HTG Molecular Announces Extension to Precision Diagnostic Partnership (PDP) Program Three for Companion Diagnostic Submission

September 27, 2018

TUCSON, Ariz., Sept. 27, 2018 (GLOBE NEWSWIRE) -- HTG Molecular Diagnostics, Inc. (Nasdaq: HTGM) ("HTG"), a provider of instruments, reagents, and services for molecular profiling applications, today announced that it has entered into an amendment to the third statement of work ("SOW Three") under its Master Assay Development, Commercialization and Manufacturing Agreement with QIAGEN Manchester Limited ("QIAGEN"). Initial assay development activities under SOW Three are complete, and this first amendment to SOW Three provides for the development of an investigational use only assay, subsequent retrospective testing of clinical trial samples, design verification and, subject to satisfactory achievement of relevant performance and regulatory milestones, regulatory submission in the US and EU necessary for the commercialization of a companion diagnostic assay for a corresponding pharmaceutical company drug.

"This amendment to our third statement of work expands our agreement and we are pleased to take this next logical step in this program with QIAGEN. We continue to look forward toward the potential commercialization of our first companion diagnostic assay," said Byron Lawson, Senior Vice President, Pharma Partnerships.

About HTG:
HTG is focused on next generation sequencing (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. Our mission is to empower precision medicine at the local level.

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 activities *expected to occur in connection with the amendment to SOW Three with QIAGEN, the anticipated benefits or outcomes of SOW Three, as amended, and the potential development and commercialization of a companion diagnostic assay. 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, the risk that the activities contemplated by the amendment to SOW Three may not be performed as expected, or at all; the risk that the work performed or to be performed under SOW Three, as amended, may not support the development and commercialization of a companion diagnostic assay; risks associated with our ability to successfully commercialize our products; 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 effectively manage our anticipated growth; 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 June 30, 2018. 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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