Co-Diagnostics, Inc. JV CoSara Receives Clearance from Indian Regulators for Hepatitis B Viral Load Test

SALT LAKE CITY, Feb. 3, 2022 /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 SARAQ™ Hepatitis B (HBV) Viral Load Kit as an *in vitro* diagnostic ("IVD").

CoSara's new real-time HBV PCR test is built on the Company's patented CoPrimer™ technology and designed to be used as an aid in assessing response to antiviral treatments in patients diagnosed with HBV, a disease that leads to more than 800,000 deaths per year according to the World Health Organization ("WHO"). HBV is highly endemic in some areas of the world, with more than 1.5 million new infections each year and roughly 300 million people living with chronic HBV infection, despite the existence of a safe, available and effective vaccine.

Dwight Egan, Co-Diagnostics CEO, stated "HBV is a prime example of the persistent toll endemic diseases can take on the populations they afflict, even those diseases which are largely preventable and for which vaccines exist, including what we are now beginning to experience in the current phase of the COVID-19 pandemic. The diagnostic markets for HBV and other endemic diseases grow on a yearly basis, which drives our goal of providing affordable, high-quality diagnostic tools for areas affected by them, both through our centralized laboratory products like CoSara's new test, and our expanded focus on at-home and point-of-care offerings."

CoSara Director Mohal Sarabhai commented, "The disease burden of HBV in India was estimated at around 50 million in 2017, and the WHO believes the number of chronic HBV infections in South-East Asia to be around 18 million people. While no cure for HBV exists, treatment can help to slow damage to the liver and ultimately improve long term survival prospects among infected individuals, provided those treatments are seen to be effective at reducing the patients' viral loads. Demand for our new SARAQ HBV viral load test has been strong, and we believe that it can play an important role in improving the quality of life of those individuals undergoing treatment for HBV in India and the surrounding regions."

CoSara has previously received CDSCO clearance for RT-PCR tests for Mycobacterium tuberculosis, malaria, hepatitis B, hepatitis C, HPV types 16 and 18 and HPV-HR, two COVID-19 assays, chikungunya, dengue, a dengue/chikungunya duplex test, and a Flu A/Flu B/COVID-19 ("ABC") multiplex 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.

SOURCE Co-Diagnostics

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