Co-Diagnostics JV CoSara Receives Indian Regulatory Approval for Five Diagnostic Assays

CoSara Saragene™ tests for tuberculosis, malaria, hepatitis B, hepatitis C, and human papillomavirus now available for sale and distribution as in vitro diagnostics

Salt Lake City, Utah – December 3, 2019 – Co-Diagnostics, Inc. **(Nasdaq: CODX)**, a molecular diagnostics company with a unique, patented platform for the development of diagnostic tests, announced today that CoSara Diagnostics Pvt Ltd ("CoSara," or the "JV"), their joint venture for manufacturing, has obtained regulatory clearance for five tests to be manufactured and sold as *in vitro* diagnostics ("IVDs") from their facility in Ranoli India.

The Saragene™ tests for Mycobacterium tuberculosis, malaria, hepatitis B, hepatitis C and human papillomavirus (HPV) meet the requirements of the Central Drug Standard Control Organization ("CDSCO") Medical Device Rules (MDR) 2017, File no. 29/Misc./3/2017-DC (292), to be manufactured and sold as IVDs. CDSCO approval was granted following the completion of the CoSara manufacturing facility and a comprehensive inspection of the location, presentation of the technology, quality system, procedures, product validation data and performance evaluation by an independent NABL & CAP accredited laboratory. The licenses and regulatory clearance allow CoSara for the first time to manufacture and sell the tests for the detection of the respective pathogens and microorganisms.

CoSara distributors have begun taking pre-orders for the five IVDs, and the Company expects sales to ramp quickly. The JV has the exclusive manufacturing rights in India for the complete menu of Co-Diagnostics infectious disease molecular diagnostics kits, designed by Co-Diagnostics using their patented CoPrimer™ technology platform.

Additional tests which are expected to be submitted to the CDSCO for approval consist of those for drug-resistant tuberculosis, HIV and more, including a multiplexed panel specifically for blood-bank screening.

Dwight Egan, Company CEO, remarked "India is soon to become the largest healthcare market on the planet and the best place for CoPrimer-powered products to be manufactured and distributed is from within the country itself. Being able to sell fully-approved IVDs to this market represents the next stage in our growth as we establish Co-Diagnostics to be a leading innovator of high-quality, affordable diagnostics solutions. We are excited to be taking this next step in our growth with such a distinguished partner and are eager to see returns on the time and effort we have spent to get to this point."

The CoSara plant is one of the first facilities for manufacturing molecular diagnostics in India and has been designed to meet both current and future requirements for medical device manufacturing, which are expected to be implemented by the Indian government. CoSara is a joint venture between the Company and Synbiotics Pvt Ltd, a group company of Asence Inc, a U.S. company that specializes in supplying pharmaceutical products to international markets across 35 countries. Asence and Synbiotics are both subsidiaries of Ambalal Sarabhai Enterprises Ltd., a continuation of one of the oldest and most respected manufacturing institutions in India in operation today.

"We are honored to be the manufacturer of the first indigenous PCR based diagnostic kits in India," said Mr. Mohal Sarabhai, CEO of Synbiotics. "Our team has worked tirelessly this year, ensuring the facility and procedures meet or exceed the requirements to fulfill our mandate of providing cutting edge molecular diagnostics technology to India. The goals of the 'make in India' initiative aligns perfectly with those of CoSara, and we look forward to serving not only the Indian market but to receiving the CE markings and other necessary regulatory approvals that will allow CoSara Diagnostics to expand on a global scale."

On Thursday December 5, Co-Diagnostics Inc will hold an invitation-only press conference for members of the media and financing partners in New York City, New York, to provide context and impact of the news on the Company. Contact Jennifer Webb of Coltrin & Associates at jennifer_webb[at]coltrin.com to request an invitation.

About Co-Diagnostics, Inc.:

Co-Diagnostics, Inc., a Utah corporation, is a molecular diagnostics company that develops, manufactures and markets a new, 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. Forward-looking statements can be identified by words such as “believes,” “expects,” “estimates,” “intends,” “may,” “plans,” “will” and similar expressions, or the negative of these words. Such forward-looking statements are based on facts and conditions as they exist at the time such statements are made and predictions as to future facts and conditions. Forward-looking statements in this release include statements regarding the (i) use of funding proceeds, (ii) expansion of product distribution, (iii) acceleration of initiatives in liquid biopsy and SNP detection, (iv) use of the Company’s liquid biopsy tests by laboratories, (v) capital resources and runway needed to advance the Company’s products and markets, (vi) increased sales in the near-term, (vii) flexibility in managing the Company’s balance sheet, (viii) anticipation of business expansion, (ix) benefits in research and worldwide accessibility of the CoPrimer™ technology and its cost-saving and scientific advantages and (x) statements regarding the intended use of proceeds. Forward-looking statements are subject to inherent uncertainties, risks and changes in circumstances. Actual results may differ materially from those contemplated or anticipated by such forward-looking statements. Readers of this press release are cautioned not to place undue reliance on any forward-looking statements. 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.

Company Contact:

Andrew Benson
Co-Diagnostics Investor Relations
801-438-1036
investors@codiagnostics.com

---

https://news.codiagnostics.com/press-releases?item=122429