Cue Health Receives FDA Emergency Use Authorization for Molecular Mpox Test

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Authorized to be used in professional point-of-care settings, the nucleic acid amplification test can detect mpox virus and deliver results in 25 minutes

SAN DIEGO--(BUSINESS WIRE)--Mar. 20, 2023-- Cue Health (“Cue”) (Nasdaq: HLTH), a healthcare technology company, today announced it has received Emergency Use Authorization (EUA) from the United States Food and Drug Administration (FDA) for its molecular test to detect the mpox virus (formerly known as monkeypox). This nucleic acid amplification test (NAAT) is run on a Cue Reader, can be performed at any CLIA-waived facility and delivers results in 25 minutes, significantly expanding access to fast and accurate testing for patients.

This EUA marks an important milestone for Cue Health, as it is the company's first non-COVID test to receive FDA authorization, as well as its initial offering in the sexual health category for point-of-care diagnostics. The authorization demonstrates the diverse applications of the Cue Health Monitoring System, proving its capability to address a wide range of testing needs.

Like all tests developed by Cue, the Cue Mpox Molecular Test was designed with ease-of-use in mind. The test simply requires using a Cue Sample Wand to collect a lesion sample or to dip into a viral transport medium (VTM) containing a specimen. The Cue Sample Wand is then inserted into the Cue Cartridge, which has been placed inside the Cue Reader. Results are delivered to a mobile device in 25 minutes. The test demonstrated high accuracy in trials, achieving 100% concordance with the CDC’s mpox test on the clinical samples tested.

"At Cue, we are committed to developing innovative diagnostic solutions that empower both patients and healthcare providers with accurate and timely results," said Ayub Khattak, CEO of Cue Health. "The FDA EUA for our Mpox Molecular Test provides a great tool for clinicians and their patients and demonstrates our platform's versatility."

Mpox is a highly contagious and potentially severe viral infection that has recently emerged as a global health concern. With symptoms ranging from fever and fatigue to severe skin eruptions and respiratory distress, early and accurate detection of mpox is crucial in controlling its spread and providing timely medical intervention.

With a diverse suite of tests utilizing the same diagnostics platform currently under FDA review and in development, Cue Health continues to innovate and expand its product offerings. Cue'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. The company has since submitted an application to the FDA for an EUA for its Cue Flu + COVID-19 Molecular Test. In addition, Cue’s standalone molecular tests for both flu and COVID-19 are under *de novo* review with the FDA for full clearance. Cue also expects to submit its RSV, strep throat, and chlamydia + gonorrhea multiplex tests to the FDA for review later this year. With an installed base of more than a quarter million Cue Readers, Cue’s COVID-19 test has been used by millions of Americans and has become a go-to solution for accuracy, speed, and convenience.

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, 2022 filed with the SEC on March 16, 2023. 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.

The Cue Mpox (Monkeypox) Molecular Test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA. This product has been authorized only for the detection of nucleic acid from monkeypox virus, not for any other viruses or pathogens. The emergency use of this product 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 infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola Orthopoxvirus, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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