Cue Health's Pioneering Smart Home Lab and PCR-quality COVID-19 Test Now Available in Canada

March 16, 2022

Cue's molecular COVID-19 self-test provides lab-quality results in 20 minutes

SAN DIEGO, March 16, 2022 /PRNewswire/ -- Cue Health ("Cue") (Nasdaq: HLTH), the healthcare technology company behind the most accurate at-home COVID-19 test* in the U.S., today announced that its molecular COVID-19 test is now available to individual consumers in Canada. The Cue Health Monitoring System (Reader) and Cue's molecular COVID-19 test for home, can be accessed through Cue's eCommerce site and in-app shop. Canadian consumers can also sign up for the Cue+ Foundation membership, which provides users with unlimited access to Cue's supervised COVID-19 test by virtual proctor in English and French for travel, work, or school; ten (10) COVID-19 tests are included in each membership, as well as ongoing discounts on Cue products.

Cue has received Interim Order authorization from Health Canada to sell and distribute its COVID-19 test for both professional use at the point-of-care and consumer self-testing. Cue's test uses molecular nucleic acid amplification technology (NAAT), providing lab-quality results directly to connected mobile devices in 20 minutes. The test can detect all known COVID-19 variants and can be used on adults and children (ages 2 and over), with or without symptoms. The supervised test meets current COVID-19 testing entry requirements for international travel in many countries around the world, including Canada and the U.S., and the results are also often accepted by employers, schools, and sports and entertainment venues.

"Following the successful launch of our smart home lab platform in the U.S., we are pleased to now offer Canadian consumers access to our molecular COVID-19 self-test that combines accuracy, speed, and reliability," said Ayub Khattak, co-founder and CEO of Cue Health. "Canadians will now have a more convenient molecular testing solution that gives them accurate results when they want peace of mind or to protect their loved ones, when traveling, returning to work, or visiting entertainment and sports venues."

Last year, Cue announced a partnership with Air Canada to provide U.S.-based passengers with access to Cue's molecular COVID-19 test for their travel needs. Cue also provides tests to other world-class organizations like Johns Hopkins Medicine, Mayo Clinic, Google, the National Basketball Association (NBA), and Major League Baseball (MLB), among many others. Looking ahead, Cue is working on new diagnostic tests - including for other respiratory illnesses, sexual diseases, women's and men's health, cardiometabolic health, and more - all of which will be compatible with the connected Cue Reader.

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

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-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.

This product is authorized for sale or importation in Canada pursuant to section 5 of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, made by the Minister of Health on March 18, 2020 and the subsequent Interim Order No. 2 on March 1, 2021.

In the United States, 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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