

Pressure Enabled Regional Immuno-oncology (PERIO™) Trials Update

November 2022

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Update on the PERIO 01 and PERIO 02 Clinical Studies



First-in-human experience in patients with liver tumors welltolerated, with no serious adverse events related to TriNav® or procedure as monotherapy or in combination with checkpoint inhibitors



Consistent with hypothesis that SD-101 delivered via TriNav® can enable broad immune effects in liver tumors and eliminate myeloid derived suppressor cells ("MDSC")



Continuing SD-101 program development, with more pivotal milestones expected over the next 6 months

https://periotrial.com

PERIO 01 for uveal melanoma with liver metastases (NCT04935229)

PERIO 02 for intrahepatic cholangiocarcinoma and hepatocellular carcinoma (NCT05220722)



Upcoming Milestones

More Pivotal Data Expected in Next 6 Months

November 2022

- Initial biopsy data readout
- Expanded from 5 to 9 clinical sites

January 2023

- PERIO 01 and PERIO 02 SD-101 + dual checkpoint inhibitor cohort
- Society of Interventional Oncology
- OncoPig TriNav® vs. standard microcatheter data release planned (pre-clinical)
- MD Anderson Cancer Center Y90 study opening

March 2023

- PERIO SD-101

 interventional radiology report and pre-clinical pancreas data release planned
- Society of Interventional Radiology

• June 2023

- American Society of Clinical Oncology
- PERIO 01 and PERIO 02 response data and PERIO 03 safety data release planned
- PERIO 01 and PERIO 02 durable response data available

• December 2022

PERIO 01 and PERIO 02 Phase 1 early response data available

February 2023

Phase 2 for Uveal Melanoma and Intrahepatic Cholangiocarcinoma Institutional Review Board submissions planned

• April 2023

- American Association for Cancer Research
- PERIO biopsy data and pre-clinical OncoPig (TriNav® vs. standard delivery PD-1) data release planned



Pressure-Enabled Regional Immuno-Oncology PERIO 01 and PERIO 02 Clinical Studies

Evaluating SD-101 in combination with checkpoint inhibitors in adults with uveal melanoma liver metastases, advanced hepatocellular carcinoma, and advanced intrahepatic cholangiocarcinoma

Overview

- Both studies initiated at The University of Texas MD Anderson Cancer Center and now open at nine sites
- First two studies in a series of clinical trials assessing TriSalus' immunotherapy platform across multiple indications
- First patients enrolled in May 2022;

27 treated to date with date with infusions

 Planning to execute registrational phase 2 studies in the first half of 2023; durable response data available in June



PERIO 01

- SD-101 monotherapy 13 patients treated
- SD-101 + CPI 7 patients treated (2 mg)
 - Enrolling at higher dose levels (4 mg and 8 mg)

PERIO 02

- SD-101 monotherapy 3 patients treated
- SD-101 + CPI 4 patients treated (2 mg)
 - Enrolling at higher dose levels (4 mg and 8 mg)



PERIO 01 and PERIO 02 Clinical Study Overview

PHASE 1 STUDY DESIGN





PERIO 01 and PERIO 02 Update: First In-Human Experience Well-Tolerated

First-in-human experience consistent with hypothesis that TriNav® can achieve high liver SD-101 levels with limited systemic exposure

- High SD-101 levels in liver following infusion with TriNav®
- Transient (<2 hour) detection in serum following SD-101 infusion with TriNav®
- No serious immune related adverse events reported to date¹



(1) No serious cytokine related events (one grade 2 cytokine release syndrome) No serious (grade 4 or 5) clinically significant liver or biliary serious adverse events No dose discontinuations due to treatment related serious advents No serious adverse events related to TriNav® or procedure

Liver tissue levels up to 2340 ng/ml at 8 mg dose level in Cohort A



SD-101 Dual Mechanism — MDSC Elimination and Broad Immune Cell Activation

Reversing immunosuppression to enhance tumor responsiveness^{1,2}



1) Looi, C.K., et al. J Exp Clin Cancer Res. 2019 Apr 15;38(1):162.

- Ribas A., et al. Cancer Discov. 2018;8(10):1250.
- 3) Feig, C. et al. The Pancreas Cancer Microenvironment. Clin. Cancer Res. 18, 4266–4276 (2012).
- 4) Cancer Immunol Immunother. 2015 Feb; 64(2): 149–159.

- 5) TriSalus data on file
- 6) TriSalus clinical data on file (PERIO-1) and Ghosh, et al. Cancer Gene Therapy. 2022 June 14 (online ahead of print).
- 7) Journal of Clinical Oncology 37, no. 15_suppl (May 20, 2019) 9534-9534.
- 8) Guha et al. Oncogene 2020 November 4 (online ahead of print).



Data Supports Hypothesis that PEDD Can Enable SD-101 to Have Broad Immune Effects in Liver Tumors and Eliminate MDSC

SD-101 Infusion With TriNav® Demonstrated Cytokine Induction and MDSC Elimination





4 of 4 patients with available immunofluorescence data demonstrate decreases in liver tumor monocytic MDSC levels

% Reduction in M-MDSCs within Tumors



Cytokine levels determined by Luminex assays

% reduction in M-MDSC concentrations within tumors calculated from earliest available time point (Day 1 or Day 57) to latest available time point (Day 57 or Day 100) M-MDSC concentrations determined by multiplex immunofluorescence microscopy



Immunocore: ctDNA Predicted Long-term Survival in Uveal Melanoma

Extent of circulating tumor DNA clearance from blood following immunotherapy treatment predicted long term survival in Immunocore clinical trial¹



1) Carvajal, R.D., Butler, M.O., Shoushtari, A.N. et al. Clinical and molecular response to tebentafusp in previously treated patients with metastatic uveal melanoma: a phase 2 trial. Nat Med 28, 2364–2373 (2022). https://doi.org/10.1038/s41591-022-02015-7

Circulating Tumor Cells and ctDNA Decreased in Most Patients Following SD-101 Infusions at 2 mg Dose Level

Data pending at higher dose levels





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