Strata Oncology, Inc.
www.strataoncology.com

Advancing immunotherapy strategies through comprehensive genomic and transcriptomic profiling

Precision medicine is at the heart of immunotherapy, yet the development of new immunotherapies is hampered by the lack of predictive biomarkers, access to NGS testing, and large prospective trials. Strata Oncology is addressing these challenges through an integrated platform.

Who will respond to immunotherapy?

It's one of the most pressing questions for clinicians and patients alike. The clinical development of immune checkpoint inhibitors (ICIs) has transformed the treatment landscape in oncology, with unprecedented responses in multiple tumors. However, only a subset of patients responds to treatment with ICIs, underscoring the need for predictive biomarkers to identify appropriate candidates for immunotherapy.

Precision oncology company, Strata Oncology, is working to answer this, and many others questions in the field of immuno-oncology, with the first comprehensive genomic and transcriptomic profiling (CGTP) platform that combines DNA and RNA sequencing, real-world data, and large-scale clinical trials to help identify and deliver optimal treatments for patients with cancer.

"Determining an optimal treatment course based on genomic variations, also known as precision medicine, emerged two decades ago as a logical next step to sequencing the complete human genome, and was seen as a panacea to rapidly reduce disease burden in the world, especially for cancer," said Dan Rhodes, co-founder and CEO of Strata. "However, we have learned that to fully realize the potential of precision medicine, we need to go beyond the DNA blueprint provided by the genome and also characterize RNA expression—the transcriptome—in order to find better outcomes for patients."

Strata's CGTP platform is powered by StrataNGS, a clinically and analytically validated next-generation sequencing profiling assay with the lowest tissue requirements for assessing DNA and quantifying RNA in solid tumors (Fig. 1). The 429-gene assay requires less than 2mm^2 of tissue to run, compared to the conventional standard of 25mm^2 or larger—ensuring more than 90% of patient samples meet minimum requirements for NGS testing, compared to roughly 40% with other NGS tests[1].

With the addition of highly quantitative RNA sequencing, performed simultaneously with DNA sequencing, Strata Oncology offers routine characterization of known and emerging immunotherapy biomarkers such as PD-L1, LAG3, CD8 and TIGIT.

Combined DNA and RNA sequencing is also helping advance research in identifying new multifactorial predictive immunotherapy biomarkers, as shown in a recent study shared at ASCO 2021[2]. The study found that PD-L1, PD-L2 and tumor mutation burden (TMB) from the CGTP test independently predicted pembrolizumab benefit in pan-solid tumors—and when combined in a multivariate signature score—predicted benefit better than PD-L1 or TMB alone.

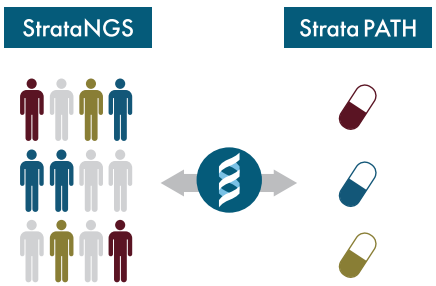

Fig. 1 | StrataNGS and Strata PATH. Leveraging comprehensive genomic and transcriptomic profiling from the StrataNGS assay, Strata PATH aims to define novel, highly responsive, pan tumor molecular indications for existing FDA-approved therapies. These include biological RNA expression signatures, and target RNA expression, including NECTIN4, TROP2, and HER2.

The results from Strata Oncology's CGTP platform may also be leveraged to match patients to innovative clinical trials conducted by Strata that are designed to answer the most pressing questions in precision cancer medicine.

A new PATH for therapeutic strategies

Strata launched the Precision Indications for Approved Therapies or Strata PATH trial, to define novel, high-response rate pan-tumor molecular indications for US Food and Drug Administration (FDA)-approved therapies. The study launched with Pfizer as a collaborator, and Strata is expecting additional biopharma companies to join.

"The Strata PATH study is an example of our commitment to delivering the best possible treatment for cancer patients," said Rhodes. "Using the latest clinical-molecular insights, and partnering with biopharma to translate them into optimized biomarker-guided treatments, we are pushing the boundaries of precision medicine and accelerating the validation of biomarkers through a large prospective trial."

Standing SENTINEL to monitor cancer recurrence

Recognizing that devising personalized therapies for advanced solid tumors is only half the battle in cancer, and that the biggest need is to identify early signals of recurring or latent disease, Strata launched the Sentinel trial, a study designed to detect disease recurrence and to monitor treatment effectiveness in patients with stage I-III solid tumors.

"With the Sentinel Trial we aim to validate our CGTP platform as a tool for guiding treatment in a wide spectrum of early stage solid tumors," said Rhodes. "Most advances in precision oncology to date have been in late-stage cancer, and we are committed to expanding the potential of precision cancer care to early-stage tumors."

Strata is focused on advancing precision in medicine in immunotherapy, but also recognizes this requires coordinated effort, and is actively interested in collaborating with new partners.

"From the beginning, the Strata vision has been to get the right drug to the right patient at the right time to make the promise of precision medicine a reality for as many patients as possible," said Rhodes. "We designed the Strata PATH and Sentinel studies to help match patients with off-label and investigational drugs through direct partnerships with pharma, and our ability to provide more treatment selection results from minute tumor tissue samples will help make these treatments available to more patients with cancer."

1. Tomlins, S. A. et al. *JCO Precis. Oncol.* **5**, 1312–1324 https://doi.org/10.1200/PO.20.00472 (2021).
2. Rhodes, D. et al. *J. Clin. Oncol.* **39** (Suppl. 15), 2609 (2021).

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