Cue Health Receives Regulatory Approval in India for its Molecular, Point-of-Care COVID-19 Test

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Cue Expands its Global Health Support Following International Authorizations in Canada and the European Union

Cue's COVID-19 Test Already Utilized in the U.S. by Enterprises, Schools, Nursing Homes, Hospitals, Professional Sports Leagues and More

SAN DIEGO, July 14, 2021 /PRNewswire/ -- Cue Health Inc. ("Cue Health" or "Cue"), a healthcare technology company, today announced it has received regulatory approval from The Central Drugs Standard Control Organisation (CDSCO) for the Cue COVID-19 Test for professional point-of-care use in India. Internationally, Cue has also received the CE mark in the European Union (EU), as well as Interim Order authorization from Health Canada.

In the U.S., the Cue Health Monitoring System, together with the Cue COVID-19 Test Kit, has been authorized both for point-of-care use by providers as well as for over-the-counter use by consumers. Cue was the first-ever U.S. Food and Drug Administration (FDA) Emergency Use Authorized molecular-based diagnostic test for home use without a prescription. Cue is being used by the National Basketball Association (NBA) and the Mayo Clinic, in addition to a range of other clinical and point-of-care settings, including essential businesses, schools, nursing homes, hospitals, physicians' offices, dental clinics, professional sports leagues, live event venues, hotels, federal and state agencies, and other settings around the country.

"There is an urgent, global demand for real-time, actionable, and connected health data and we plan to fill that unmet need around the world. Now, with this authorization, we can make a positive impact in India, just as we have been able to do in the United States," said Ayub Khattak, co-founder and CEO of Cue. "By making diagnostic testing accessible, fast, accurate and easy to use, we can facilitate faster and better-informed decision making."

Cue's easy-to-use, portable COVID-19 test provides highly accurate, lab-quality results – including detection of emerging variants – directly to connected mobile smart devices in about 20 minutes, and Cue's natively digital platform allows for end-to-end integrated reporting of test results.

Cue expects to enable end-to-end care journeys from diagnostic tests to physician consultation via telemedicine through intervention. The Cue Health Monitoring System is designed to deliver a broad menu of tests through one system. Cue plans to develop a suite of offerings to address respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management by connecting diagnostics with telemedicine.

About Cue

Cue is a health technology company that puts consumers in control of their health information and places diagnostic information at the center of care. Cue enables people to manage their health through real-time, actionable and connected health data. Cue offers individuals and healthcare providers access to lab-quality diagnostic testing at home, at work, or at the point-of-care, all in a device that fits in the palm of your hand. Cue was founded in 2010 and is headquartered in San Diego. For more information, please visit www.cuehealth.com.

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

SOURCE Cue Health Inc.