



HTG and Icahn School of Medicine at Mount Sinai Announce Bladder Cancer Research Collaboration

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HTG's Innovative Transcriptome Panel Technology to be Leveraged in Retrospective Studies

TUCSON, Ariz., Nov. 17, 2021 (GLOBE NEWSWIRE) -- HTG Molecular Diagnostics, Inc. (Nasdaq: HTGM) (HTG), a life science company advancing precision medicine through its innovative transcriptome-wide profiling technology, and the Icahn School of Medicine at Mount Sinai (Icahn Mount Sinai), world-renowned for its groundbreaking research, announced they have entered into a new research collaboration as part of HTG's Transcriptome Panel Early Adopter Program. HTG will provide in-kind laboratory services utilizing its proprietary HTG EdgeSeq technology in connection with multiple Icahn Mount Sinai bladder cancer studies.

"The Precision Immunology Institute and The Tisch Cancer Institute at the Icahn School of Medicine at Mount Sinai have long been distinguished for their innovative approaches to pioneering basic and translational research and we are honored to have the opportunity to expand our collaboration with this talented team of researchers," said Byron Lawson, Senior Vice President and Chief Commercial Officer of HTG.

"We believe HTG's profiling technology is poised to dramatically reshape the scientific discovery process, enabling researchers to more quickly and cost effectively interrogate the entire transcriptome with smaller sample requirements and higher success rates," Lawson added. "Since launching our HTG Transcriptome Panel commercially in the U.S. and Europe, there has been significant enthusiasm about the opportunity this technology presents among research institutes and biopharma companies. We are grateful to our early adopters such as the Icahn School of Medicine at Mount Sinai and look forward to future partnerships with those operating at the forefront of discovery to unlock the full potential of our platform."

Launched in August 2021, HTG's Transcriptome Panel, is designed to measure approximately 20,000 mRNA targets using the HTG EdgeSeq technology. HTG's panel reduces sample input requirements, is less sensitive to sample age, provides for faster turnaround times than other currently available methods and has a higher sample success rate than RNA-Seq for gene expression profiling.

"I have been collaborating with HTG since 2018, utilizing their HTG EdgeSeq platform to interrogate bladder tumors which are known to be highly necrotic. I immediately appreciated that HTG's technology offers an enhanced ability to capture signal from degraded RNA," said Dr. Amir Horowitz, Assistant Professor of Oncological Sciences at Icahn Mount Sinai. "With the added flexibility that comes from being able to use a single 5mm section of tissue, we are now interrogating consecutive tissue sections for imaging analyses to validate statistically meaningful genes and pathways that are identified from the genomic studies with HTG. As cancer immunologists, we are trying to define meaningful interactions between immune cells, stroma and tumors to better understand the tumor microenvironment and identify pathways to exploit for immunotherapeutic purposes.

"I believe the ability to capture ~20,000 genes from a single tissue section with the HTG Transcriptome Panel will be a game-changer," Dr. Horowitz continued. "We can now learn from the HTG sequencing analyses and design data-driven approaches to comprehensively define tumor biology. The minimal requirements for tissue as well as the ability to yield signal from poor-quality RNA should afford us the opportunity to look back to our archival tissues and start addressing some really challenging questions."

"Additional to HTG's chemistry, the Reveal software suite provides a cloud-based environment that is developed and curated specific to the HTG EdgeSeq analyses, allowing users who lack programming experience to immediately dive into their analyses and start defining meaningful biology," he also noted.

The collaboration between HTG and Icahn Mount Sinai involves three separate clinical study cohorts focused on bladder cancer.

The first project includes approximately 160 non-muscle-invasive bladder samples from cancer patients treated at hospitals across Sweden and were part of the "25-year-follow-up of the 1995-1996 Stockholm bladder cancer" project. Utilizing the HTG Transcriptome Panel, Icahn Mount Sinai will examine treatment-naïve samples for transcriptional signatures that could be used to potentially predict treatment outcomes and long-term survival.

The second project includes muscle-invasive bladder cancer (MIBC) samples from patients treated with immune checkpoint blockade immunotherapies at hospitals across the United States. From this study, pre-treatment trans-urethral resections of bladder tumors (TURBTs) from 108 patients (54 complete responders and 54 non-responders) will be assessed with the HTG Transcriptome Panel, with the goal of identifying transcriptional signatures that may predict treatment response or treatment failure.

The third project includes MIBC samples from patients treated with chemotherapy (gemcitabine and cisplatin) along with PD-1 blockade as a potential bladder-sparing approach. Data from the HTG Transcriptome Panel of TURBTs from 68 patients (34 complete responders and 34 non-responders) will be evaluated with the goal of identifying transcriptional signatures that may predict treatment response or treatment failure as part of a bladder sparing treatment protocol.

About HTG:

HTG is accelerating precision medicine from diagnosis to treatment by harnessing the power of transcriptome-wide profiling to drive translational research, clinical diagnostics and targeted therapeutics across a variety of disease areas.

Building on more than a decade of pioneering innovation and partnerships with biopharma leaders and major academic institutes, HTG's proprietary RNA platform technologies are designed to make the development of life science tools and diagnostics more effective and efficient and to unlock a differentiated and disruptive approach to transformative drug discovery. For more information visit www.htgmolecular.com.

About the Mount Sinai Health System

The Mount Sinai Health System is New York City's largest academic medical system, encompassing eight hospitals, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. We advance medicine and health through unrivaled education and translational research and discovery to deliver care that is the safest, highest-quality, most accessible and equitable, and the best value of any health system in the nation. The Health System includes approximately 7,300 primary and specialty care physicians; 13 free-standing joint-venture centers; more than 410 ambulatory practices throughout the five boroughs of New York City, Westchester, and Long Island; and more than 30 affiliated community health centers. The Mount Sinai Hospital is ranked in *U.S. News & World Report's* "Honor Roll" of the top 20 U.S. hospitals and among the top in the nation by specialty: No. 1 in Geriatrics and top 20 in Cardiology/Heart Surgery, Diabetes/Endocrinology, Gastroenterology/GI Surgery, Neurology/Neurosurgery, Orthopedics, Pulmonology/Lung Surgery, Urology, and Rehabilitation. Mount Sinai Kravis Children's Hospital is ranked in *U.S. News & World Report's* "Best Children's Hospitals" among the country's best in four out of 10 pediatric specialties. New York Eye and Ear Infirmary of Mount Sinai is ranked among the Top 20 nationally for ophthalmology. The Icahn School of Medicine at Mount Sinai is one of three medical schools that have earned distinction by multiple indicators: ranked in the top 20 by *U.S. News & World Report's* "Best Medical Schools," aligned with a *U.S. News & World Report* "Honor Roll" Hospital, and No. 14 in the nation for National Institutes of Health funding. *Newsweek's* "The World's Best Smart Hospitals" ranks The Mount Sinai Hospital as No. 1 in New York and top five globally, and Mount Sinai Morningside as top 20 globally, and "The World's Best Specialized Hospitals" ranks Mount Sinai Heart as No. 1 in New York and No. 4 globally and the Division of Gastroenterology as No. 3 globally. For more information, visit <https://www.mountsinai.org> or find Mount Sinai on [Facebook](#), [Twitter](#) and [YouTube](#).

Safe Harbor Statement:

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding future events and activities under the collaboration with Icahn Mount Sinai, the capabilities of HTG's profiling technology, our belief that HTG's profiling technology is poised to dramatically reshape the scientific discovery process, and future partnerships. Words such as "designed to," "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements necessarily contain these identifying words. These forward-looking statements are based upon management's current expectations, are subject to known and unknown risks, and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation, risks associated with the impact of the COVID-19 pandemic on us and our customers; the risk that our transcriptome panel and advanced chemical library designs may not provide the benefits that we expect; risks associated with our lack of experience in drug discovery and related collaborations; risks associated with our ability to develop and commercialize our products, including our transcriptome panel; the risk that our products and services may not be adopted by biopharmaceutical companies or other customers as anticipated, or at all; our ability to manufacture our products to meet demand; competition in our industry; additional capital and credit availability; our ability to attract and retain qualified personnel; and product liability claims. These and other factors are described in greater detail in our filings with the Securities and Exchange Commission ("SEC"), including under the "Risk Factors" heading of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, as filed with the SEC on November 10, 2021. All forward-looking statements contained in this press release speak only as of the date on which they were made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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