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Vivera Pharmaceuticals Files First of Two US Made COVID-19 Antibody Tests

NEWPORT BEACH, Calif., June 10, 2020 /PRNewswire/ -- Vivera Pharmaceuticals, Inc., a California-based pharmaceutical company focused on putting patients first, announces the launch of their point-of-care ready rapid serology tests.

Bringing manufacturing of vital supply back to the United States has been Vivera's top priority during the COVID-19 pandemic. Working closely with domestic suppliers, Vivera has now filed an Emergency Use Authorization (EUA) for the first of its two "Made in the USA" serology antibody tests with the FDA. Both are point-of-care tests designed to serve where patients most critically require screening testing. With one test optimized for use in mass-screening settings, such as drive through testing centers, and the other more suitable for use in doctor's offices and health clinics.

"Vivera has undergone clinical trials with nursing homes and health clinics and we have made refinements we feel will best serve the doctors and nurses who will be the ones using the test," stated Dr. Stephen McColgan, Vivera Pharmaceuticals' Chief Medical Officer. "Eventually, as the FDA finds the right pathway, we hope to transition into supporting telemedicine providers and expanding the availability of screening testing," he continued.

Once authorized, Vivera's tests would be the first true point-of-care tests designed for convenience and ease of use, allowing providers to triage their patients as efficiently as possible. Following in the footsteps of its first EUA filing, Vivera is voluntarily taking part in the National Cancer Institute backed validation studies for its two new filings.

"We have been working on a truly U.S. solution to the testing crises. The flood of poorly performing tests – such as the 30 or so removed from the FDA's website – have hurt more than helped," says Paul Edalat, CEO. "In the rush to find an 'answer' many of those responsible for testing gravitated toward cheaper imported options since there were few truly U.S. made tests available."

With an eye towards the future, Vivera will use its United States manufactured products to begin its forthcoming clinical trials in support of eventual medical device filings with the FDA as the Company further expands its advanced diagnostics division.

Vivera's COVx-RT Rapid Test is currently available for use by qualified CLIA laboratories as it awaits final Emergency Use Authorization approval.

Vivera Pharmaceuticals, Inc. is an innovative, science-driven pharmaceutical company focused on novel therapies for a variety of indications. In addition to its pharmaceutical and medical device products, the company has global exclusivity to license the patented and

patent-pending TABMELT[®] sublingual drug-delivery system for the pharmaceutical use of therapeutic compounds. The company is vertically integrated with patented technology, manufacturing capabilities, and distribution for its products.

For more information, visit www.viverapharmaceuticals.com and www.COVxRT.com

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