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: (Study Doctor)	[redacted]
Telephone:	[redacted]
Address:	[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 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.

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.

ARE THERE ANY ADDITIONAL STUDY PROCEDURES IF I AM ASSIGNED TO 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 participate in the study if you are pregnant.

After the Screening 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 (PHASE II, COMPARISON TO PLACEBO)

Entry Visit (Day 0)

- 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 or 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 or placebo at about the same time every day.
- You will record whether or not you gave yourself inhaled SNG001 or 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)

Study Visit on Day 14
- You will return the controller cable, wall charger, and sharps container to the study clinic.

IF YOU ARE IN THE SECOND PART OF THE STUDY (PHASE III, COMPARISON TO CASIRIVIMAB PLUS IMDEVIMAB) AND ARE ASSIGNED TO SNG001:

Entry Visit (Day 0)
- Site staff will show you how to administer SNG001 to yourself at home using the Aerogen nebulizer.

Study Events and Evaluations Day 0-13
- You will administer SNG001 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 at about the same time every day.
- You will record whether or not you gave yourself inhaled SNG001 each day for 14 days.

Study Visit on Day 28
- You will return the controller cable, wall charger, and sharps container to the study clinic.

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 April 23, 2021, there have been no serious unwanted effects reported by greater than 300 healthy participants with asthma, as well as greater than or equal to 100 non-hospitalized COVID-19 participants, taking inhaled SNG001. There has been one report of bronchospasm (Narrowing and obstruction of breathing) following administration of either SNG001 or placebo in a hospitalized subject with COVID-19. 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
- Wheezing
- Narrowing of airways which can cause shortness of breath
- 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 participate in the study 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 SAB-185

A study drug that you might be assigned to in this study is one of two doses of the SAB-185 or the placebo. Each dose of SAB-185 is considered a separate study drug in the study.

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.

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 participate in the study if you are pregnant.

After the Screening 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 (PHASE II, COMPARISON TO PLACEBO)

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.

Extra Visits

Approximately 56 participants (28 per dose group) 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 56 participants.

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)

IF YOU ARE IN THE SECOND PART OF THE STUDY (PHASE III, COMPARISON TO CASIRIVIMAB PLUS IMDEVIMAB) AND ARE ASSIGNED TO SAB-185:

Entry Visit

- You will have blood drawn. This blood will be used for the following tests:
  - 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. 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 on Day 28 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)

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. As of February 2021, 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 cannot participate in the study 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.

FOR STUDY DRUGS BMS-986414 (C135-LS) and BMS-986413 (C144-LS)

A study drug that you might be assigned to in this study is called BMS-986414 (C135-LS) combined with BMS-986413 (C144-LS).

BMS-986414 (C135-LS) and BMS-986413 (C144-LS) are both a type of study drug called a monoclonal antibody (mAb). Many antibodies are naturally made by your body and help fight diseases. BMS-986414 (C135-LS) and BMS-986413 (C144-LS) are made in a laboratory. "Monoclonal" means that BMS-986414 (C135-LS) and BMS-986413 (C144-LS) are each made up of many copies of each of these antibodies.

The United States Food and Drug Administration (FDA) has not approved BMS-986414 (C135-LS) and BMS-986413 (C144-LS) 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.

ARE THERE ANY ADDITIONAL STUDY PROCEDURES IF I RECEIVE BMS-986414 (C135-LS) and BMS-986413 (C144-LS) OR PLACEBO?

Screening Visit
At your screening visit, if you are able to become pregnant, you will be asked to give blood (1 teaspoon) or a urine sample for a pregnancy test. You cannot participate in the study if you are pregnant.

After the Screening 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 (PHASE II, COMPARISON TO PLACEBO)

Entry Visit
- You will have blood drawn that will be used for:
    - Routine safety tests (liver and kidney tests and blood counts)
    - Measurement of the levels of study drug in your blood
    - Measurement of the levels of antibodies to the study drug (your body's immune response to the study drug)
- Your vital signs (temperature, heart rate, respiratory rate, blood pressure and oxygen level in your blood) will be measured before you receive your study drug.
- The study drug will be administered as either 4 injections or 2 injections that will be given subcutaneously (under the skin), one right after the other, at separate sites in either your abdomen, thigh, or upper arms. You will be monitored in the clinic every 30 minutes for two hours after you receive the injections.

Study Visit on Day 1
If you are one of the approximately 40 participants who will have an additional blood sample collected, you will have blood drawn to measure the level of study drug in your blood.

Study Visits on Days 3, 7, 14, and 28, Week 12, Week 24, Week 48, and Week 72
- You will have blood drawn:
    - For routine safety tests (liver and kidney tests and blood counts) (Days 3, 14, and 28)

- To measure the levels of the study drug and levels of antibodies to the study drug (your body's immune response to the study drug)

IF YOU ARE IN THE SECOND PART OF THE STUDY (PHASE III, COMPARISON TO CASIRIVIMAB PLUS IMDEVIMAB) AND ARE ASSIGNED TO BMS-986414 (C135-LS) AND BMS-986413 (C144-LS):

Entry Visit

- You will have blood drawn that will be used for:
  - Measurement of the levels of study drug in your blood
  - Measurement of the levels of antibodies to the study drug (your body's immune response to the study drug)
- The study drug will be administered as either 4 injections or 2 injections that will be given subcutaneously (under the skin), one right after the other, at separate sites in either your abdomen, thigh, or upper arms. You will be monitored in the clinic every 30 minutes for two hours after you receive the injections.

Study Visits on Days 3, Day 28, Week 24

- You will have blood drawn that will be used for:
  - Measurement of the levels of study drug in your blood
  - Measurement of the levels of antibodies to the study drug (your body's immune response to the study drug)

WHAT ARE THE RISKS OF BMS-986414 (C135-LS) and BMS-986413 (CS144-LS)?

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.

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 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 BMS-986414 (C135-LS) and BMS-986413(CS144-LS)

There is limited safety data on BMS-986414 (C135-LS) and BMS-986413 (CS144-LS) since they have not been given to a lot of people. As of March 19, 2021, 23 healthy participants have received injections or infusions of BMS-986414 (C135-LS) and BMS-986413 (CS144-LS) in studies.

As of 12 March 2021, eight participants in these studies have reported mild adverse events (negative symptoms):

- Itching at the injection site

- Lightheadedness
- Temporary tingling or “pins and needles” sensation during infusion of the mAbs.

No abnormal lab values have been noted and none of these events required discontinuation of study treatment.

Administration of mAbs such as BMS-986414 (CS135-LS) and BMS-986413 (CS144-LS) can result in allergic reactions. Signs and symptoms of these reactions include:

- Chills
- Skin rash
- Itching
- Hives
- Flushing (reddening) of the skin
- 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 BMS-986414 (CS135-LS) and BMS-986413 (CS144-LS) may theoretically induce release of chemicals called cytokines in the body. Cytokine release syndrome can be serious, potentially life-threatening. The release of these chemicals has not been observed in laboratory studies of BMS-986414 (CS135-LS) and BMS-986413 (CS144-LS). 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 BMS-986414 (CS135-LS) and BMS-986413 (CS144-LS) can also cause the following risks and discomforts:

- Development of proteins (antibodies) against BMS-986414 (CS135-LS) and BMS-986413 (CS144-LS). This may cause your body to get rid of BMS-986414 (CS135-LS) and BMS-986413 (CS144-LS) 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 BMS-986414 (CS135-LS) and BMS-986413 (CS144-LS). The anticipated risk of this is low because BMS-986414 (CS135-LS) and BMS-986413 (CS144-LS) 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.
- Binding of mAbs to other chemicals in the body that may be deposited in tissues such as blood vessels or organs such as kidneys. In the kidneys, this could lead to inflammation and kidney disease.
- An unexpected increase in SARS-CoV-2 virus reproduction in your body. Increases in virus reproduction have been observed with some other viruses when people have antibodies to these viruses. However, increases in SARS-CoV-2 virus reproduction are not known to occur in people given mAbs or serum-containing antibodies for COVID-19. The theoretical risk of increased virus reproduction is perhaps greater when there are lower levels of antibodies in the blood in the presence of virus. To avoid this, BMS-986414 (CS135-LS) and BMS-986413 (CS144-LS) 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 BMS-986413 (CS135-LS) and BMS-986414 (CS144-LS) 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

You cannot participate in the study if you are pregnant because there are no data regarding the use of this study drug in people who are pregnant.

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

If you are reproductive potential, and if you engage in sexual activity that could lead to pregnancy, you must agree to use highly effective contraception for 48 weeks after the study drugs are administered. This includes oral contraceptives, implanted contraceptives, and intrauterine devices (IUDs).

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

You are not eligible to receive this study drug if you are breastfeeding because it is not known if this study drug is safe to use in people who 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) SNG001 INHALATION ADMINISTRATION

_____ (initials) SAB-185 INTRAVENOUS ADMINISTRATION

_____ (initials) BMS-986414 (CS135-LS) and BMS-986413 (CS-144LS) SUBCUTANEOUS 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	Date
Participant's Legally Authorized Representative (As appropriate) (print)	Legally Authorized Representative Signature	Date
Study Staff Conducting Consent Discussion (print)	Study Staff's Signature	Date
Witness's Name (print) (As appropriate)	Witness's Signature	Date