Co-Diagnostics JV CoSara Receives Clearance from Indian Regulators for ABC Multiplex Test

SALT LAKE CITY, Dec. 7, 2021 /PRNewswire/ -- Co-Diagnostics, Inc. (Nasdaq: CODX) (the "Company"), a molecular diagnostics company with a unique, patented platform for the development of molecular diagnostic tests, announced today that CoSara Diagnostics Pvt Ltd ("CoSara," or the "JV"), its joint venture for manufacturing and sales in India, has received clearance by the Central Drugs Standard Control Organization ("CDSCO") in India to manufacture and sell its SARAPLEX™ Flu A/Flu B/COVID-19 (ABC) RT-PCR test as an *in vitro* diagnostic ("IVD").

CoSara's new test, the 4th CoSara assay to receive CDSCO approval this year and 11th overall, is built on the Company's patented CoPrimer™ technology and designed for the simultaneous detection and differentiation of influenza A, influenza B, and SARS-CoV-2. As with earlier CoSara tests that detect the disease that causes COVID-19, the SARS-CoV-2 targets in the test remain effective in detecting all known strains of the virus, including the Omicron variant.

Co-Diagnostics CEO Dwight Egan commented "As we continue to see variants arise and spread across the world, it has never been more important to have access to reliable, accurate, and affordable diagnostics as the first line of defense, and we are pleased about the role our CoPrimer technology is playing across the world to help increase this availability."

"With several million cases of severe flu infections every year, and with such similar symptoms to the evermutating COVID-19, accurately detecting and distinguishing between these diseases will play a vital role in bolstering the global healthcare response to respiratory illnesses," remarked CoSara Director Mohal Sarabhai. "We are excited to be able to provide additional tools to our growing client base to assist in these efforts in accordance with the 'Make in India' initiative and to address the needs of the Indian market and the surrounding region."

CoSara has previously received CDSCO clearance for RT-PCR tests for Mycobacterium tuberculosis, malaria, hepatitis B, hepatitis C, human papillomavirus (HPV), two COVID-19 assays, chikungunya, dengue, and a dengue/chikungunya duplex test, all designed using the Company's patented CoPrimer technology and cleared to be manufactured and sold as IVDs in the Indian market.

About Co-Diagnostics, Inc.:

Co-Diagnostics, Inc., a Utah corporation, is a molecular diagnostics company that develops, manufactures and markets a state-of-the-art diagnostics technology. The Company's technology is utilized for tests that are designed using the detection and/or analysis of nucleic acid molecules (DNA or RNA). The Company also uses its proprietary technology to design specific tests to locate genetic markers for use in industries other than infectious disease and license the use of those tests to specific customers.

Forward-Looking Statements:

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA) that are subject to a number of risks and uncertainties. Risks and uncertainties that may cause such differences include, among other things: our products may not prove to be as effective as other products currently being commercialized or to be commercialized in the future by competitors; risks inherent in manufacturing and scaling up to commercial quantities while maintaining quality controls; the uncertainties inherent in new product development, including the cost and time required to gain regulatory clearance for such product and to commercialize such product(s);and, market acceptance of our products once commercialized. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date on which they are made and reflect management's current estimates, projections, expectations, and beliefs. There can be no assurance that any of the anticipated results will occur on a timely basis or at all due to certain risks and uncertainties, a discussion of which can be found in the Risk Factors disclosure in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 25, 2021, and in our other filings with the SEC. The Company does not undertake any obligation to update any forward-looking statement relating to matters discussed in this press release, except as may be required by applicable securities laws.

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