Cue Health Makes De Novo Submission to FDA for Full Clearance of Its Molecular COVID-19 Test

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SAN DIEGO, May 2, 2022 /PRNewswire/ -- Cue Health ("Cue") (Nasdaq: HLTH) today became the first company to submit to the U.S. Food and Drug Administration (FDA) for full clearance of its molecular COVID-19 test for at-home and point-of-care use. FDA clearance would provide the public with a molecular COVID-19 test that has been fully reviewed by the FDA for safety and effectiveness.

A prior submission to the FDA for Emergency Use Authorization of Cue's COVID-19 at-home, over-the-counter test showed 98.9% accuracy. An independent study by Mayo Clinic showed Cue's COVID-19 test to be in 97.8% overall concordance with central lab PCR testing.

"This FDA submission marks a major milestone for the company and begins to define a new space of molecular testing in the home and at the point-of-care. We hope this will be the first of many submissions for Cue's molecular testing as we look to address a range of diseases and conditions and make healthcare more responsive, convenient, and effective," said Ayub Khattak, CEO and co-founder of Cue Health.

With an installed base of nearly a quarter million Cue Readers to date, Cue's COVID-19 test has been used by millions of Americans. Cue is a COVID-19 testing solution in a number 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, and the National Basketball Association.

About Cue Health

Cue Health (Nasdaq: HLTH) is a healthcare technology company that makes it easy 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 the Form 10-K dated March 29, 2022 filed by Cue with the SEC. 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.

These products have not been FDA cleared or approved; but have been authorized by FDA 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.

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