Mission Bio Transfers First Tapestri GMP-Ready CGT Assay to Avance Biosciences for Cell-Based Therapies

NEWS PROVIDED BY
Mission Bio
02 Feb, 2022, 08:00 ET

GMP-compliant test for transduction efficiency marks a key milestone for Tapestri's ability to power single-cell analysis in clinical trial settings for cell & gene therapies

SOUTH SAN FRANCISCO, Calif., Feb. 2, 2022 /PRNewswire/ -- Mission Bio, the pioneer in high-throughput single-cell DNA and multi-omics analysis, announced today the first tech transfer of a clinical trial-ready cell and gene therapy (CGT) assay from its Tapestri Platform to Avance Biosciences, Inc., a leading-edge CRO based in Houston, Texas, to assess transduction efficiency for an autologous cell therapy currently under development. This collaboration marks the first time the Tapestri Platform will undergo qualification and validation within a good manufacturing practice (GMP) setting, paving the way for its routine use in clinical trials on CGT materials to support the next wave of life-saving CGT treatments.

The Tapestri Platform will allow Avance to analyze cells that have been transduced with lentivirus, identifying transgene integration within individual cells without the need to grow clonal populations. Tapestri analysis not only reduces the timeframe of conventional workflows, but also enables large sample sizes (at the scale of thousands of individual cells) to be rapidly assessed — yielding highly accurate and precise measurements of transduction efficiency.

Assessing the safety and efficacy of CGT products is more challenging than conventional therapies because of the many potential variations between genetically altered cells. Cells modified with a viral vector will differ in transduction efficiency and the number of copies incorporated into the genome. Cells modified with tools like CRISPR can vary in on- and off-target edits, zygosity, or aberrant translocations. Before Tapestri, workflows required synchronizing data from multiple genotypic and phenotypic assays over several weeks, an approach with reduced specificity and limited ability to characterize cells with simultaneous edits.

The qualification and adoption of Tapestri assays – already used in pre-clinical settings to assess critical quality attributes of cell and gene therapy candidates – in a GMP environment validates their utility at the clinical and chemistry, manufacturing, and control (CMC) phases. With GMP compliance, Tapestri can be used for batch release assays to assess products prior to administration to patients.

"As the demand for cell and gene therapies continues to increase, the need to understand which genomic modifications are taking place in which specific cells is paramount for ensuring clinical safety and efficacy," said Yan Zhang, Ph.D., CEO of Mission Bio. "To our knowledge, this is the first high-throughput single-cell assay in use for clinical-grade cell therapy manufacturing. We're excited to see how a partner with Avance's experience and reputation for high-quality GMP compliant assay validation and its client harness Tapestri's capabilities."

"We are excited to add another state-of-art technology to our biological assay toolkit to support our ever-growing base of clients for their gene and cell therapy development initiatives," said Xuening (James) Huang, Ph.D., co-founder and CEO of Avance. "Tapestri will allow us to assess transduction efficiency at single-cell resolution, skipping laborious steps that delay these therapies from patients who are in dire need."

To learn more about Mission Bio and the Tapestri platform, please visit www.missionbio.com.

About Mission Bio

Mission Bio is a life sciences company that accelerates discoveries and cures for a wide range of diseases by equipping researchers with the tools they need to better measure and predict our resistance and response to new therapies. Mission Bio's multi-omics approach improves time-to-market for new therapeutics, including innovative cell and gene therapies that provide new pathways to health. Founded in 2014, Mission Bio has secured investment from Novo Growth, Cota Capital, Agilent Technologies, Mayfield Fund, and others.

The company's Tapestri platform gives researchers around the globe the power to interrogate every molecule in a cell together, providing a comprehensive understanding of activity from a single sample. Tapestri is the only commercialized multi-omics platform capable of analyzing DNA and protein simultaneously from the same sample at single-cell resolution. The Tapestri Platform is being utilized by customers at leading research centers, pharmaceutical, and diagnostics companies worldwide to develop treatments and eventually cures for cancer. To learn more, visit missionbio.com.

About Avance Biosciences

Avance Biosciences is a leading CRO specializing in biological assays to support the biopharma industry. With years of experience in assay design, assay validation, and sample testing in compliance with GLP and GMP regulations, Avance supports many clients' gene and cell therapy therapeutic pipelines through biological drug discovery, PK and preclinical safety studies, clinical trials, and CMC of biologics production.

Founded in 2011, Avance has grown rapidly and has become a prominent CRO partner to the biopharma cell and gene therapy segment. The company was one of the first to use next-generation DNA sequencing (NGS) and droplet digital PCR (ddPCR) technologies in a regulated environment. To learn more, visit avancebio.com.

Media Contact

Consort Partners for Mission Bio
missionbio@consortpartners.com