



HTG Completes Product Design Lock for its Planned Transcriptome Panel and Announces the Signing of the Three Early Adopter Program Collaboration Agreements

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TUCSON, Ariz., June 14, 2021 (GLOBE NEWSWIRE) -- [HTG Molecular Diagnostics](#), Inc. (Nasdaq: HTGM) (HTG), a life science company whose mission is to advance precision medicine, today announced it has completed product design lock for the HTG Transcriptome Panel and announced three Early Adopter Program (EAP) collaborators. HTG continues to progress in its development of a planned transcriptome panel using the HTG EdgeSeq technology. This panel, expected to be called the HTG Transcriptome Panel, will measure approximately 20,000 mRNA targets, with a planned research use only commercial launch in the third quarter of 2021.

"I am excited to report that we have fully implemented all planned requirements for our HTG Transcriptome Panel and achieved product design lock," said Dr. Marian Navratil, Senior Vice President of Research and Development. "Our development team has spent the past four months characterizing and optimizing the panel's design in an effort to ensure its peak performance and robustness. Product design lock is one of the most critical milestones in the product development lifecycle, allowing the project to advance into design verification. During the design verification phase, we will independently confirm that all performance requirements, including precision and accuracy, have been implemented before we proceed to commercialization. We believe this second-generation HTG chemistry will serve as the backbone for our future RNA gene expression products."

Achieving design lock also allows HTG to formally begin its previously announced Early Adopter Program with several collaborators with whom HTG has been planning studies with for the past several months. The EAP allows this select group of customers access to the initial transcriptome panel for use in their laboratories or through services performed by HTG prior to the planned commercial launch of the panel in the third quarter. The EAP will also provide collaborators with priority access to product purchases and the ability to contract with HTG to execute laboratory service projects on their behalf prior to commercial launch.

"Successful completion of this key milestone has allowed us to begin the finalization of EAP agreements, study details and logistics, and we believe it will allow us to begin study execution in the next few weeks," said Byron Lawson, Senior Vice President and Chief Commercial Officer. "Demand for access to our Early Adopter Program has exceeded our expectations, with discussions ongoing with nearly 40 potential EAP collaborators in academia and pharma. Several top prestigious cancer centers and research institutions throughout the US and Europe have expressed interest in our planned HTG Transcriptome Panel and participation in the EAP. In the past week, we signed EAP Collaboration Agreements with three top institutions in the US, including the University of Texas MD Anderson Cancer Center, Duke University Medical Center and Saint John's Cancer Institute, each of which is at the leading edge in delivering precision medicine with a focus on novel technologies like our HTG EdgeSeq technology.

"In addition to those expected to participate in the EAP, many new and existing customers have requested pricing quotes for kit purchases or lab service projects leveraging the HTG Transcriptome Panel, and commercialization plans continue to progress as we move toward a planned global commercial launch in the third quarter of 2021," Mr. Lawson continued.

About HTG:

HTG is focused on NGS-based molecular profiling. The company's proprietary HTG EdgeSeq technology automates complex, highly multiplexed molecular profiling from solid and liquid samples, even when limited in amount. HTG's customers use its technology to identify biomarkers important for precision medicine, to understand the clinical relevance of these discoveries, and ultimately to identify treatment options. Its mission is to empower precision medicine.

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: our planned HTG Transcriptome Panel, including the timing of its planned commercial launch and its expected capabilities and performance; our expectations as a result of our completion of product design lock; our belief that the HTG Transcriptome Panel and second-generation HTG chemistry will serve as the backbone for our future RNA gene expression products; the anticipated timing of our EAP study execution; the utility and use of our HTG EdgeSeq technology; and our ability to grow our customer base and penetrate new markets. Words such as "believe," "expect," "will," "planned," "future" 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 HTG EdgeSeq technology may not have the utility and be used by our customers as we expect; risks associated with our ability to develop and commercialize our products, including the HTG 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; the level and availability of third party payor reimbursement for our products; our ability to protect our intellectual property rights and proprietary technologies; our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties; 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, including without limitation our Quarterly Report on Form 10-Q for the period ended March 31, 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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