



The Fundación Instituto Valenciano de Oncología Leverages HTG Technology for Breast Cancer Laboratory-Developed Test

September 20, 2022

TUCSON, Ariz., Sept. 20, 2022 (GLOBE NEWSWIRE) -- HTG Molecular Diagnostics, Inc. (Nasdaq: HTGM) (HTG), a life science company advancing precision medicine through its innovative transcriptome-wide profiling technology, announced that the Fundación Instituto Valenciano de Oncología, located in Valencia, Spain (IVO), with its partners, the Fundación Pública Andaluza Progreso y Salud (FPS) and the Centro de Investigación Biomédica en Red (CIBER), have developed a laboratory-developed test (LDT) (the MPD Test) for the assessment of breast cancer recurrence based on their use of the HTG EdgeSeq™ technology.

This innovative test for patients with HR+/HER2- early-stage breast cancer was developed by IVO and its partners to identify patients with an increased risk of developing distant metastasis or relapse who may benefit from adjuvant chemotherapy. IVO is among the top 50 cancer hospitals in the world; FPS is a public entity mainly dedicated to research and information technology; and CIBER is a public research consortium devoted to advancing research in biomedicine and health sciences.

This highly qualified and experienced team of researchers has partnered to develop and validate the MPD Test using the HTG EdgeSeq technology, which typically requires only one single 5 µm-thin FFPE tissue biopsy section, coupled with the sensitivity and dynamic range of next-generation sequencing (NGS)-based detection, to generate results in as little as 3 days.

"We are thrilled that three of Spain's most renowned cancer research organizations have chosen to leverage HTG's innovative technology to improve precision medicine for breast cancer patients," said Byron Lawson, Senior Vice President and Chief Commercial Officer of HTG. "The MPD Test is a great example of how the HTG EdgeSeq technology can be used not only for molecular profiling and analysis, but also as a predictive tool for advancing precision medicine."

"Among the challenges of traditional genomic testing in early-stage HR+/HER2- breast cancer is the wide variation in risk assessment," said Dr. José Antonio López-Guerrero, Head of Molecular Biology Laboratory at IVO. "Discordant results between two different genomic assays can have a significant clinical impact on patients, determining, for example, whether or not a patient chooses to undergo chemotherapy. Leveraging HTG's EdgeSeq technology, we believe that the MPD Test represents a cost-effective option to shorten the time to result, reduce the risk of potential bias and improve the overall risk profile using only a small sample from a tissue biopsy."

The MPD Test is available as an LDT provided by IVO and its partners.

About HTG:

HTG is accelerating precision medicine from diagnosis to treatment by harnessing the power of transcriptome-wide profiling to drive translational research, novel therapeutics and clinical diagnostics across a variety of disease areas.

Building on more than a decade of pioneering innovation and partnerships with biopharma leaders and major academic institutes, HTG's proprietary RNA platform technologies are designed to make the development of life science tools and diagnostics more effective and efficient and to unlock a differentiated and disruptive approach to transformative drug discovery.

For more information visit www.htgmolecular.com.

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: sample requirements and turnaround times expected while utilizing HTG EdgeSeq technology; the MPD test being indicative of how HTG EdgeSeq technology can be used for molecular profiling and analysis and as a predictive tool for advancing precision medicine; the belief that the MPD Test represents a cost-effective option to shorten the time to result, reduce the risk of potential bias and improve the overall risk profile using only a small sample from a tissue biopsy; and the capabilities, applications and design benefits of using HTG's EdgeSeq technology. Words such as "can be," "designed to," "believe," "typically" "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 HTG EdgeSeq technology or our RNA platform technology may not perform as expected or provide the benefits that we expect; uncertainties regarding the effectiveness of using HTG EdgeSeq technology as a predictive tool; risks related to reliance on third parties utilizing and validating our technologies; risks associated with our ability to develop and commercialize our products, including our HTG EdgeSeq technology; our ability to manufacture our products to meet demand; 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 (SEC), including under the "Risk Factors" heading of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, as filed with the SEC on August 12, 2022. 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.