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NEW RAPID MOLECULAR COVID-19 TEST FROM ANAVASI DIAGNOSTICS AWARDED $14.9 MILLION BY NIH TO ACCELERATE TEST AVAILABILITY

Pending EUA Certification from the FDA AscencioDx™ Molecular Diagnostic System Expected to Provide Results Equivalent to PCR Testing in Less Than 30 minutes

WOODINVILLE, WASHINGTON (November 9, 2021) - Anavasi Diagnostics, a medical technology company focused on the development of novel molecular diagnostic testing using a proprietary patent-pending reverse transcriptase methodology, today announced it has been awarded $14.9 million from the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx℠) initiative. The funding will accelerate the launch and broad market availability of the AscencioDx™ molecular diagnostic platform for the detection of RNA indicative of the SARS-CoV-2 / COVID-19 virus.

Currently in clinical trials in the U.S., Anavasi expects to file its submission to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) in the near future. The initial EUA submission will claim effectiveness for administration by a licensed medical professional in a point-of-care setting, including physician offices, hospital emergency rooms, urgent care clinics, mobile testing sites, colleges and universities, as well as workspaces and other sites deemed appropriate by the healthcare professionals involved. Based on its technology and easy-to-perform test procedure, the AscencioDx has potential for at-home use pending further clinical validation and FDA clearance.

Previous NIH funding in August 2020 had allowed the Anavasi team to pivot from HIV to COVID-19 detection. Funding under today's award will accelerate hiring additional production staff, the acquisition of improved manufacturing automation equipment, and further development of Anavasi's portal for healthcare reporting via a Department of Health and Human Services-sponsored reporting platform for customers.

"We are honored that the NIH has recognized the AscencioDx molecular diagnostic system as a significant advancement in rapid, precise and affordable diagnostic testing for the SARS-CoV-2 virus," said Nelson Patterson, CEO of Anavasi Diagnostics. "At a time when Americans are seeking accurate testing options, our simple system promises to be the new gold standard. It can provide results in approximately 30 minutes comparable to lab-based polymerase chain reaction (PCR) tests. In addition, the AscencioDx platform almost completely eliminates false positives and negatives so frontline health workers no longer need to order multiple tests to ensure an absolute diagnosis. It's a one and done process that's like having a PCR lab in the palm of your hand. We believe that fast, accurate and affordable testing will lead to faster treatment and better healthcare outcomes for patients. We want to save lives."

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The AscencioDx uses sophisticated LAMP (loop-mediated isothermal amplification) molecular diagnostic chemistry and hardware technology first developed at the University of Washington to detect HIV viral variants. Now, the same approach is poised to make COVID-19 testing easier and more accurate for everyone.

"The AscencioDx will set a new precedent in rapid affordable, simple-to-complete COVID-19 testing," said Patterson. "When our clinical testing is complete and our submission presented to the FDA, we expect results to demonstrate that no point-of-care test is more accurate. The novel combination of features will make this product unique in the marketplace."

The AscencioDx offers:

- Rapid test results equivalent to lab-based PCR tests
- Easy and comfortable lower nasal swab sampling procedure
- Positive test results in approximately 30 minutes
- Simple reporting process **not** requiring a complicated phone app or use of Bluetooth™
- Price comparable to less accurate antigen tests and much lower than lab-based PCR tests
- Detector reusable for at least 3,000 single-use COVID-19 tests

While the initial application of the AscencioDx platform is for the detection of COVID-19, Patterson noted the technology is a perfect platform for the future of bacterial and viral testing: "Its origins detecting HIV variants make it ideal for the additional detection of other viruses such as Influenza A and/or B, as well as respiratory syncytial virus, a respiratory disease that severely impacts young children, older adults, and the immunologically impaired."

"Future products are expected to include an all-in-one multiplex capability for testing various respiratory diseases at one time, which may ultimately provide impressive accuracy and flexibility, while also saving time and money," Patterson added.

This project is supported by the NIH Rapid Acceleration of Diagnostics (RADx[SM]) initiative and has been funded in whole or in part with federal funds from National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N92022C00005.

Anavasi Diagnostics is a medical technology company focused saving lives by developing novel molecular diagnostic testing using a proprietary patent-pending reverse transcriptase methodology. It was founded by world-leading university researchers, top medical device and clinical diagnostics executives, manufacturing experts and a former Microsoft software veteran. Throughout their careers, the team has altogether been responsible for the introduction of more than forty medical/diagnostic products and hundreds of peer-reviewed research publications.

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