



Lucira Health Submits EUA for Over-The-Counter (OTC) Use of its COVID-19 & Flu Test

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EMERYVILLE, Calif., Jan. 03, 2023 (GLOBE NEWSWIRE) -- Lucira Health, Inc. (Nasdaq: LHDX) ("Lucira Health" or "Lucira"), a medical technology company, announced that it submitted an Emergency Use Authorization application to the FDA for OTC use of its simple, at-home molecular COVID-19 & Flu test. Lucira's test for COVID-19 & Flu was granted Emergency Use Authorization for Point-of-Care (POC) use in a healthcare setting in November 2022. In seeking OTC authorization, Lucira intends to make the test broadly available to consumers both online as well as in pharmacies. Lucira worked closely with the FDA to complete additional testing to demonstrate that the COVID & Flu test could be used by consumers at home.

COVID-19 and influenza have similar symptoms but different treatments that are most effective early in an infection, making it important to differentiate between the viruses quickly. Lucira at-home COVID-19 test users have access to Lucira Connect, which allows them to scan their test result with their smartphone, and if positive, join an immediate and free telehealth visit to get treatment without leaving home. Upon authorization of the COVID & Flu test, Lucira test users will be able to learn if they are sick with COVID-19 or the influenza, talk to a doctor about treatment, and access the appropriate prescription within hours.

About the Lucira COVID-19 & Flu Test

The Lucira COVID-19 & Flu Test is a NAAT test utilizing the same platform and device design as Lucira's COVID-19 Test that has been available since November 2020. The test provides independent diagnoses for COVID-19, Flu A, and Flu B. The molecular single-use test fits in the palm of your hand, runs on 2 AA batteries, and with one shallow nasal swab provides a positive or negative result for COVID-19, Flu A, and Flu B in less than 30 minutes. Each Lucira test contains everything needed to run a single test. There is no separate reader or instrument to purchase and maintain.

About Lucira Health

Lucira is a medical technology company focused on the development and commercialization of innovative infectious disease tests to make lab-quality diagnostics more accessible. Lucira designed its test platform to provide accurate, reliable, PCR-quality test results anywhere and at any time. Beyond its already commercialized COVID-19 and Point of Care COVID-19 & Flu Tests, Lucira is working on new diagnostic tests for respiratory infections and other categories including women's health and sexually transmitted infections (STIs). For more information, visit www.lucirahealth.com.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "can," "will," "intends," "could," "expected," "allow," "aim" and similar expressions are intended to identify forward-looking statements. These forward-looking statements, including but not limited to, statements regarding the accuracy of our COVID-19 test; the timing of results from the Lucira COVID-19 & Flu Test multi-center study designed to enable at-home over-the-counter use of the test; Northern Hemisphere experiencing a challenging season due to the unprecedented co-circulation of COVID-19, flu and RSV; COVID-19 and flu viruses causing serious illness with very similar symptoms; clinicians facilitating mass testing at a rapid scale to get patients on the path to recovery quickly, are based upon our current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties. These risks and uncertainties are described more fully in the "Risk Factors" section and elsewhere in our filings with the Securities and Exchange Commission and available at www.sec.gov, including in our most recent Annual Report on Form 10-K and subsequently filed reports. Any forward-looking statements that we make in this announcement speak only as of the date of this press release, and we assume no obligation to update forward-looking statements whether as a result of new information, future events or otherwise after the date of this press release, except as required under applicable law.

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