HTG Molecular Diagnostics Announces New Commercialization and Distribution Agreement for Companion Diagnostics with QIAGEN

August 10, 2020

TUCSON, Ariz., Aug. 10, 2020 (GLOBE NEWSWIRE) -- HTG Molecular Diagnostics, Inc. (Nasdaq: HTGM) (HTG), a life science company whose mission is to advance precision medicine, today announced the signing of a Commercialization and Distribution Agreement (Master Agreement) with QIAGEN Manchester Limited, a wholly owned subsidiary of QIAGEN N.V. (NYSE: QGEN; Frankfurt Prime Standard: QIA) (QIAGEN).

The 10-year agreement provides a foundation for both companies to combine their technological and commercial strengths with the goal to offer pharmaceutical companies global development, distribution and commercialization capabilities for companion diagnostic (CDx) assays based on HTG EdgeSeq, HTG's novel RNA platform.

The Master Agreement allows HTG to engage directly with biopharma customers for CDx development programs including assay development, clinical trial oversight and global regulatory submissions, with potential CDx assays developed leveraging either an Illumina, Inc. or a Thermo Fisher Scientific NGS platform. In the event a CDx assay is required, the agreement provides HTG's customers global distribution and commercialization options with QIAGEN, a proven world-class molecular diagnostics leader.

"Our biopharma customers want the ability to develop new biomarkers with our HTG EdgeSeq technology, along with the ability to distribute them globally. This new agreement is designed to allow them to do just that," said Byron Lawson, Senior Vice President and Chief Commercial Officer. "Ultimately, we can now provide our customers with the confidence that they will be able to use our HTG EdgeSeq technology and capabilities, while leveraging the proven commercial expertise and distribution scale of QIAGEN."

John Lubniewski, President and Chief Executive Officer, added, "This new agreement preserves the original value we saw when we initially collaborated with QIAGEN in 2016; HTG EdgeSeq technology, leveraging either an Illumina or Thermo Fisher Scientific sequencer, with global commercialization and distribution options offered by QIAGEN, one of the largest molecular diagnostic companies in the industry. We are extremely pleased we were able to renew our partnership with QIAGEN and look forward to contracting new CDx programs to deliver on our mission to advance precision medicine."

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 potential benefits to HTG under the Master Agreement including our ability to contract for new CDx agreements as a result of the agreement. 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 but not limited to, the risk that the Master Agreement may not provide the expected benefits to HTG or its customers; the risk the we may not be successful in our efforts to commercialize CDx opportunities; the risk that our products and services may not be adopted by biopharmaceutical companies or other customers as anticipated, or at all; and our ability to manufacture our products to meet demand. 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 March 31, 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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