HTG Molecular Diagnostics and Firalis Announce an Agreement Enabling Firalis' Commercialization of Theranostic and Research Products and Services Based on HTG EdgeSeq Technology

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TUCSON, Ariz. and HUNINGUE, France, May 07, 2018 (GLOBE NEWSWIRE) -- HTG Molecular Diagnostics, Inc. (Nasdaq:HTGM) ("HTG"), a provider of instruments, reagents and services for molecular profiling applications, and Firalis S.A. ("Firalis"), a provider of bioanalytical services and biomarker-based products and services, today announced a non-exclusive license and supply agreement ("Agreement") that will enable Firalis to commercialize a next-generation sequencing (NGS)-based theranostic product and services to predict rheumatoid arthritis (RA) patients response to anti-TNFα therapy, and other research products and services for mRNA profiling of inflammatory-autoimmune disorders.

The Agreement is a next step in the parties' relationship following the successful adaptation of Firalis' BIOPRED* research -use assay to HTG EdgeSeq technology. Under the Agreement, HTG will supply assay components to Firalis, who will manufacture, obtain applicable regulatory approvals for and sell the BIOPRED assay as kits and Firalis-based services in the applicable diagnostic and research fields worldwide. All such kits and services will be automated on HTG EdgeSeq systems purchased directly from HTG by end users.

"Firalis was one of the first adopters of the HTG EdgeSeq system in Europe, and we are pleased to support them in the next steps in this personalized medicine initiative," said TJ Johnson, Chief Executive Officer of HTG. "Strategic supply and non -exclusive technology out-licensing is another way to further our business objectives of market recognition and expansion and revenue growth.

"Millions of RA patients are treated with TNFα inhibiting agents, but these expensive biologicals are effective in only 30 to 40 percent of patients," explained Hueseyin Firat, President & CEO of Firalis. "We believe our BIOPRED assay will identify patients who will not successfully respond to such therapies. This Agreement is expected to, among other things, bring to market a product and services to improve clinical decision-making, improve health outcomes for RA patients, and contribute to cost reduction and sustainability of the health care system in the multibillion dollar global RA drug market."

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. 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 associated with the benefits of our agreement with Firalis S.A., the impact of TNFα inhibiting therapies on rheumatoid arthritis treatment and the size of the clinical market, the ability to predict treatment response in rheumatoid arthritis, the potential to contribute to health care system improvements, and our ability or strategies to expand the markets for or increase market recognition of our technology, products or solutions and grow our revenue. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential," and similar expressions are intended to identify forward-looking statements, though 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 utility of our automation systems, proprietary technology, products and solutions, and our ability to successfully manufacture and supply our products. These and other factors are described in greater detail in our filings with the Securities and Exchange Commission, including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2017. 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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About FIRALIS

Firalis is a biotechnology company with a mission to improve disease outcome, therapeutic decisions and generate savings in healthcare through biomarker discovery, development and regulatory qualification that ultimately leads to biomarker-based diagnostics. Firalis develops and markets RUO (Research-use-only) and IVD (In-vitro-diagnostic) kits in the field of cardiovascular, inflammatory and autoimmune diseases with particular interest in rheumatoid arthritis. Using cutting-edge technology platforms in a very high-quality environment (ISO 9001, ISO 13845, ISO 17025 and NF S 96-900), Firalis provides a comprehensive range of biomarker services from research to clinical applications in key therapeutic areas.

*****BIOPRED is a product, realized in the framework of IMI BT-Cure (Grant # 115142) and Horizon 2020 SME3 Instrument (Grant # 666798) funded by European Commission.

To get further information on Firalis Biomarker Services and its capabilities to successfully level up customer's projects, please contact sales@firalis.com.

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Primary Logo

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