HTG Demonstrates Technical Feasibility for a Whole Transcriptome Panel Using HTG EdgeSeq Technology

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TUCSON, Ariz., Nov. 02, 2020 (GLOBE NEWSWIRE) -- HTG Molecular Diagnostics, Inc. (Nasdaq: HTGM) (HTG), a life science company whose mission is to advance precision medicine, today announced the completion of proof of concept for a whole transcriptome panel using the HTG EdgeSeq technology, and release of a White Paper illustrating the feasibility and performance of this prototype panel relative to RNA sequencing (RNA-Seq). As previously discussed, HTG is developing a whole transcriptome panel utilizing the HTG EdgeSeq technology to measure approximately 20,000 mRNA targets, with a planned RUO launch in mid-2021.

“Demonstrating technical feasibility of a prototype panel covering the whole transcriptome with our HTG EdgeSeq chemistry was critical to establish the ability to scale from our current targeted panels of less than 3,000 targets to measuring approximately 20,000 targets, while maintaining the advantages of our HTG EdgeSeq technology,” said Marian Navratil, Vice President of Research and Development. “Additionally, evaluating the performance of this prototype panel versus traditional RNASeq was vital in the development of our first assay to measure the entire human transcriptome from a single tissue section without RNA extraction.”

The White Paper released today illustrates the feasibility and expected performance of this prototype assay, including:

- **Measurement of the whole transcriptome** – Supported use of HTG EdgeSeq technology as a highly scalable measurement of the entire human transcriptome.
- **Correlation with RNA-Seq** – Demonstrated directional alignment in expression data, and highly correlated differential expression results versus traditional RNA-Seq. Additionally, exceptional accuracy of differential expression analysis using spiked-in reference material was demonstrated.
- **Robust alternative to RNA-Seq** – This proof of concept study demonstrates 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 FFPE tissue.

“Over the next several months, we plan to complete technology feasibility and development of the final assay per formal design verification leading up to planned launch of this novel product in mid-2021,” said Marian Navratil, Vice President, Research and Development.

“In parallel to assay development, we expect to begin our commercialization of this potentially game-changing product with the launch of our Early Access Program in the fourth quarter of 2020,” said Byron Lawson, Senior Vice President and Chief Commercial Officer. “We believe this whole transcriptome panel will be a foundational product not only for RUO profiling, but also for potential companion diagnostic partnerships and proprietary diagnostic products. We also expect this product to allow for further expansion of our product offerings outside of oncology and immune response diseases and into markets such as transplant diagnostics and rare diseases.”

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; 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 10Q for the quarter ended June 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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