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Codexis and Nestlé Health Science Announce Interim Results from Phase 1 Clinical Trial of CDX-7108 for Exocrine Pancreatic Insufficiency

Interim Data from Phase 1 Proof-of-Concept Arm Indicates CDX-7108 Improves Lipid Absorption

REDWOOD CITY, Calif., Feb. 23, 2023 (GLOBE NEWSWIRE) -- Codexis, Inc. (NASDAQ: CDXS), a leading enzyme engineering company, and Nestlé Health Science, a leader in the science of nutrition, today announced interim results from a Phase 1 study to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics of CDX-7108.

CDX-7108 is a lipase variant specifically engineered to overcome the limitations of existing pancreatic enzyme replacement therapy (PERT). PERT is the main treatment for exocrine pancreatic insufficiency (EPI), a debilitating condition of the GI tract that is caused by conditions that impair pancreatic function such as pancreatitis, pancreatic cancer, Crohn's disease, celiac disease, and cystic fibrosis. CDX-7108 was engineered to be highly stable to the acidic conditions in the stomach and resistant to proteases in the upper intestines.

"We are excited by the early clinical data for CDX-7108, the most advanced candidate from our partnership with Nestlé Health Science," said Stephen Dilly, MBBS, PhD, President and Chief Executive Officer of Codexis. "Preliminary data from an interim analysis of our Phase 1 study proof-of-concept arm has shown indication of improved lipid absorption when patients were administered CDX-7108 versus placebo. Importantly, no safety issues were noted in the 48 subjects who participated in the single ascending dose and multiple ascending dose portion of the study. These encouraging data support a path forward further developing CDX-7108 with Nestlé Health Science. We aim for the potential initiation of a Phase 2 study in early 2024."

"Patients who suffer from exocrine pancreatic insufficiency are in need of new treatment options," said Dr. Hans-Juergen Woerle, Chief Scientific and Medical Officer of Nestlé Health Science. "This interim Phase 1 data suggests that CDX-7108 could be that potential new option and we are excited to move forward to a Phase 2 clinical trial. We are pleased with this positive update and are proud to be driving the development of a novel approach for this condition as part of our strategic collaboration with Codexis."

Results of Interim Analysis

The CDX-7108 Phase 1 clinical trial is a study evaluating the safety, tolerability, and pharmacokinetics (PK) of escalating oral doses of CDX-7108 in 48 healthy adult subjects and to assess the pharmacodynamics of oral doses of CDX-7108 as part of a proof-of-concept study in 10 subjects with EPI. The interim analysis included 5 subjects and

examined lipid absorption as measured by $^{13}CO_2$ excretion. No safety issues were noted with no Serious Adverse Events (SAE) observed and no treatment discontinuations in the Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) healthy subject groups. Every participant with EPI in the proof-of-concept portion of the study showed improved lipid absorption when administered CDX-7108 versus placebo. Combining the data from each participant, a significant increase in the cumulative excretion rate of $^{13}CO_2$ was observed for CDX-7108 versus placebo.

Codexis and Nestlé Health Science expect to file an Investigational New Drug (IND) application for the Phase 2 study by the end of 2023. The Phase 2 study is expected to be conducted over approximately 12 months, with topline data expected in 2025.

About Nestlé Health Science (NHSc)

Nestlé Health Science, a leader in the science of nutrition, is a globally managed business unit of Nestlé. We are committed to redefining the management of health, offering an extensive portfolio of science-based consumer health, medical nutrition, pharmaceutical therapies, and vitamin and supplement brands. Our extensive research network provides the foundation for products that empower healthier lives through nutrition. Headquartered in Switzerland, we have more than 12,000 employees around the world, with products available in more than 140 countries. www.nestlehealthscience.com.

About Codexis

Codexis is a leading enzyme engineering company leveraging its proprietary CodeEvolver® platform to discover and develop novel, high performance enzymes and biotherapeutics. Codexis enzymes have applications in the sustainable manufacturing of small molecule pharmaceuticals, in RNA and DNA synthesis and the creation of next generation life science tools, and as gene therapies and oral enzyme therapies. Codexis' unique enzymes can drive improvements such as higher yields, reduced energy usage and waste generation, improved return on capital in manufacturing, improved sensitivity in genomic and diagnostic applications, and more efficacious therapeutics. For more information, visit www.codexis.com.

Forward-Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Codexis, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements regarding the Company's programs having the potential to create significant value over the next few years and the Company's enzymes being able to drive improvements. You should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond Codexis' control and that could materially affect actual results. Additional information about factors that could materially affect actual results can be found in Codexis' Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on February 28, 2022 and in Codexis' Quarterly Report on Form 10-Q filed with the SEC on November 4, 2022, including under the caption "Risk Factors," and in Codexis' other periodic reports filed with the SEC. Codexis expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law.

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