form antibodies against them.
- Mixture of antibody and other chemicals in the body that may be deposited in tissues such as blood vessels and kidneys.
- Unexpected increase in virus reproduction in your body. Although this has been observed with some viruses, this has not been observed with COVID-19 or with the use of serum-containing antibodies given to people with COVID-19. This risk of increased viral growth is perhaps greater when there are lower levels of antibodies in the blood in the presence of virus. To avoid this, SAB-185 will be given at a dose that is felt to be high enough to keep this from occurring.

Effect on Future Vaccination

The US Centers for Disease Control and Prevention (CDC) currently recommends that people wait at least 90 days after receiving antibody treatment before receiving a COVID-19 vaccine, because some antibodies remain in the body for about 90 days, and there is a chance that these antibodies could interfere with how your body responds to the vaccine during those 90 days. Some of the antibodies in this study including SAB-185 are designed to remain in the body for longer than 90 days. Although there is no further guidance available, there is a chance that these longer-lasting antibodies could interfere with how your body responds to the vaccine even if you wait at least 90 days for the vaccine.

ARE THERE RISKS RELATED TO PREGNANCY AND BREASTFEEDING?

Pregnancy

Since there are no data regarding the use of this study drug in people who are pregnant, you are not eligible to receive this study drug if you are pregnant.

The study drug may involve risks to you (or to the embryo or fetus, if you or your partner become pregnant), which are currently unforeseen.

If you are engaging in sexual activity that could lead to pregnancy, you must agree to use effective contraception for 24 weeks after the study drugs are administered. This would include oral contraceptives, implanted contraceptives, intrauterine devices, and/or barrier methods.

If you are engaging in sexual activity that may lead to pregnancy in your partner, you must agree to either remain abstinent or use male contraceptives. You are also advised to inform your non-pregnant sexual partners that can become pregnant to use effective contraceptives for 24 weeks after the study drugs are administered to you.

If you have a pregnant partner you should use condoms during vaginal intercourse through 24 weeks after the study drugs are administered.

If applicable, you should refrain from sperm donation for 24 weeks after study drug administration.

If at any point during the study you think you may be pregnant, you should let the study staff at your site know so that a pregnancy test can be done.

Let your study doctor know immediately if you become pregnant. If you become pregnant while on the study, the study staff would like to obtain information from you about the outcome of the pregnancy (even if it is after your participation in the study ends).

Breastfeeding

It is not known if this study drug is safe to use in people who are breastfeeding. You are not eligible to receive this study drug if you are breastfeeding.

SIGNATURE PAGE

Sites should mark agents that do not apply to the subject with “N/A” before presenting to the subject.

Consent forms for the following study drugs were reviewed (initial if reviewed with you):

_____ (initials) BR11-196 and BR11-198 INTRAVENOUS ADMINISTRATION

_____ (initials) AZD7442 INTRAVENOUS ADMINISTRATION

_____ (initials) AZD7442 INTRAMUSCULAR ADMINISTRATION

_____ (initials) SNG001 INHALATION ADMINISTRATION

_____ (initials) CAMOSTAT ORAL ADMINISTRATION

_____ (initials) SAB-185 INTRAVENOUS ADMINISTRATION

If you have read this consent form addendum (or had it explained to you), all your questions have been answered and you agree to take part in this study, please sign and date your name below.

Participant’s Name (print)

Participant’s Signature and Date

Participant’s Legally Authorized Representative
(print) (As appropriate)

Legally Authorized Representative
Signature and Date

Study Staff Conducting Consent Discussion
(print)

Study Staff’s Signature and Date

Witness’s Name (print)
(As appropriate)

Witness’s Signature and Date

