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Natera and CytoDyn Announce Strategic Collaboration to Advance ctDNA-Guided Development and Molecular Response Analysis in Metastatic Colorectal Cancer

AUSTIN, Texas & VANCOUVER, Wash.--(BUSINESS WIRE)--Natera, Inc. (NASDAQ: NTRA), a global leader in cell-free DNA and precision medicine, and CytoDyn Inc. (OTCQB: CYDY) ("CytoDyn"), a clinical-stage oncology company advancing leronlimab, a first-in-class humanized monoclonal antibody targeting the CCR5 receptor with therapeutic potential across multiple indications, today announced a strategic collaboration to evaluate circulating tumor DNA (ctDNA) dynamics and generate real-world molecular insights to support CytoDyn's metastatic colorectal cancer (mCRC) development program.

Under the agreement, Natera will assess CytoDyn clinical trial samples from the CLOVER Phase 2 study (ClinicalTrials.gov Identifier: NCT06699836) in patients with mCRC. Signatera™, Natera's personalized assay for the detection of molecular residual disease (MRD), will be used to evaluate ctDNA dynamics and molecular response patterns associated with leronlimab treatment.

Natera will also provide customized real-world data (RWD) analyses leveraging its proprietary oncology database, which is the largest multi-timepoint early- and late-stage oncology dataset with more than 2 million plasma timepoints and enriched clinical and imaging records. By integrating molecular response data from its MRD testing platform with curated electronic medical record (EMR) data, this multimodal dataset enables analyses of patient populations, treatment patterns, ctDNA response rates, and response dynamics across diverse clinical settings. Together, these capabilities are expected to generate insights into molecular response and disease progression that may help inform future clinical development of leronlimab, including clinical trial design, biomarker-driven patient selection strategies, and broader translational research efforts.

The collaboration builds on CytoDyn's growing oncology program and follows completion of enrollment in the CLOVER study, which is evaluating leronlimab in combination with trifluridine/tipiracil (TAS-102) and bevacizumab in patients with previously treated mCRC. The collaboration is also expected to complement ongoing translational and biomarker analyses from the study aimed at further characterizing treatment response and informing future development strategies.

"Signatera has become an increasingly important tool in precision oncology and clinical development," said Jacob Lalezari, M.D., chief executive officer, CytoDyn. "Through this collaboration, we expect to gain valuable insights into ctDNA response kinetics and disease progression that may help guide future development strategies for leronlimab in colorectal cancer and potentially other solid tumor indications."

“We are pleased to partner with CytoDyn and provide their team with insights derived from one of the largest and most comprehensive real-world molecular oncology data platforms,” said Matt Love, vice president, biopharma data & AI partnering, Natera. “Our platform enables biopharma partners to better understand disease biology, treatment response, and patient outcomes, helping inform key development decisions throughout the drug development lifecycle.”

About Natera

Natera™ is a global leader in cell-free DNA and precision medicine, dedicated to oncology, women’s health, and organ health. We aim to make personalized genetic testing and diagnostics part of the standard-of-care to protect health and inform earlier, more targeted interventions that help lead to longer, healthier lives. Natera’s tests are supported by more than 400 peer-reviewed publications that demonstrate excellent performance. Natera operates ISO 13485-certified and CAP-accredited laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) in Austin, Texas, and San Carlos, California, and through Foresight Diagnostics, its subsidiary, operates an ISO 27001-certified and CAP-accredited laboratory certified under CLIA in Boulder, Colorado. For more information, visit www.natera.com.

About CytoDyn

CytoDyn is a clinical-stage oncology company dedicated to advancing leronlimab, a first-in-class humanized monoclonal antibody that targets the CCR5 receptor, a key regulator of immune function implicated in cancer, infectious diseases, and autoimmune disorders. Guided by a mission to improve patients’ quality of life through therapeutic innovation, CytoDyn is committed to integrity, responsibility, and service as it works to bring transformative treatments to patients worldwide. For more information, please visit www.cytodyn.com and follow us on LinkedIn.

Forward-Looking Statements (for Natera)

All statements other than statements of historical facts contained in this press release are forward-looking statements and are not a representation that Natera’s plans, estimates, or expectations will be achieved. These forward-looking statements represent Natera’s expectations as of the date of this press release, and Natera disclaims any obligation to update the forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially, including with respect to our or our partners’ efforts to develop and commercialize new product offerings, whether the results of clinical or other studies will support the use of our product offerings, the impact of results of such studies, our expectations of the reliability, accuracy, and performance of our tests, or of the benefits of our tests and product offerings to patients, providers, and payers. Additional risks and uncertainties are discussed in greater detail in "Risk Factors" in Natera’s recent filings on Forms 10-K and 10-Q, and in other filings Natera makes with the SEC from time to time. These documents are available at www.natera.com/investors and www.sec.gov.

Forward-Looking Statements (for CytoDyn)

This news release may contain forward-looking statements relating to, among other things,

the mechanism of action of leronlimab, clinical trial results, product development, market position, future operating and financial performance, and business strategy. The reader is cautioned not to rely on these statements, which are based on current expectations of future events. For important information about these statements and our Company, including the risks, uncertainties and other factors that could cause actual results to vary materially from the assumptions, expectations and projections expressed in any forward-looking statements, the reader should review our Annual Report on Form 10-K for the fiscal year ended May 31, 2025, including the section captioned “Forward-Looking Statements” and in Item 1A, as well as subsequent reports filed with the Securities and Exchange Commission. CytoDyn Inc. does not undertake to update any forward-looking statement as a result of new information or future events or developments except as required by applicable law.

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