HTG Concludes Feasibility Testing & Releases Second White Paper for its Planned Whole Transcriptome Panel Using HTG EdgeSeq Technology

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TUCSON, Ariz., Feb. 26, 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 its feasibility testing for a planned whole transcriptome panel using the HTG EdgeSeq technology, and has released a follow-on whole transcriptome product white paper (White Paper Two), regarding the performance of a prototype panel for multiple cancer indications compared to RNA sequencing (RNA-Seq). HTG is developing a whole transcriptome panel using the HTG EdgeSeq technology to measure approximately 20,000 mRNA targets, with a planned research use only launch in the third quarter of 2021.

“Since demonstrating initial technical feasibility with our prototype whole transcriptome panel in November 2020, we have continued to iterate our prototype panel, mature the gene content and probe designs and improve the sample preparation process, to reduce background and increase the robustness of the panel across a variety of cancer indications,” said Dr. Marian Navratil, Senior Vice President of Research and Development.

“We are very excited to share what we believe is compelling data generated in studies performed since the demonstration of initial feasibility with the release of White Paper Two today. As outlined in this white paper, in addition to an assessment of repeatability of our latest prototype panel, we have completed an evaluation of the accuracy of differential expression analysis using a three-pronged accuracy assessment which included: (1) a comparison to RNA-Seq, (2) independent evaluation of differential expression using external RNA controls consortium (ERCC) control materials, and (3) a tissue mixture study. In all three assessments, the panel demonstrated a high degree of accuracy when measuring differential gene expression and in comparison to RNA-Seq,” continued Dr. Navratil.

White Paper Two further demonstrates the feasibility and expected performance of the whole transcriptome prototype panel, including:

- **Ability to differentiate samples based on gene expression profiles** – The data generated in the studies demonstrated the ability to generate unique gene expression profiles for multiple cancer indications with comparable sample clustering relative to RNA-Seq.

- **Repeatability with archived samples** – In the studies performed, the panel achieved an equally high degree of repeatability amongst replicates from multiple cancer indications in both 5- and 10-year-old formalin-fixed paraffin-embedded (FFPE) samples, with all but one sample requiring only a single FFPE section for sample input, compared with RNA-Seq, which required 4-8 FFPE sections per sample for RNA extraction and 25% of samples failed to generate sufficient extracted RNA material.

- **Accuracy of differential expression** – The accuracy of differential expression analysis using a direct comparison to RNA-Seq, and spiked-in reference material in a complex FFPE matrix, was demonstrated in studies across multiple cancer indications. Additionally, a tissue mixture study demonstrated equivalent accuracy of differential expression analysis.

- **Robust alternative to RNA-Seq** – These studies demonstrate that the HTG EdgeSeq technology is a robust alternative to RNA-Seq for gene expression profiling, in addition to maintaining advantages such as less sample input, extraction-free chemistry and the ability to test low-quality and limited quantity FFPE tissue specimens.

“Now that we have concluded feasibility testing for all elements of the panel’s design, we are proceeding to the optimization phase of this development program, where we expect to further improve the panel’s design, workflow and robustness. Final product design lock is scheduled to occur in the second quarter of 2021, followed by formal design verification and commercialization in the third quarter of 2021,” Dr. Navratil concluded.

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 the benefits of and timing for development and commercialization of our planned whole transcriptome panel, and our expectations for increased demand for our products and services in the future and our ability to meet those demands and for growth in our business. Words such as “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 we may not establish new and significant collaboration development arrangements; the risk that the planned whole transcriptome panel may not provide the benefits or be developed or commercialized as expected, or at all; the risk that future performance of the planned whole transcriptome panel may not match the performance observed in the studies outlined in White Paper Two; risks associated with our ability to develop and commercialize our products, including a whole 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 quarter ended September 30, 2020. 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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Source: HTG Molecular Diagnostics, Inc.