Co-Diagnostics, Inc. JV CoSara Receives Clearance from Indian Regulators for High-Risk HPV Multiplex Test

SALT LAKE CITY, Jan. 13, 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 SARAGENE™ Human Papillomavirus High-Risk (HPV-HR) Real-Time PCR test as an *in vitro* diagnostic ("IVD").

Human papillomavirus ("HPV") is the most common sexually transmissible infection in the world and the cause of almost all cervical cancer worldwide (the 4th deadliest cancer in women), as well as a substantial portion of certain other cancers, totaling over 600,000 cases of cancer per year being attributable to HPV. CoSara's new multiplex test, the 12th CoSara assay to receive CDSCO approval, is built on the Company's patented CoPrimer™ technology and designed to detect and differentiate between HPV genotypes 16 and 18, while simultaneously detecting high-risk carcinogenic HPV types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68.

"The multiplexing capabilities of cutting-edge CoPrimer technology make it an ideal platform for such an important diagnostic and screening tool as this test for HPV-HR, marking an expansion in the breadth of tests built on this platform for endemic diseases around the world," remarked Dwight Egan, Co-Diagnostics CEO. "We believe that the first step in reducing transmission in those less developed areas where HPV vaccination rates remain low is affordable, high-quality diagnostic tools, and we are pleased about the role that Co-Diagnostics technology will be playing in helping to increase the accessibility of such products."

CoSara Director Mohal Sarabhai commented, "Despite the existence of safe, effective vaccines for HPV, the burden of HPV-related cancer and disease remains high. The World Health Organization has also stated that HPV is the most common viral infection of the reproductive tract. HPV-HR has been one of the most in-demand tests among our distributor and customer base, and we are excited to be able to now offer this diagnostic tool in accordance with the 'Make in India' initiative for India and the surrounding region, where limited access to vaccines remains an ongoing struggle."

CoSara has previously received CDSCO clearance for RT-PCR tests for Mycobacterium tuberculosis, malaria, hepatitis B, hepatitis C, HPV (types 16 and 18 only), 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: McKenzie Cloutier, Coltrin & Associates, Inc., +1.212.221.1616, mckenzie_cloutier@coltrin.com

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