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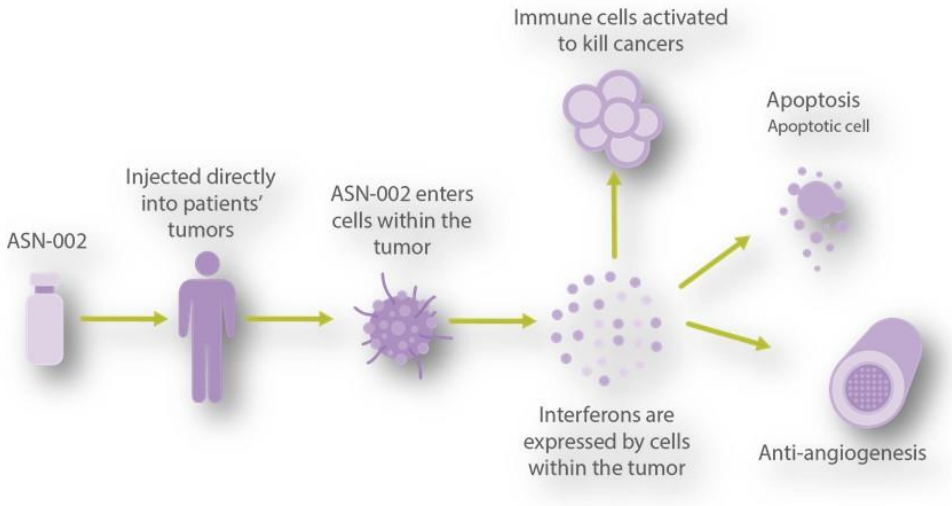
ASN-002 in the treatment of basal cell carcinoma

1. Tell us about Ascend

Ascend is a Melbourne-based public company that is developing treatments for skin and other types of cancer. The company is current performing a clinical trial in a type of non-melanoma skin cancer known as nodular basal cell carcinoma (nBCC). These clinical trials are being conducted in Melbourne and Brisbane. The company may expand the study next year to include additional sites across Australia.

2. What is ASN-002 and how does it work?

ASN-002 is a gene therapy (made from a virus) product being developed by Ascend to treat skin and other types of cancers. The product is based on a common flu virus engineered to make a common human protein known as Interferon-gamma which it part of the natural immune system. ASN-002 has been modified such that once the virus enters the cancer cells, it will not produce new viruses thereby becoming safer to use



Interferon-gamma has been shown to have a number of powerful anti-cancer effects. These include shutting off the blood supply to the cancer (anti-angiogenesis), training and activating the immune system to attack the cancers and stopping the growth of the tumor and also programming the

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cancer cells to self-destruct (apoptosis). The virus used in ASN-002 has been shown to be safe in humans especially at the doses planned in the current study.

3. What is the clinical data to date and in nodular BCC in particular?

To date ASN-002 has been injected in 73 patients and has shown a favorable safety and tolerability profile. Patients at the highest does do experience mild flu like symptoms for about 24-48 hours after the first injection. In previous clinical trials that studied patients with advance melanoma and patients with lymphomas that arise in the skin, between 40-87% of patients shown a response. These include patients where the cancer completely disappeared (Complete response) and patients that experienced at least a one third reduction in the size of the cancerous lesion (Partial response).

Currently ASN-002 is being studied in patients with the nodular form of BCC, in 24 patients. The study has been designed to evaluate three different doses of ASN-002 (low, medium and high) over a 17-week period for each patient. To date the first nine patients have completed the study and one out of three patients showed a complete response at the low dose; two out of three patients experiencing a complete response and one out of three experiencing a partial response at the medium dose and three out of three patients showing a complete response at the high dose. In one patient that had seven lesions, where only one lesion was injected, the non-injected lesions also showed significant clinical responses. Sporadic nodular BCC patients on ASN-002 generally tolerated the treatment well with only mild flu like symptoms observed at the highest dose.

4. What are the side effects?

Most commonly, following injections, patients had mild injection site redness, swelling and pain. Mild flu-like symptoms for high dose patients only. Lesions all healed well with or without minor scarring in the 3 to 4 months following injection

5. What are the potential benefits for patients with many lesions?

ASN-002 offers a less invasive treatment with less pain and complications compared to surgery. Treatment can be limited to only three injections per lesion. Healing is quick and expected to have good cosmetic outcomes.

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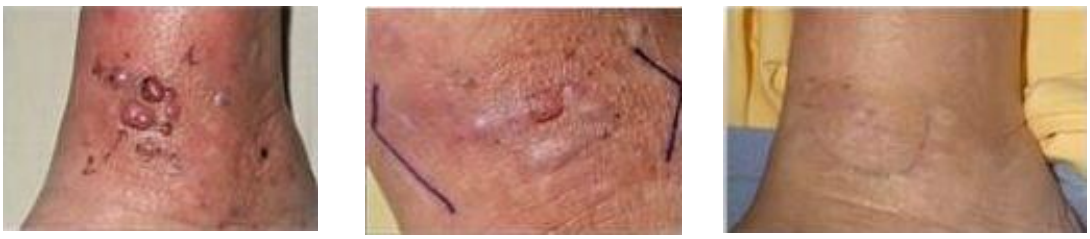

Day 0 **Month 1.5** **Month 4**

Treatment of patients with multiple cutaneous melanomas

6. What is being planned in the clinical trial

Currently there are three sites actively evaluating ASN-002 in nodular BCC patients. There may be the opportunity for a small number of basal cell nevus syndrome (BCNS) patients as well to participate at these sites in the current trial. Interested patients should contact the sites directly, details for each of the participating sites are enclosed below. Ascend is planning a larger formal clinical trial in BCNS later in 2017 or early 2018 involving sites from Australia, USA and if possible European region. As plans for this follow-on study is finalized, further details will be available.

- **How is the drug administered?**

ASN-002 is injected into the center of the skin cancer by the treating doctor with a volume dependent on the size of the cancer

- **Patients that may be eligible**

Male and female patients aged 18 years or older who provide written informed consent, have been diagnosed with a previously untreated, low-risk nodular BCC that does not require immediate surgical removal, are not pregnant or breastfeeding, and are willing to comply with all study requirements will be included into the study, including surgical removal of the tumor at completion of the study.

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- **Number of injections**

Each patient will have three injections in the selected cancer with one injection administered each week for three weeks.

- **Number of visits**

For a 17-week study period, patients must come in once a week for the first three injections followed by monthly visits until week 17. At the end of the study, the lesion site is excised and studied histologically to confirm if the treatment has been effective and that all the cancer cells have been removed.

7. Where are the investigator sites located?

Site	Principal Investigator	Site Name & address	Contact
01	Prof. Lynda Spelman	Veracity Clinical Research, 250, Ipswich Road, Wooloongabba, QLD 4102, Australia	Mr. Kurt Davidson +61 7 3039 1346
02	Prof. Rodney Sinclair	Sinclair Dermatology, 2-Wellington Parade East Melbourne VIC 3002, Australia	Dr. Carol Robinson +61 488 965 426
03	Prof. Gregory Siller	Central Brisbane Dermatology, Level 9, Silverton Place 101 Wickham Terrace, Brisbane QLD 4000	Ms. Cath Armany +61 7 38314382

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8. Where can I find more details about the study

The study is registered at www.clinicaltrials.gov (**ClinicalTrials.gov Identifier:** NCT02550678) and at www.anzctr.org.au (**Identifier:** ACTRN12615001017516).

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