Cue Health Makes De Novo Submission to FDA for Full Clearance of its Cue® Flu Molecular Test

September 1, 2022

SAN DIEGO, Sept. 1, 2022 /PRNewswire/ -- Cue Health ("Cue") (Nasdaq: HLTH) today announced that it has made a *de novo* submission to the U.S. Food and Drug Administration (FDA) for full clearance of the Cue® Flu Molecular Test for at-home and point-of-care (POC) use. There are currently no flu tests on the market for home use. FDA clearance of Cue's test would provide the public, for the first time, an at-home and POC molecular flu test that has been fully reviewed by the FDA for safety and effectiveness.

Clinical study results with the Cue Flu Molecular Test were favorable, demonstrating 99% accuracy[1] compared to FDA cleared molecular (PCR) laboratory tests for influenza A&B. The Cue Flu Molecular Test cartridge uses a lower nasal swab and is compatible with the Cue Reader, which communicates test results digitally via Bluetooth to a mobile device in approximately 25 minutes.

"This FDA submission for our Cue Flu Molecular Test is another important milestone on Cue's path to pioneer a new approach to diagnostics in homes, enterprises, and healthcare settings," said Ayub Khattak, Chairman and CEO of Cue Health. "Early detection and treatment can meaningfully improve health outcomes. There are multiple FDA-approved antiviral treatments for influenza available today, and we expect we will soon be able to promptly get these medications into the hands of patients who need them thanks to our recently launched Cue Care service."

Cue's molecular COVID-19 test, which is authorized by the FDA for home and POC use under an Emergency Use Authorization (EUA), is also currently under *de novo* review with the FDA. With an installed base of over a quarter million Cue Readers shipped to date, Cue's COVID-19 test has been used by millions of Americans. Cue is used by some of the nation's leading healthcare institutions, including 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, Bridgewater, among others.

This project has been funded in whole or in part with Federal funds awarded by the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, in June 2018 under Contract No. HHSO100201800016C.

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.

[1] With discordance analysis using a second FDA-cleared laboratory PCR test

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