Modulating immune responses to personalized cancer vaccines using PharmaJet Needle-free Injection Systems

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PharmaJet® is transforming vaccine delivery through innovative Needle-free Injection Systems. Our enabling technology can enhance immune response and provides safety, efficacy, efficiency, and patient comfort using intradermal (ID), intramuscular (IM), or subcutaneous (SC) applications.[a, b, c]

PharmaJet®

Tropis® ID
provides intradermal injections

Stratis® IM/SC
provides intramuscular or subcutaneous injections

Recent Strategies for Personalized Cancer Vaccines

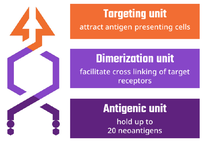
Personalized vaccine strategies for cancer treatment include nucleic acid platforms with antigen presenting cell (APC) targeting to boost T cell activation and the addition of neoantigenic epitopes. Combined with checkpoint inhibitors (CPIs), therapeutic cancer vaccines significantly enhance anti-tumor and clinical responses. PharmaJet devices can improve DNA vaccine delivery[d] and have been successfully adopted into multiple vaccine development programs while demonstrating both immunogenicity and clinical efficacy for novel personalized therapeutic vaccines as shown below.

nykode therapeutics

VB10.NEO DNA vaccine Phase 1/2a Trial

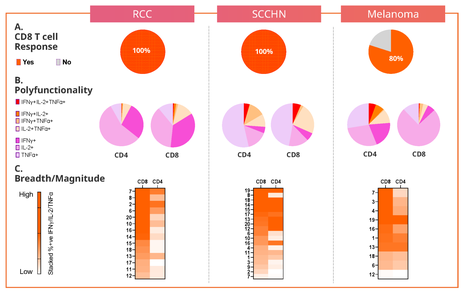
INTRODUCTION: VB10.NEO was administered to patients with locally advanced or metastatic solid cancers in combination with CPI and/or other anti-cancer therapies at investigator's discretion.

Each individual VB10.NEO vaccine contains up to 20 patient-specific neoantigens and is designed to target APCs (CCL3L1) using Nykode Therapeutics' modular Vaccibody™ vaccine platform.

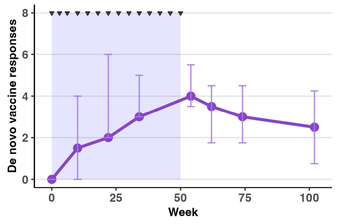


***VB10.NEO administration with Stratis*:**

T cell responses (n=7, 22 weeks)[1]



Durability of De Novo Vaccine Responses (n=8, 100 weeks)[2]



CONCLUSION: Assessment of neoantigen-specific T cell reactivity demonstrated **VB10.NEO** induced **broad and long-lasting T cell responses** almost a year after the last vaccination, and the majority of tested neoantigens activated polyfunctional CD8+ T cells.

[1]Krauss, et al (2023). Individualized APC targeting VB10.NEO cancer vaccines induce broad neoepitope-specific CD8 T cell responses in patients with advanced or metastatic solid tumors: interim results from a phase 1/2a trial. American Association for Cancer Research (AACR) 2023 poster. [2]Weinert, et al (2025). DNA-encoded individualized neoantigen vaccines elicit durable and functional immune responses. Association for Cancer Immunotherapy CIMT 2025 poster.

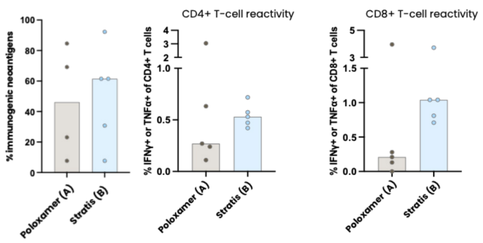
EVAXION

EVX-02 & EVX-03 DNA vaccines Phase 1/2 Trial

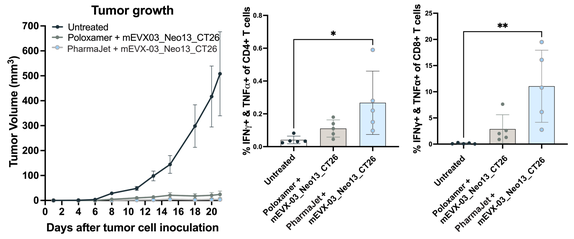
INTRODUCTION: EVX-02 was administered to patients that had a complete resection of Stage IIIB/IIIC/IIID or Stage IV melanoma and were at a high risk of recurrence, in combination with CPI (nivolumab).

Each EVX-02 vaccine encoded up to 13 patient-specific neoantigens. Study compared **Stratis** delivery to poloxamer delivery with needle and syringe (NS). **EVX-03** additionally encodes APC-targeting and dimerization units.

EVX-02 administration with Stratis (n=5):



- Induced neoantigen-specific T cell responses in all patients and CD4+ and CD8+ T cells contributed to these responses.
- Immune responses trended higher in response magnitude with **Stratis** (cohort B) compared to poloxamer delivery with NS (cohort A).



EVX-03 delivered by PharmaJet in a mouse pre-clinical model induced a strong antitumor effect and neoepitope-specific T cell response more potent than 1st generation delivery with poloxamer.

CONCLUSION: EVX-02 was immunogenic and efficacious when delivered with **Stratis**, showing an improvement in T cell induction compared to NS. These patients were relapse-free at their last assessment (1 year after treatment start). The 2nd generation **EVX-03** vaccine induced a more potent response in a mouse pre-clinical model.

Kleine-Kohlbrecher, et al (2023). AI-designed personalized neoantigen vaccine, EVX-02, induces robust T-cell responses in melanoma patients. Society for Immunotherapy of Cancer (SITC) 2023 poster.

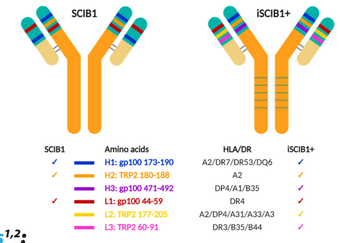
SCANCELL

SCIB1/ iSCIB1+ DNA vaccines Phase 2 Trial

INTRODUCTION: The SCOPE trial is evaluating **SCIB1** and next-generation **iSCIB1+** therapeutic vaccines delivered with **Stratis** IM, combined with checkpoint inhibitors in patients with advanced melanoma. A new trial arm is evaluating **Tropis** ID delivery of iSCIB1+.

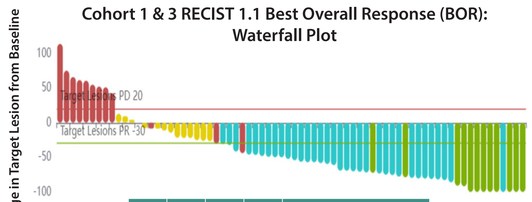
SCIB1 (Cohort 1): ImmunoBody® DNA vaccine, TRP-2, gp100; limited to specific human leukocyte antigen (HLA) types.

iSCIB1+ (Cohort 3): AvidiMab®-modified, includes additional melanoma epitopes, broadening HLA coverage.



***SCIB1 and iSCIB1+ administration with Stratis*[1,2]:**

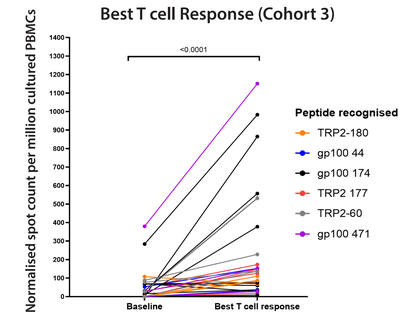
Cohort 1 & 3 RECIST 1.1 Best Overall Response (BOR): Waterfall Plot



PD	SD	PR	CR	RESPONSES
13	13	34	12	ORR: 64% (46/72) DCR: 82% (59/72)

PD: Progressive Disease
SD: Stable Disease
PR: Partial Response
CR: Complete Response
ORR: Overall Response Rate
DCR: Disease Control Rate

Best T cell Response (Cohort 3)



T cell Responses - ELISpot Assays (n=33)

CLINICAL RESPONSE	NUMBER OF PATIENTS	POSTIVE T CELL RESPONSE	% POSITIVE
CR/PR	19	15	79%
SD	7	5	71%
PD	7	4	57%

- All six iSCIB1+ epitopes generated CD8+ T cell responses.
- 72% of patients responded to both TRP-2 & gp100, reducing risk of immune escape.
- 19/31 (61%) HLA-matched patients made a T cell response
- 15/19 (79%) amongst clinical responders.
- 10/12 (83%) with a CD8+ T cell response were clinical responders.

Summary

- Both Cohort 1 and Cohort 3 showed impressive efficacy in the proposed development population.
- CD8 T cell responses are important for clinical responses.
- The safety profile of SCIB1& iSCIB1+ is benign with no potentiation of CPI toxicities (data not shown).
- iSCIB1+ selected for further development with PharmaJet delivery: shows eqi-potency and safety compared to SCIB1 and is efficacious in a wider population.

CONCLUSION: SCIB1 and iSCIB1+ DNA vaccines are immunogenic and lead to significant melanoma lesion size regression in a majority of treated patients.

[1]Scancell (2025, July 22). Active Immunotherapy for a Cancer-Free Future: Immunobody® iSCIB1+ strongly improved outcomes in Late-Stage Melanoma SCOPE study results. [Company presentation]. [2]Scancell (2025, September). Active Immunotherapy for a Cancer-Free Future [Company presentation].

Conclusions

- **PharmaJet devices enable DNA personalized cancer vaccine delivery: Vaccinations are safe and well tolerated, induce neoantigen-specific T cell responses, and lead to favorable clinical outcomes.**
- **PharmaJet devices can be easily incorporated into novel personalized therapeutic strategies to treat various types of cancer.**

References: *[a]Alberer, M. et al. (2017). Safety and immunogenicity of a mRNA rabies vaccine in healthy adults: an open-label, non-randomised, prospective, first-in-human phase 1 clinical trial. Lancet 390, 1511-1520. [b]Mohan, D. et al. (2025). Evaluating the Impact of Needle-Free Delivery of Inactivated Polio Vaccine on Nigeria's Routine Immunization Program: An Implementation Hybrid Trial. Vaccines (Basel) 13. [c]Bavdekar, A. et al (2018). Immunogenicity and safety of measles-mumps-rubella vaccine delivered by disposable-syringe jet injector in India: A randomized, parallel group, non-inferiority trial. Vaccine 36, 1220-1226. [d]Ledesma-Feliciano C, et al (2023). Improved DNA Vaccine Delivery with Needle-Free Injection Systems. Vaccines. 11(2):280.*

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