# A CLINICAL TRIAL OF SCIB1, A DNA VACCINE THAT TARGETS DENDRITIC CELLS *IN VIVO*, IN FULLY RESECTED MELANOMA PATIENTS: A VACCINE TO PREVENT RECURRENCE

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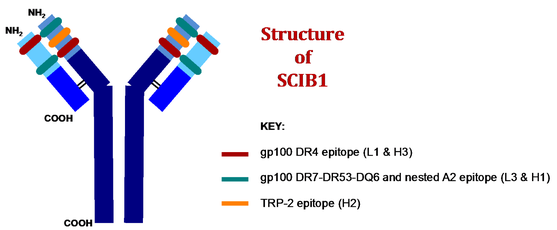
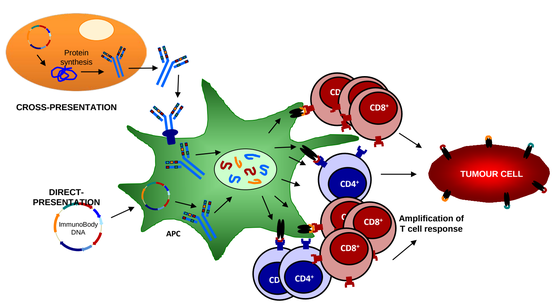
## INTRODUCTION

**SCIB1** is a DNA **ImmunoBody®** immunotherapy encoding a human IgG1 antibody, with three epitopes from gp100 and one from TRP-2 engineered into its CDR regions. This immuno-stimulatory antibody targets dendritic cells *in vivo* via the high affinity Fc receptor, CD64, and stimulates high avidity T cells.




## DUAL MECHANISM OF ACTION FOR SCIB1 IMMUNOBODY®

- Combination of **CROSS-PRESENTATION** with **DIRECT-PRESENTATION**
- Results in amplification of immune response to induce **HIGH FREQUENCY, HIGH AVIDITY** T cells
- Potent **ANTI-TUMOUR** response




## METHODS

16 patients with fully resected Stage III (n=9) or Stage IV (n=7) melanoma were immunised with 4 mg of SCIB1 by intramuscular electroporation at 3-weekly intervals, then subsequently at 3 and 6 months. Patients tolerating treatment were allowed to continue treatment for up to 5 years.
Immune responses were assayed by proliferation and Elispot assays

## SCIB1 SAFETY PROFILE

- SCIB1 was safe and well-tolerated
- More than 190 doses administered
- No CTC grade 4/5 toxicities except disease-related and one case of pneumonia (g4)
- Most common adverse events were injection site reactions (pain, tenderness, bruising, erythema and swelling)

## CONCLUSIONS

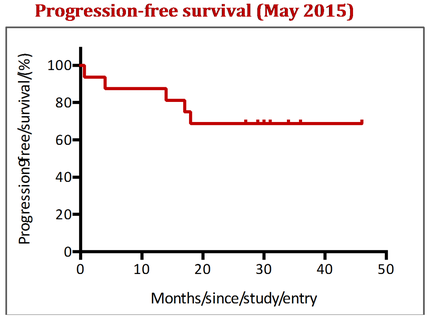
**These results suggest that SCIB1 may confer protection from recurrence of melanoma with little associated toxicity**

## CLINICAL RESPONSES

- Only 5/16 patients have had a recurrence of disease at 1, 4, 14, 17 and 18 months and **NONE HAVE DIED**
- All other patients have been disease-free for between 27 and 46 months since study entry
- Median survival time for Stage III patients (n=9) and Stage IV patients (n=7) is 34 and 31 months, respectively

| Fully resected melanoma patients | No patients | Disease-free survival (%) | Died (%) |
|---|---|---|---|
| Stage III/IV | 16 | 69 | 0 |
| Stage III | 9 | 67 | 0 |
| Stage IV | 7 | 71 | 0 |

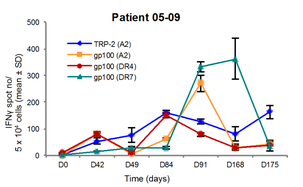
**Resected patients (n=16)**
**Progression-free survival (May 2015)**

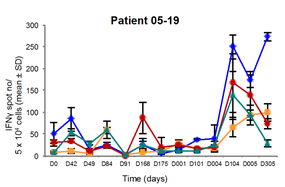



| Patient | No doses (+cont[N]) | Stage at study entry | Months since first diagnosis of mets | Months since study entry | Treatment post-SCIB1 | Disease status | Status |
|---|---|---|---|---|---|---|---|
| 01-24 | 5 | IV | 71 | 46 | - | Disease-free | Alive |
| 01-32 | 5 + 5 | IIIC | 37 | 34 | - | Recurrence | Alive |
| 01-34 | 5 | IIIC | 40 | 36 | - | Disease-free | Alive |
| 01-37 | 5 | IV | 153 | 35 | Ipilimumab, Nivo | Recurrence | Alive |
| 02-21 | 5 | IIIB | 38 | 34 | - | Disease-free | Alive |
| 02-33 | 5 | IIIB | 37 | 29 | - | Disease-free | Alive |
| 04-03 | 5 | IV | 49 | 44 | Ipilimumab | Recurrence | Alive |
| 04-22 | 3 (2mg) | IV | 38 | 31 | - | Disease-free | Alive |
| 05-08 | 5 + 3 | IIIC | 40 | 36 | Ipi, radiotherapy | Recurrence | Alive |
| 05-09 | 5 (4/2mg) | IIIA | 38 | 35 | Surgery | Recurrence | Alive |
| 05-11 | 5 + 8 | IV | 39 | 30 | - | Disease-free | Alive |
| 05-13 | 5 | IIIC | 40 | 34 | - | Disease-free | Alive |
| 05-18 | 5 + 7 | IV | 36 | 27 | - | Disease-free | Alive |
| 05-19 | 5 + 7 | IIIA | 36 | 30 | - | Disease-free | Alive |
| 05-21 | 5 + 9 | IV | 54 | 31 | - | Disease-free | Alive |
| 05-24 | 5 + 8 | IIIA | 31 | 30 | - | Disease-free | Alive |
| | Survival (median, months) | | 39 | 34 | | | Analysis date 11May15 |

## IMMUNE RESPONSES

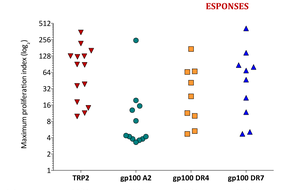
- All 16 patients showed a vaccine-epitope specific proliferation response *ex vivo* and γIFN Elispot responses *in-vitro* after T cell expansion
- 12 patients responded to all 4 epitopes, two patients to 3 epitopes, one patient to 2 epitopes and one patient to 1 epitope
- All patients who continued treatment showed strong T cell memory responses following 3 monthly boosts with SCIB1




ESPONSES

MAXIMUM ELISPOT RESPONSES




| Antigen response: | 14/16 | 12/16 | 9/16 | 10/16 |
|---|---|---|---|---|