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Codexis and Nestlé Health Science Initiate a Phase 1 Clinical Trial of CDX-7108 for Exocrine Pancreatic Insufficiency

REDWOOD CITY, Calif., Nov. 03, 2021 (GLOBE NEWSWIRE) -- Codexis, Inc. (NASDAQ: CDXS), a leading protein engineering company and developer of novel biotherapeutics, and Nestlé Health Science, a globally recognized leader in the field of nutritional science, announced today the dosing of the first subject in 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 traditional pancreatic enzyme replacement therapy (PERT) deficiencies. 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.

The integrated, three-part Phase 1a/1b study comprises a randomized, double-blind, placebo-controlled dose escalation to investigate the safety, tolerability, immunogenicity, and PK of CDX-7108 after single (part A) and multiple (part B) oral dose administration in healthy adult subjects. Part C is a randomized, double-blind, placebo-controlled, single-dose, 2-way crossover study to assess proof-of-concept of CDX-7108 for pharmacodynamics, safety, tolerability, and immunogenicity in subjects with EPI.

"Our partnership with Nestlé Health Science aims at leveraging the CodeEvolver® protein engineering platform to create novel orally administered enzyme therapies for patients. We are excited to advance the first candidate from this partnership, CDX-7108, into clinical development", according to John Nicols, Codexis' President and CEO. "The complementarity of Nestlé Health Science's gastrointestinal experience and Codexis' proven ability to discover and develop differentiated enzymes, has led to the rapid advancement of CDX-7108 into the clinic", Gjalt Huisman, Senior Vice-President, Codexis Biotherapeutics added.

"The goal of our strategic collaboration is to offer an effective new treatment for people who suffer from exocrine pancreatic insufficiency," said Hans-Juergen Woerle, Chief Scientific and Medical Officer at Nestlé Health Science. "The CDX-7108 program has advanced rapidly, discovering and developing this orally-administrable enzyme candidate for clinical development."

About Nestlé Health Science and Aimmune Therapeutics

Nestlé Health Science is a leader in the science of nutrition and a globally managed business unit of Nestlé. We believe in empowering healthier lives through nutrition and are committed to redefining the management of health, offering an extensive portfolio of

science-based active lifestyle nutrition, medical nutrition and pharmaceutical solutions. Our extensive research network, both within Nestlé's R&D centers as well as with external partners, provides the foundation for products that can help people to live their healthiest lives. Headquartered in Switzerland, we have more than 11,000 employees around the world, with products available in more than 140 countries. www.nestlehealthscience.com

Aimmune Therapeutics, Inc., a Nestlé Health Science Company, is a biopharmaceutical company developing and commercializing treatments for potentially life-threatening gastrointestinal, metabolic, and food-mediated allergic conditions. www.aimmune.com

About Codexis

Codexis is a leading enzyme engineering company leveraging its proprietary CodeEvolver® platform to discover and develop novel, high performance enzymes and novel biotherapeutics. Codexis enzymes have applications in the sustainable manufacturing of pharmaceuticals, food, and industrial products; in the creation of the next generation of life science tools; and as gene therapy and biologic therapeutics. The Company's unique performance enzymes drive improvements such as: reduced energy usage, waste generation and capital requirements; higher yields; higher fidelity diagnostics; and more efficacious therapeutics. Codexis enzymes enable the promise of synthetic biology to improve the health of people and the planet. 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. 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. These include, without limitation, statements about the stability and manufacturability of CDX-7108 and the potential use of CDX-7108 for the treatment of exocrine pancreatic insufficiency. 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. Factors that could materially affect actual results include, among others: our and our partners' biotherapeutic programs are early stage, highly regulated and expensive; our and our partners' ability to advance our product candidates to clinical trials and to ultimately receive regulatory approvals is highly uncertain; the regulatory approval processes of the U.S. Food and Drug Administration and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we and our partners are unable to obtain or maintain regulatory approval for our products and product candidates, our business will be substantially harmed; results of preclinical studies and early clinical trials of product candidates may not be predictive of results of later studies or trials; product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval; if any product candidates do not work as intended or cause undesirable side effects, it could hinder or prevent receipt of regulatory approval or realization of commercial potential for them or our other product candidates and could substantially harm our business; and even if we obtain regulatory approval for any products that we develop alone

or with our partners, such products will remain subject to ongoing regulatory requirements, which may result in significant additional expense.. 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 March 1, 2021, and in Codexis' Quarterly Report on Form 10-Q filed with the SEC on August 6, 2021, 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.

Investor Relations Contact:
Argot Partners
Stephanie Marks/Carrie McKim
Codexis@argotpartners.com
(212) 600-1902

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