Cue Health Applies with FDA for Emergency Use Authorization of its Cue Flu + COVID-19 Molecular Test

October 4, 2022

At-home or point-of-care test can simultaneously detect and differentiate between flu and COVID-19, delivering diagnostic results to mobile devices in 25 minutes

SAN DIEGO, CA, October 4, 2022 —Cue Health ("Cue") (Nasdaq: HLTH), a healthcare technology company that puts diagnostic information at the center of care, today announced that on September 30, 2022, it submitted an application with the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) for its Cue® Flu + COVID-19 Molecular Test for at-home and point-of-care (POC) use.

The new Cue Flu + COVID-19 Molecular Test can simultaneously detect and differentiate between influenza and COVID-19 in approximately 25 minutes, with results delivered digitally to the Cue Health App on the user's mobile device. If authorized, Cue's Flu + COVID-19 test will be integrated into Cue Care™, the company's same-day, test-to-treatment solution within the Cue Health App, which enables individuals to consult with a healthcare professional and get treatment delivered to their home within hours if medically indicated.

"An accurate flu and COVID-19 test that can be done anywhere is a powerful tool. Combining this with the capability to treat on the same day enables a paradigm shift in respiratory diseases," said Ayub Khattak, Chairman and CEO of Cue Health. "We hope to enable this paradigm shift across the spectrum of infectious diseases and more with the many additional products in our pipeline."

Timely differential diagnosis of influenza versus COVID-19 is important because the two viruses present with many of the same symptoms but can be treated with distinct FDA-authorized antiviral medications, which must be administered soon after infection to be the most effective. Early treatment for both COVID-19 and flu can reduce an individual's risk of getting seriously ill1. Experts are warning that this year's respiratory infection season could be especially severe, placing a significant burden on the healthcare system due to the combined threat of a resurgent flu2 and new COVID-19 variants3. The FDA's Emergency Use Authorization pathway could allow for Cue's test to be deployed within this respiratory infection season.

The Cue Flu + COVID-19 Molecular Test Cartridge uses a lower nasal swab sample and runs on the Cue Reader, which communicates test results digitally to the Cue Health App on a mobile device. Currently, Cue's standalone molecular tests for both flu and COVID-19 are under *de novo* review with the FDA for full clearance.

Cue's COVID-19 test is in use today by millions of Americans, including by some of the nation's leading healthcare institutions, such as Johns Hopkins Medicine, Mayo Clinic, Memorial Hermann, and UPMC Children's Hospital of Pittsburgh. Cue is also used by world-class organizations such as Major League Baseball, Google, the National Basketball Association, and Bridgewater, among others.

1https://www.cdc.gov/flu/symptoms/flu-vs-covid19.htm2https://www.npr.org/sections/health-shots/2022/09/23/1124311571/flu-season-2022-covid-twindemic3https://www.science.org/content/article/big-covid-19-waves-may-be-coming-new-omicron-strains-suggest

About Cue Health

Cue Health (Nasdaq: HLTH) is a healthcare technology company that makes it easier for individuals to access health information and places diagnostic information at the center of care. Cue Health enables people to manage their health through real-time, actionable, and connected health information, offering individuals and their healthcare providers easy access to lab-quality diagnostics anywhere, anytime, in a device that fits in the palm of the hand. Cue Health's first-of-its-kind COVID-19 test was the first FDA-authorized molecular diagnostic test for at-home and over-the-counter use without a prescription and physician supervision. Outside the United States, Cue Health has received the CE mark in the European Union, Interim Order authorization from Health Canada, regulatory approval from India's Central Drugs Standard Control Organization, and PSAR authorization from Singapore's Health Sciences Authority. Cue was founded in 2010 and is headquartered in San Diego. For more information, please visit www.cuehealth.com.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements". The words, without limitation, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these or similar identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including those related to the expected future diagnostic test menu and the factors discussed in the "Risk Factors" section of Cue's Annual Report on Form 10-K for the year ended December 31, 2021 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 10, 2022. Any forward-looking statements contained in this press release are based on the current expectations of Cue's management team and speak only as of the date hereof, and Cue specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Cue's COVID-19 tests have not been FDA cleared or approved; but have been authorized by FDA and under an Emergency Use Authorization (EUA). These products have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of these products is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

MEDIA INQUIRIES

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