Cue Health Makes De Novo Submission to FDA for Full Clearance of its Cue® RSV Molecular Test

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SAN DIEGO--(BUSINESS WIRE)--May 9, 2023-- Cue Health (“Cue”) (Nasdaq: HLTH), a healthcare technology company, today announced that it has made a De Novo submission to the U.S. Food and Drug Administration (FDA) for full clearance of the Cue RSV Molecular Test for at-home and point-of-care use. There are currently no respiratory syncytial virus (RSV) tests on the market for home use. Pending FDA clearance, Cue’s test would provide the public, for the first time, an at-home molecular RSV test to use on people of all ages that has been fully reviewed by the FDA for safety and effectiveness.

RSV is a common, seasonal respiratory virus that can be serious, especially for infants and older adults. It is the most common cause of bronchiolitis and pneumonia in children younger than 1 year of age in the United States. According to the CDC, RSV leads to 2.1 million outpatient hospital visits per year among children younger than 5 years old and 58,000-80,000 hospitalizations among that age group. Additionally, RSV leads to between 60,000-160,000 hospitalizations each year among adults 65 years and older.

“Both young children and older adults are at high risk for severe RSV infection, which includes symptoms similar to the flu, COVID-19, and the common cold, but has a distinct plan for managing care,” said Dr. David Tsay, Chief Medical Officer for Cue Health. “This makes early detection of the virus even more important to lower the risk of a severe infection, especially among high-risk populations.”

The Cue RSV Molecular Test Cartridge uses a lower nasal swab and is compatible with the Cue Reader, which communicates test results digitally via Bluetooth to a mobile device in approximately 25 minutes.

Ayub Khattak, Chairman and CEO of Cue Health, added, “With our submission to the FDA, we are one key step closer to providing a user-friendly, advanced molecular RSV test that has the potential to be a landmark new tool to manage the threat of RSV, which is the leading cause of hospitalization of young children and a significant risk to the elderly.”

Earlier this month, the FDA approved the first RSV vaccine for individuals 60 years of age and older and three other RSV vaccines for older adults are in the final phases of testing. Additionally, earlier this year, the FDA granted Fast Track designation for an RSV treatment to accelerate its development and review.

Cue has an installed base of more than a quarter million Cue Readers and continues to make progress to advance a wide range of future diagnostic tests and related services that are compatible with this system. Cue's COVID-19 test was the first FDA-authorized molecular diagnostic test for at-home and over-the-counter use without a prescription, which is currently under De Novo review with the FDA.

Earlier this year, Cue received Emergency Use Authorization (EUA) from the FDA for its molecular mpox (monkeypox) test. The company has submitted an application to the FDA for an EUA for its Cue Flu + COVID-19 Molecular Test. Cue’s standalone molecular Flu test is also under De Novo review with the FDA for full clearance.

About Cue Health

Cue Health Inc. (Nasdaq: HLTH) is a healthcare technology company that uses diagnostic-enabled care to empower people to live their healthiest lives. The Cue Health platform offers individuals and healthcare providers convenient and personalized access to lab-quality diagnostic tests at home and at the point of care, as well as on-demand telehealth consultations and treatment options for a wide range of health and wellness needs. Cue’s customers include federal and state public sector agencies and the private sector, which includes healthcare providers, enterprises, and individual consumers. Cue’s COVID-19 test was the first FDA-authorized molecular diagnostic test for at-home and over-the-counter use without a prescription. Cue has since received Emergency Use Authorization from the FDA for its molecular mpox test at the point of care and, to expand its test menu, the company has a number of other submissions under review by the FDA. Cue, founded in 2010, owns over 100 patents 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.

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