Cue Health to Develop Omicron-Genotyping COVID-19 Test in Partnership with the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA)

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New test will provide clinicians and researchers with advanced health information to enable better-informed treatment and containment decisions in real-time

SAN DIEGO, Jan. 6, 2022 /PRNewswire/ -- Cue Health ("Cue") (Nasdaq: HLTH), a healthcare technology company, today announced it will develop an Omicron-Genotyping COVID-19 test to be used in professional point-of-care settings as part of the company's ongoing work with the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response. The Omicron-specific test will complement Cue's existing highly-accurate, molecular COVID-19 test, which can detect all known COVID-19 variants, including Omicron, a finding announced by the company in November.

The additional funding from BARDA will be used to accelerate the development, validation, and regulatory authorization of a single-plex assay designed solely to detect the Omicron variant in nasal samples. The new test will be compatible with the Cue Health Monitoring System and the Cue Health Mobile Application.

"An Omicron-specific test will assist clinicians in providing patients better treatment options and containment strategies at the time of a positive diagnosis," said Ayub Khattak, Co-Founder and CEO of Cue. "We are proud to partner with BARDA to develop this new test, which will help eliminate guesswork, provide more choices for patients, and strengthen public health outcomes for communities."

Cue has worked with BARDA since 2018, when the Company received $30 million in base funding to accelerate the development and regulatory validation of over-the-counter and professional use Influenza and Multiplex Respiratory Pathogen diagnostic cartridges for the Cue Health Monitoring System. In March 2020, Cue was awarded $13 million by BARDA to accelerate the development, validation, and FDA clearance of a portable, molecular diagnostic test capable of detecting SARS-CoV-2. Cue received Emergency Use Authorization (EUA) from the FDA in June 2020 for professional point-of-care use of its COVID-19 test. In March 2021, Cue was the first molecular test to receive FDA authorization for at-home and over-the-counter use without a prescription.

During the early stages of the pandemic, Cue's team of scientists and bioinformatic experts implemented a surveillance program to monitor and analyze all relevant SARS-CoV-2 variant sequences globally. These sequences are routinely compared to the primers in Cue's COVID-19 test to determine if any mutations are present that could affect the sensitivity or specificity of Cue's test. Cue's tests work by targeting a region of the nucleocapsid gene (n gene) that is highly conserved, and Company scientists have found that the test's accuracy has remained unaffected by the mutations in the Omicron variant and other variants of concern to date.

Cue uses molecular nucleic acid amplification technology (NAAT) and is the most accurate* self-test for COVID-19, providing lab-quality results

directly to connected mobile devices in 20 minutes and can be used on adults and children (2 years and over), with or without symptoms, wherever they are.

**Based on clinical study results submitted to FDA for other EUA molecular home tests.*

This project has been funded in whole or in part with federal funds from the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201800016C.

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 the factors discussed in the "Risk Factors" section of the Form 10-Q dated November 10, 2021 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.

The Cue COVID-19 Test for Home and Over The Counter (OTC) Use and the Cue COVID-19 Test (for professional use) 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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