AvantGen awarded contract from NIH to expedite the commercialization of its AccuRate™ COVID-19 SelfCheck OTC test

AvantGen, a San Diego based biotechnology company with a superior yeast display technology for facile antibody discovery and optimization, has entered the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx®) Tech program to expedite the commercialization of its sensitive AccuRate™ COVID-19 SelfCheck Over-the-Counter (OTC) test.

Applying their robust antibody discovery platform, AvantGen identified a panel of ultra-performing high affinity and specificity monoclonal antibodies against the nucleocapsid protein (N protein) of SARS-CoV-2. They developed a lateral flow rapid antigen test using these antibodies. The prototype was shown to exhibit ultra-high sensitivity and specificity in analytical studies.

In studies supported by RADx, the Limit of Detection (LoD), a key factor for test sensitivity, was determined to be 70 $TCID_{50}$/mL. The $TCID_{50}$/mL is the median (50%) Tissue Culture Infectious Dose ($TCID_{50}$) per microliter (mL), often used to quantify virus titers in order to determine how many virus particles per volume are inside a sample. This LoD of the AvantGen AccuRate™ test outperforms many emergency use authorization (EUA) OTC tests currently being sold in the U.S. The test is now entering a clinical trial to evaluate other clinical performance parameters.

As part of a RADx validation study performed in February, the analytical sensitivity of the AvantGen AccuRate™ test revealed that it was able to detect the Omicron variant. “Compared to the polymerase chain reaction (PCR) tests, rapid antigen tests are simple and convenient to use, however they can lack the necessary sensitivity, which translates to concerning false negative results, limiting the effectiveness of early screening and prevention of viral spread”, said Dr. Xiaomin Fan, President & CEO of AvantGen. “In addition to the high sensitivity, the data also showed that our test is able to detect Omicron variants in clinical samples in higher cycle threshold values compared to other rapid antigen tests. We look forward to assessing the field performance from the clinical testing in the coming weeks.”

About AvantGen

AvantGen is a biotechnology company with Therapeutic and Diagnostics divisions. The therapeutic division is dedicated to novel human antibody discovery, antibody humanization, antibody affinity maturation and optimization for therapeutic development. The company has a proprietary and robust Yeast Display System, large natural human antibody database, fully human antibody (Germliner™) libraries and rapid screening technologies. Additionally, it has developed a novel platform to generate rabbit monoclonal antibodies and VHH nanobodies with remarkably high affinity and specificity by combining the Yeast Display System and the robust immune responses generated in rabbits and alpaca. The company has received more than 20 NIH SBIR grants and contract awards to develop novel antibodies against multiple targets for therapeutic, diagnostic, and research reagents. To date, AvantGen has successfully fulfilled hundreds of projects, including some for NIH, universities, pharmaceutical and

biotechnology companies, facilitating and accelerating their antibody-based therapeutic development through services, partnership collaborations, and technology licensing. AccuRate™ is a trademark registered by AvantGen Diagnostics.

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