Participant Information Sheet and Consent Form (BCNS)

Protocol Title	A Phase I/IIa Study of the Efficacy and Safety of ASN-002 Alone or in Combination with 5-Fluoruracil (5-FU) in Adult Patients with Low-Risk Nodular Basal Cell Carcinoma
Protocol Number:	ASN-002-001
PISCF Version #/Date	Version 1.0, 03 Jul 2017
Study Sponsor	Ascend Biopharmaceuticals Ltd.
Principal Investigator	Dr Gregory Siller
Site	1. Central Brisbane Dermatology: Level 9, Silverton Place, 101 Wickham Terrace, Brisbane QLD 4000 2. Q-Pharm Pty Limited: 300C Herston Road, Herston QLD 4006

Participant Identification

Participant's full name
(in BLOCK LETTERS) _____

(to be completed by the participant)

PART 1 What does my participation in this study involve?

1. Introduction

You are invited to take part in this research project because you are in general good health but have been diagnosed with Basal Cell Nuvus Syndrome (BCNS) and have multiple basal cell carcinoma (BCC) tumors.

This research project is testing the safety and effectiveness (efficacy) of ASN-002, (an experimental treatment being developed by the study sponsor, Ascend Biopharmaceuticals) alone or in combination with 5-Fluorouracil (5-FU), an anticancer chemotherapy drug. The study will also look at the changes in your BCC(s) over time, when ASN-002 alone or in-combination with 5-FU is administered directly into the BCC(s) by intra-tumoural injection.

This Participant Information Sheet and Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not you want to take part, you might want to talk about it with a relative, friend or your local doctor.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign a Consent Form (the final page of this document). By signing the Consent Form, you are telling us that you:

- Understand what you have read;
- Consent to take part in the research project;

- Consent to have the tests and treatments that are described;
- Consent to use of your personal and health information as described.

If there is anything you do not understand about this study or about the experimental treatment after you have read this Participant Information Sheet, please ask the Study Doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any time.

Central Brisbane Dermatology is based at Silverton Place on Wickham Terrace in the Brisbane CBD. This study is being conducted at the Central Brisbane Dermatology clinic, and at the Q-Pharm clinic at the Royal Brisbane Hospital Complex at Herston. We have indicated the location of each stage of the study in this Participant Information Sheet.

The study has been reviewed by the Bellberry Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007 – Updated May 2015). We will follow the Australian National Health and Medical Research Council's guidelines when conducting this study.

You will be given a copy of both the Participant Information Sheet, and the signed Consent Form to keep.

You will be asked to provide a photo ID at every visit to Central Brisbane Dermatology and Q-Pharm for this study.

2. What is the purpose of this research?

BCC is the most common malignant skin cancer in Caucasians, particularly in Australia. Currently, the main treatment for BCC is surgical excision (cutting the tumour out), but this can be clinically complex to perform especially with wound closures, can cause scarring and is cumbersome, especially when many lesions are present. Other treatments include cryosurgery (application of intense cold), radiation therapy (strong beams of energy), and photodynamic surgery (nontoxic light-sensitive compounds that are exposed selectively to light), which are generally not as effective.

BCNS, also known as Gorlin Syndrome or Gorlin–Goltz Syndrome, as you probably are well aware, is a rare, inherited disorder that was first described by Gorlin and Goltz in 1960. While rarely life-threatening, BCNS significantly diminishes patient quality of life because of the multiple cancerous skin lesions that appear predominantly on the head, neck and trunk. The numerous BCCs that occur in affected individuals are usually very frustrating for both affected individuals and their dermatologists because of their sheer number and recurring nature, requiring frequent and individual therapy.

Therefore, the sponsor of the study, Ascend Biopharmaceuticals, is developing ASN-002, which the Sponsor is investigating as a potential treatment for BCCs in individuals with the BCNS.

ASN-002 is an experimental product. 'Experimental' means that the product is currently being tested and has not been approved by any government agency for routine use in people. In Australia, new medications, treatments, drugs and devices have to be approved for human use by the Australian Federal Government. ASN-002, the experimental study product, has not been approved for use by the Therapeutics Goods Administration (TGA) in Australia (and is not yet approved anywhere else in the world).

ASN-002 is a suspension of genetically modified adenovirus particles. Adenoviruses are a type of virus which most commonly cause illness of the respiratory system e.g. the common cold. Normally, when a virus infects a cell in your body, the viral DNA (**d**eoxyribo**n**ucleic **a**cid), or genetic code, is incorporated into the infected cell. The viral DNA then tells the infected cell to make more and more viral particles, which break out of the infected cell in order to infect other cells.

The virus particles in ASN-002 have been modified in two ways:

1. The viral DNA has been changed to include a human gene, which tells the infected cells to produce human interferon gamma (IFNγ). IFNγ is a protein produced naturally by the body's immune system in response to infection, cancer or foreign bodies (things which are not supposed to be in the body). It has a variety of important roles in the functioning of the immune system and has been found to boost the immune system's activity against tumours.
2. The viral DNA has also been changed so that the infected cells cannot make more viral particles i.e. the viral 'infection' of the cells within the tumour, cannot spread outside of the area where ASN-002 is injected.

Fluorouracil is an anti-cancer ("antineoplastic" or "cytotoxic") chemotherapy drug. Fluorouracil is classified as an "antimetabolite". Antimetabolites are very similar to normal substances within the cell, but they are different enough that when the cells incorporate these substances into the cellular metabolism, they are unable to divide and hence die. 5-FU is used in higher doses than will be used in this study to treat different types of cancers, including breast, bowel, stomach, oesophagus, pancreatic, head and neck, cervical, bladder and skin cancers. 5-FU is also available as topical cream to treat BCC and actinic keratosis (a pre-cancerous skin condition).

It is hoped that by injecting ASN-002 directly into the tumour, the tumour cells and normal cells within the tumour will produce localized amounts of IFNγ, thus allowing the anti-tumour properties of IFNγ to act locally on the tumour cells, as well as boosting the activity of the immune system to react against BCC, whether directly injected or not. It is also hoped that the anti-tumour activity of 5-FU will not only kill some tumour cells by itself, but also make the tumour cells more sensitive to the anti-tumour effects of the IFNγ.

This study will evaluate the safety and effectiveness of ASN-002 alone or in combination with 5-FU (Study drug(s)), and the changes in your BCC(s) over time.

ASN-002 alone or in combination with 5-FU will be injected directly into your tumour once a week for 3 weeks or on week 1 and week 3, based upon the treatment groups (Cohorts) you are in. Three or four BCC tumors will be injected concurrently.

This study is being sponsored in Australia by Ascend Biopharmaceuticals Ltd. A sponsor company financially supports a study and takes responsibility for the overall conduct of the study.

3. What does participation in this research involve?

Before you begin the study, you will attend the Central Brisbane Dermatology clinic for an initial assessment visit (screening visit). This Participant Information Sheet gives you detailed information about the experimental study treatment, the study procedures, and other relevant information, which will also be explained to you by the research staff. You can discuss any of these details with the Study Doctor. You are encouraged to ask questions until you are sure that you fully understand the nature and requirements of the study.

If you decide you would like to participate in the study, you will be asked to sign the consent form at the end of this document, before any procedures are undertaken. You will then have some tests to check that the study is suitable for you. The screening visit may take between 1 and 2 hours. When results of the examinations performed at this visit are available, the study staff will confirm whether the trial is suitable for you, and which cohort you are in. You will be asked questions about the BCCs you have had in the past, other problems you have related to BCNS and the results of any genetic testing you have had previously.

This study will be conducted in up to 54 participants, comprising initial cohorts (groups) of 3-6 patients. Depending on the results, one of these cohorts may be extended to include 24 participants. You will attend Q-Pharm to receive ASN-002 alone or in combination with 5-FU once a week for three weeks or at week 1 and week 3. You will attend the Central Brisbane Dermatology clinic to undergo surgical

excision of your BCC(s), 6 months following your first dose of ASN-002 alone or in combination with 5-FU. The surgical removal of the treated and other untreated BCC lesions is required regardless of whether the lesion has reduced in size or remains visible or not.

All volunteers will be aged 18 years and over. You will be required to attend an outpatient visit at either Central Brisbane Dermatology and/or Q-Pharm for all screening, treatment and follow up visits.

Your total participation in the study will be approximately 7 months with 3-4 tumors injected concrurrently once a week for 3 weeks, then monthly follow up visits until the week prior to your surgery to remove your BCC(s), and another follow up visit one month after your surgery.

You will be required to attend the Central Brisbane Dermatology and/or Q-Pharm clinics for about 9 – 11 outpatient visits (including a screening visit). The Screening visit could take approximately 3 hours, depending on whether or not a biopsy needs to be done. You will be required to stay at the Q-Pharm clinic approximately 3 hours for the first treatment visit (including 2 hours of observation after you receive the ASN-002), and for approximately 2 hours for the second and third treatment visits (including 1 hour of observation after you receive the ASN-002).

Screening visit (week 0 – up to 15 days before your first study treatment day) – Central Brisbane Dermatology and Q-Pharm.

The study doctor will perform a medical examination to ensure that your general health does not preclude you from taking part in the study.

- You will be asked about previous medical problems, your current health and any medications you may be taking. You will undergo a physical examination. This will include an assessment of your overall appearance, heart and lung review, review and palpation of abdominal area, examination of arms and legs or any other area of the body that may be giving you symptoms or appear abnormal. You will be required to disrobe sufficiently to permit adequate, appropriate physical examination.
- You will have your vital signs (i.e. blood pressure, heart rate, respiratory rate and oral temperature), recorded along with your height and weight.
- A biopsy of your BCC(s) lesion will be performed if not performed previously as part of your routine clinical check.

Following these assessments you will attend the Q-Pharm clinic where the following will be performed:

- You will be asked to provide blood and urine samples to assess your general health, and immune system.
- A blood sample will be collected for pregnancy testing if your are female.

If for any reason, the trial is found to be not suitable for you, staff from Central Brisbane Dermatology will contact you and provide follow-up treatment advice if applicable.

Treatment visits (Weeks 1, 2 and 3) – Central Brisbane Dermatology and/or Q-Pharm

If you are eligible to enter the study, you will be required to attend a number of outpatient visits at the Central Brisbane Dermatology and/or Q-Pharm clinics for dosing. Your study doctor will inform you about the cohort you are enrolled for and about your future clinical visits as a study participant. The first outpatient visit will take approximately 3-4 hours and subsequent outpatient visits approximately 2 hours.

Prior to your dose on treatment visits (weeks 1, 2 & 3), you will first attend Central Brisbane Dermatology where photographs of the BCC(s) lesion site will be taken (you will not be identifiable from the photographs). Following the photography of your lesion, and for all other dosing visits, you will attend the Q-Pharm clinic where the following will be performed:

- Before you receivestudy drug(s), your vital signs (heart rate, blood pressure, respiratory rate and oral temperature) will be measured.

- A physical examination will be conducted IF clinically indicated. You may have to remove some of your clothing for this.
- Blood and urine samples will be collected for routine measurements including clinical laboratory safety testing, baseline assessments, and testing of your immune system.
- If you are female a urine pregnancy test will be performed.
- The study drug ASN-002 will be injected first. If you are in a combination Cohort, the ASN-002 injections will be followed 30-60 minutes later by the 5-FU. Both injections are given intra-tumorally (directly into the BCC(s)).
- Vital sign measurements will be performed immediately, 30 minutes and 60 minutes after the treatment while in the unit.

You must remain at the Q-Pharm clinic for at least 2 hours following the injections in first treatment visit and at least 1 hour following the injections, in the remaining treatment visits, so that your safety can be monitored. The study staff will make sure you are well before you leave the clinic.

Phone call follow ups (day 2 and day 3 after each injection)

You will be followed up by phone on Day 2 and Day 3 after each administration of ASN-002. In the event of any health problems, you may be asked to attend the Central Brisbane Dermatology or Q-Pharm clinics to be evaluated by a study doctor.

Follow-up Visits (Month 1, 2, 3 and 4) – Central Brisbane Dermatology and Q-Pharm

You will be followed up at monthly intervals following the last administration of ASN-002 (alone or in combination with 5-FU). You will be required to return to the Central Brisbane Dermatology and Q-Pharm monthly. The following procedures will be performed at Central Brisbane Dermatology at the follow-up visits:

- Physical examination (limited to the injection site, and if required clinically)
- Vital signs
- BCC lesion photography and response evaluation of all BCC lesions including any that have appeared since your screening examination

Following the completion of these assessments you will attend the Q-Pharm clinic where the following will be performed:

- Safety blood samples
- Blood for testing of your immune system

Pre-Surgery Visit and Surgery (Month 6) - Central Brisbane Dermatology and Q-Pharm

Prior to your surgery you will be required to attend an outpatient visit at Central Brisbane Dermatology and Q-Pharm for a pre-surgery visit. The following procedures will be performed:

- A complete physical examination. This will include an assessment of your overall appearance, heart and lung review, review and palpation of abdominal area, examination of arms and legs or any other area of the body that may be giving you symptoms or appear abnormal. You will be required to disrobe sufficiently to permit adequate, appropriate physical examination.
- Vital signs
- Lesion photography of the BCC lesions being treated
- An assessment of the BCC lesions

After these assessments you will attend Q-Pharm for the following procedures:

- Blood and urine samples for safety testing and and immune system assessment

At the surgery visit you will be required to attend an outpatient visit at Central Brisbane Dermatology. At this visit you will be given a local anaesthetic and your BCC lesions will be removed. The surgical removal of the treated BCC lesions is required regardless of whether the lesion has reduced in size or remains visible or not.

Surgery Follow up Visit - Central Brisbane Dermatology

A month after the surgery visit you will be required to attend an outpatient visit (week 21) at Central Brisbane Dermatology to review the outcome of surgery.

Thereafter, will we ask you or your doctor from time to time how you are doing, and in particular, how many new BCCs you have developed and what therapies you have received.

4. What do I have to do?

It is important for your own safety that you inform us of your complete medical history and all medications/supplements/herbal preparations that you are taking at the time of enrolment into the study and that you take during the study. You will be required to provide this information at each study visit, and will be asked how you are feeling. If you notice any health problems, please notify your study doctor immediately. You must always follow the instructions of the study doctor and staff.

Note that smoking or recreational drug use is not permitted in the Q-Pharm clinic or at Central Brisbane Dermatology.

You will receive a document from Q-Pharm called 'Code of Conduct'. For your own safety, we ask that you obey without exception, the rules listed in this document. If you do not obey these rules and regulations you may be withdrawn from the study.

You will be given a Participant Identification (ID) wallet card which shows you are a participant in a clinical study, and gives you the contact telephone numbers for the study staff. You must always carry with you the Participant ID Card that you have been given until the end of the study.

5. Other relevant information about the research project

This study is being conducted at four study centres in Australia, one of which is Central Brisbane Dermatology/Q-Pharm. Approximately 54 participants across Australia may be enrolled into this study, however, depending on the results, the study sponsor may decide to run additional groups.

A description of this clinical trial will be available on http://www.anzctr.org.au/, and https://clinicaltrials.gov/ as required by Australian and USA law.

6. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with Central Brisbane Dermatology or Q-Pharm and will not involve any penalty or loss of benefits to which you would be otherwise entitled.

Before you make your decision on whether or not to take part in the study, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want. Sign the Consent Form at the end of this document **only** if you agree to participate and only after you have had a chance to ask your questions and have received satisfactory answers.

7. What are the alternatives to participation?

Participation in this study is not your only option. Your other options are standard of care, which includes surgical removal of a BCC lesion, and/or cryosurgery (application of intense cold), radiation therapy (strong beams of energy), and photodynamic surgery (nontoxic light-sensitive compounds that are exposed selectively to light, whereupon they become toxic to the BCC(s)). This study differs from standard treatment by delaying the time that standard treatment would be administered by 7 months. You should discuss your options with the study doctor before deciding whether or not to take part in this study.

8. What are the possible benefits of taking part?

We cannot say if ASN-002, the experimental study treatment, alone or in combination with 5-FU, will be effective for your BCC(s). Most likely, you will not personally directly benefit from this research study. The information collected from this study, however, may help develop a new effective therapy for BCC(s).

9. What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. ASN-002, the experimental treatment, has previously been tested in two clinical trials in a total of 51 adult volunteers who had other types of skin cancer.

The most common side effects experienced by these trial participants were the following:

Type of side effect	*Patients who experienced this at least once*
Fever	61%
Chills	57%
Fatigue	57%
Injection site reactions (redness, swelling, soreness)	51%
Headache	47%

These side effects were generally rated as mild or moderate, i.e. only 3% were rated as severe and only 8% of patients withdrew from these studies because of side effects. Most side effects occurred 1-2 days after study drug injection and resolved quickly, though the onset and resolution of the injection site reactions were more delayed. In these studies, many patients received many drug injections; the greatest number of injections received by any patient was 45. You may have none, some or all of the effects listed above or other less common or not previously seen side effects, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about any that you might be experiencing, you should talk with your study doctor.

5-FU is commercially available chemotherapeutic agent. Reported adverse events of systemic 5-FU given at doses higher than will be used in this study include diarrhea, nausea and vomiting, mucositis, anorexia, tearing, photosensitivity, taste change (metallic taste in mouth), discoloration along the vein through which the infusion is given low and myelosuppression. These adverse events are related to the dose administered and to the route of administration. The reported adverse events of topical or intralesional 5-FU are related to inflammation at the site of application and include itching, pain, erythema (redness), burning sensation, crusting, ulceration, swelling and necrosis (skin breakdown with open sore), again related to the dose and frequency of administration.

Most side effects from medical treatments go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. There may be side effects that the researchers do not expect or do not know about and that may be serious. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Tell your study doctor if you have any problems. Your study doctor will discuss the best way of managing any side effects with you.

If participation in this research project uncovers a medical condition of which you are unaware, the study doctors will discuss:

- whether you are suitable for the research project
- if you require referral to your GP or to a specialist

This study involves having an experimental treatment injected into your BCC(s) and blood being taken. Having a substance injected, or blood or tissue taken may cause some discomfort or bruising. Sometimes the blood vessel may swell, or blood may clot in the blood vessel, or the spot from where the tissue is taken could become inflamed. Rarely, there could be minor infection or bleeding. If this happens, it can be easily treated.

The BCC(s) being treated will be surgically removed using local anaesthesia. Minor discomfort (pain, bruising and swelling) may be experienced during or after removal of the BCC(s). Rarely patients can faint or develop an infection when a BCC(s) is surgically removed.

Contraception

The effects of ASN-002 on an unborn child or on a newborn baby are not known. 5-FU may harm a baby developing in the womb. Because of this, it is important that study participants are not pregnant or breast-feeding. You must not participate in this study if you are pregnant, trying to become pregnant, or breast-feeding. If you are female and childbearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the study. It is important not to become pregnant or father a child while you are having treatment with this drug and for at least 6 months afterwards. If you do become pregnant whilst participating in this study you should advise your study doctor immediately. Your study doctor may withdraw you from the study and advise on further medical attention should this be necessary. You will be invited to give consent to allow access to information regarding any pregnancy and its outcome for the purpose of determining any effect from study drgu(s) ASN-002 on the developing baby.

You should advise your study doctor if you father a child while participating in this study. You study doctor will advise on medical attention for your partner should this be necessary.

Both male and female participants are required to use effective birth control during the course of the study and until after completion of the study. You should discuss methods of effective birth control with your study doctor.

10. What will happen to my test samples?

By consenting to take part in this study, you also consent to the collection and testing of your urine and blood samples for the purposes of this research study only.

The total volume of blood taken for the entire study could be up to 500 mL (approximately 2 cups) over 21 weeks. For comparison, a standard blood donation is 470 mL. The blood and urine samples collected for the assessment of your health status (e.g. liver and kidney function tests) will be processed by a local pathology laboratory. These samples will be destroyed once the analysis is complete.

Blood samples taken for testing how your immune system responds to the study drug(s) will be sent to an Ascend Biopharmaceuticals approved laboratory in Australia. These blood samples will be labelled with your unique study participant number and will not contain any information that can identify you personally. These blood samples will be destroyed upon completion of the study.

Nodular BCC biopsy samples taken during the study and the tissue removed surgically toward the end of the study will be sent to an Ascend Biopharmaceuticals approved pathology laboratory in Australia, to process and describe the tissue specimens taken for this study. All tissue samples will be retained indefinitely for possible additional review or studies relevant to the biology and mechanism of action

of study drug(s). These biopsy samples will be labelled with your unique study participant number and will not contain any information that can identify you personally.

11. What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

12. Can I have other treatments during this research project?

It is important to tell your study doctors and the study staff about any treatments or medications you have been taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. Most medications are permitted, but should not be changed during the course of the study.

Whilst you are participating in this research project, you should not start any new medications without discussing this with the study doctor or his/her representative. Most 'over-the-counter' medicines will be permitted, including paracetamol, antihistamines, sleep aids, etc. but you still should discuss this with study staff before you start.

13. What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the Central Brisbane Dermatology and/or Q-Pharm research teams before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be properly assessed and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

Your participation may also be stopped without your consent if your doctor feels that it is in your best interest. The Sponsor Company, Ascend Biopharmaceuticals can also stop this project at any time.

14. Could this research be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons, some not related and some related to you. These may include reasons such as:

- Unacceptable side effects
- The experimental treatment being shown not to be effective
- The experimental treatment being shown to work and not need further testing
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities
- If you don't follow the instructions of the research staff; or
- If the study doctor decides it is in the best interest of your health and welfare to stop.

15. What will happen when the research project ends?

The experimental study treatment, ASN-002, will not be made available to you after either the research project ends or your participation ends.

A final report will be provided to the Principal Investigator who will share the results with you if requested. Any published results will be available to all participants if requested. It is usual for a number of years to elapse before definitive results of this type of study are available. These may be published in medical journals that are available to the public. You should feel free to ask the study staff about this.

Part 2 How is the research project being conducted?

16. What will happen to information about me?

Any information obtained during the study that can identify you will remain confidential.

- In accordance with relevant Australian and/or Queensland privacy and other relevant laws, you have the right to access the information about you which has been collected and stored by the researchers. You also have the right to request that any information with which you disagree be corrected. If you want to know more about Central Brisbane Dermatology's and/or Q-Pharm's approach to privacy, or access any of your information held by Central Brisbane Dermatology and/or Q-Pharm, you can contact Dr Gregory Siller or Central Brisbane Dermatology and/or Q-Pharm staff. It is desirable that your local doctor be advised of your decision to participate in this research project. By signing the consent section, you agree to your local doctor being notified of your decision to participate in this research project.
- Information about your participation in this research project may be recorded in your health records.

Study Medical Records

- Data from your study medical record will be identifiable and stored in secured offices at Central Brisbane Dermatology and Q-Pharm. This information will be reviewed by authorised individuals from the sponsor, Ascend Biopharmaceuticals, or affiliates and may also be reviewed by Health Authorities or Government Agencies (including the Therapeutic Goods Administration, as well as health authorities in the USA and other countries) and delegates of the Bellberry Human Research Ethics Committee, for the purpose of confirming the accuracy of the research study data.
- You have a right to access and request correction to your information.

Case Report Form (CRF)

- Information about you may also be obtained from your medical records held at Central Brisbane Dermatology/Q-Pharm, and other health services for the purpose of this research. Any information taken from these records will be recorded on special case report forms (CRFs) by the study doctor and Central Brisbane Dermatology/Q-Pharm staff. These forms will be coded by your study number, your gender and birth date. The original pages of these forms will be sent to the study sponsor, Ascend Biopharmaceuticals, in Australia during the study. Information from these forms will be added to a computerised database managed by Ascend Biopharmaceuticals in Australia and will be part of the study results, which may be published. The study results may also be used for future research. This database will have limited access and will be protected by the use of a password.

- A copy of these forms and your study medical record will be kept indefinitely with all other study related documents by Central Brisbane Dermatology/Q-Pharm.
- This information will be reviewed by authorised individuals from Ascend Biopharmaceuticals or affiliates and may also be reviewed by Health Authorities or Government Agencies (including the Therapeutic Goods Administration, as well as health authorities in the USA and other countries) and delegates of the Bellberry Human Research Ethics Committee for the purpose of confirming the accuracy of the research study data.
- By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Publications

- A report of the study results may be submitted for publication. In any publication and/or presentation, information will be provided in such a way that you cannot be identified (except with your permission).
- A description of this clinical trial will be available on http://www.anzctr.org.au/ and https://clinicaltrials.gov/ as required by Australian and U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the study results. You can search this web site at any time.

17. Complaints and compensation

If you suffer any injuries or complications as a result of participating in this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

If you are injured as a result of your participation in this trial you may be entitled to compensation.

There are two avenues that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:

- The pharmaceutical industry has set up a compensation process, with which the sponsor of this research project, Ascend Biopharmaceuticals Ltd, has agreed to comply. Details of the process and conditions are set out in the Medicines Australia *Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial*. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and if so, how much. These guidelines are available for your inspection on the Medicines Australia Website (www.medicinesaustralia.com.au) under Issues/Information – Clinical Trials – Indemnity & Compensation Guidelines. Alternatively, your Study Doctor can provide you with a hard-copy of the guidelines. If you have any questions about the guidelines, please contact Central Brisbane Dermatology/Q-Pharm. As guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation, however, the sponsor is obliged to follow these guidelines.
- You may be able to seek compensation through the courts.

It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.

If you think that you have suffered injury that has occurred as a result of your involvement in this study, you must contact your Study Doctor immediately.

18. Who is organising and funding the research?

The study sponsor, Ascend Biopharmaceuticals, may benefit financially from this research project if, for example, it assists Ascend Biopharmaceuticals to obtain approval for a new treatment.

Ascend Biopharmaceuticals may directly or indirectly benefit financially from samples of your blood or tissues, or from scientific knowledge acquired through analysis of your samples.

You will not receive any financial benefit for being involved in this research project, even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to Ascend Biopharmaceuticals.

Ascend Biopharmaceuticals, other researchers, or research companies may patent or sell discoveries that result from this research. Neither Ascend Biopharmaceuticals, nor the study doctor will compensate you, or your family, if this happens.

Central Brisbane Dermatology and Q-Pharm will receive a payment from Ascend Biopharmaceuticals for undertaking this research project. No member of the Central Brisbane Dermatology or Q-Pharm research teams, however, will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

Will I be paid to take part in this research project?

There are no additional costs associated with participating in this study, nor will you be paid. All tests and medical care required as part of the study will be provided to you free of charge.

The costs you incur for travel, including parking, to and from your study-related visits will be reimbursed to you, if applicable.

19. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been reviewed and approved by Bellberry Human Research Ethics Committee.

This project will be conducted according to the National Statement on Ethical Conduct in Human Research (March 2007) incorporating all updates as produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Committee chair, Bellberry Human Research Ethics Committee on 08 8361 3222.

All study participants must be provided with a signed and dated copy of the Participant Information Sheet and Consent Form for their personal record.

20. Further information and who to contact

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the Principal Investigator (study doctor) on 07 3831 4382 or any of the following people:

Enquiries should be directed to

Central Brisbane Dermatology, Level 9, Silverton Place, 101 Wickham Terrace, Brisbane QLD 4000:

Principal Investigator: Dr Gregory Siller Ph: 07 3831 4382 Mobile/Pager: 0408 066 857 (after-hours only)	
Q-Pharm Pty Limited, 300C Herston Road, Herston QLD 4006:	
Sub-Investigator: Dr Paul Griffin Ph: 07 3845 3636 or Mob: 0413 636 284 (after-hours only)	Project Manager: Hilary Morrison Ph: 07 3845 3657 or Mob: 0418 577 534 (after-hours only)

You will be given a card with additional contact details at the start of the study.

Mobile and pager telephone numbers are provided for after hours emergency use only. Please address routine or procedural questions to one of the study staff during working hours.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact the Bellberry HREC Secretary on (08) 8361 3222.

Informed Consent Form (BCNS Patients)

Protocol Title	A Phase I/IIa Study of the Efficacy and Safety of ASN-002 Alone and in Combination with 5- Fluorouracil (5-FU) in Adult Patients with Low-Risk Nodular Basal Cell Carcinoma
Protocol Number	ASN-002-001
Study Sponsor	Ascend Biopharmaceuticals Ltd.
Study Centre	1. Central Brisbane Dermatology: Level 9, Silverton Place, 101 Wickham Terrace, Brisbane QLD 4000 2. Q-Pharm Pty Limited: 300C Herston Road, Herston QLD 4006
Principal Investigator	Dr Gregory Siller

I _____, the undersigned, hereby voluntarily consent to my involvement in the research project named above.

I acknowledge that the nature, purpose and risks of the research project, and alternatives to participation have been fully explained to my satisfaction by _____.

Specifically, the details of the procedure(s) proposed and the anticipated length of time it will take, the frequency with which the procedure(s) will be performed and an indication of any discomfort that may be expected have been explained to me.

- I have read, and I understand the Central Brisbane Dermatology/Q-Pharm Participant Information Sheet, version 1.0, dated 03 July 2017, and confirm a copy has been provided to me.
- I am 18 years of age or older.
- I freely agree to participate in this research project according to the conditions in the Participant Information Sheet.
- I understand that my involvement in this study may not be of any direct benefit to me.
- I have been told that no information regarding my medical history will be divulged to unauthorised third parties and the results of any tests involving me will not be published so as to reveal my identity.
- I understand that access may be required to my medical records for the purpose of this study as well as for quality assurance, auditing and in the event of a serious adverse event.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Central Brisbane Dermatology and/or Q-Pharm concerning my treatment that is needed for this project. I understand that such information will remain confidential.
- I understand that I am free to withdraw from the study at any stage without prejudice to future treatment and without the need to give a reason. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- I consent to my GP being notified of my participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial, if appropriate.
- I understand that I will be given a copy of this signed and dated document to keep.

Participant:

Print Name	Signature	Date	Time

Witness* to Participant's Signature:

I have witnessed the informed consent process and attest that the participant was given a verbal explanation of the research project, its procedures and risks, and I believe that the participant has understood that explanation, and that informed consent has been freely given.

Print Name	Signature	Date	Time

* If a participant is unable to read, an impartial person (Witness) must be present during the entire informed consent process and may assist the participant during that process, such as by reading aloud the informed consent form. The witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†:

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Print Name	Signature	Date	Time

†A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Reminder: A copy of this signed consent form must be given to the participant.

This study has been reviewed by the Bellberry Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research 2007 incorporating all updates.