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

SALT LAKE CITY, April 19, 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 C ("HCV") Viral Load Kit as an *in vitro* diagnostic ("IVD").

CoSara's new real-time HCV 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 HCV, a disease with no effective vaccine that leads to nearly 300,000 deaths in 2019 according to the World Health Organization ("WHO"). Access to effective diagnosis and antiviral therapeutics is limited for the more than 1.5 million new chronic infections each year, and roughly 58 million people living with chronic HCV infection.

Dwight Egan, Co-Diagnostics CEO, commented "The enduring market for HCV diagnostics is a result of the persistent spread of the disease and highlights the importance of providing accurate, affordable PCR testing solutions on a global level, especially to those regions where the disease burden is highest. We are pleased that our CoPrimer technology will play a significant role in helping to reduce this burden in India and the surrounding areas."

CoSara Director Mohal Sarabhai remarked, "The approval of this important test marks the 14th IVD to receive clearance by the CDSCO, and strengthens our foundation for future growth. Effective HCV treatments are especially useful when used in tandem with tests for diagnosing and monitoring those therapies. This HCV Viral Load kit test adds to our expanding menu of valuable diagnostic tools available to our growing distributor and laboratory customer base."

CoSara has previously received CDSCO clearance for RT-PCR tests for Mycobacterium tuberculosis, malaria, hepatitis B, hepatitis B viral load, 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

For further information: Company Contact: Andrew Benson, Head of Investor Relations, +1.801.438.1036, investors@codiagnostics.com; Media Contact: Jennifer Webb, Coltrin & Associates, Inc, jennifer_webb@coltrin.com

---

https://news.codiagnostics.com/2022-04-19-Co-Diagnostics,-Inc-JV-CoSara-Receives-Clearance-from-Indian-Regulators-for-Hepatitis-C-Viral-Load-Test