Codexis Announces Nestlé Health Science Exercises Option for Exclusive Global License to CDX-6114 for the Management of Phenylketonuria

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REDWOOD CITY, Calif., Feb. 14, 2019 (GLOBE NEWSWIRE) -- Codexis, Inc. (Nasdaq: CDXS), a leading protein engineering company, announces that Nestlé Health Science has exercised its option to obtain an exclusive license for the global development and commercialization of Codexis' novel, orally delivered enzyme CDX-6114 for the management of phenylketonuria (PKU), an orphan metabolic disorder. Nestlé Health Science was granted this option under the Development, Option and Licensing Agreement with Codexis announced in October 2017. CDX-6114 is Codexis' first internally developed biotherapeutic product candidate.

The exercise of the option triggers a $3 million milestone payment. Upon exercising its option, Nestlé Health Science has now assumed all responsibility for future clinical development and commercialization of CDX-6114.

"We are proud to have discovered an enzyme that shows promise as a novel treatment for patients with PKU and are delighted that Nestlé Health Science has elected to take on its continued development," said Codexis President and CEO John Nicols. "The exercise of this option further validates our strategy to partner biotherapeutics discovered using our CodeEvolver® protein engineering platform, and to do so early in the process of clinical development."

"We are excited about taking the next step in developing this enzyme that could lead to the first orally available and convenient therapeutic option for those afflicted with PKU," said Greg Behar, CEO, Nestlé Health Science. "PKU is the result of a missing enzyme, and left untreated it can lead to intellectual disability, seizures and cognitive and behavioral disabilities. Current treatment options are limited, with most patients managing PKU through restrictive diets. CDX-6114 is a therapeutic enzyme candidate that compensates for the missing natural enzyme with the advantage of being orally dosed and stable in the gastrointestinal tract which presents an attractive option for the management of the disease."

About Phenylketonuria (PKU)

PKU is an inborn metabolic disorder resulting from a mutation in the gene for the enzyme that converts the essential amino acid phenylalanine, which is present in almost all dietary protein, into tyrosine. As a result of this deficiency, phenylalanine builds up to levels that are toxic in the brain, causing serious neurological symptoms including intellectual disability, seizures and cognitive and behavioral disabilities. To avoid phenylalanine toxicity and the most severe disease symptoms, individuals with PKU must follow a strict, lifelong diet that is low in phenylalanine and must supplement their diet with a synthetic phenylalanine-free formula to provide sufficient nutrients. Maintaining a strict, lifelong diet is a challenge for individuals with PKU. There are an estimated 50,000 people with PKU in the developed world.

About Nestlé Health Science

Nestlé Health Science (NHSc), a wholly-owned subsidiary of Nestlé, is a globally recognized leader in the field of nutritional science. At NHSc we are committed to empowering healthier lives through nutrition for consumers, patients and their healthcare partners. We offer an extensive consumer health portfolio of industry-leading medical nutrition, consumer and VMS brands that are science-based solutions covering all facets of health from prevention, to maintenance, all the way through to treatment. NHSc is redefining the way we approach the management of health in several key areas such as pediatric health, allergy, acute care, oncology, metabolic health, healthy aging, gastrointestinal health, and inborn errors of metabolism. Headquartered in Switzerland, NHSc employs over 5,000 people around the world, who are committed to making a difference in people's lives, for a healthier today and tomorrow. For more information, please visit www.nestlehealthscience.com.

About Codexis, Inc.

Codexis is a leading protein engineering company that applies its proprietary CodeEvolver® technology to develop proteins for a variety of applications, including as biocatalysts for the commercial manufacture of pharmaceuticals, fine chemicals and industrial enzymes, and enzymes as biotherapeutics and for use in molecular diagnostics. Codexis' proven technology enables improvements in protein performance, meeting customer needs for rapid, cost-effective and sustainable manufacturing in multiple commercial-scale implementations of biocatalytic processes. For more information, see 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. 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: Codexis' dependence on its licensees and collaborators, including Nestlé Health Science; our biotherapeutic programs are early stage, highly regulated and expensive; there is no guarantee that CDX-6114 or any other biotherapeutic program of Codexis will achieve relevant regulatory filings or approvals; the regulatory approval process of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable; clinical testing and trials are difficult to design and implement, time-consuming and involve an uncertain outcome; results of preclinical studies and early clinical trials of product candidates may not be predictive of results of later studies or trials; Codexis' dependence on a limited number of products and customers in its biocatalysis business; potential adverse effects to Codexis' business if its customers' pharmaceutical products are not received well in the markets; and Codexis' dependence on a limited number of contract manufacturers for large-scale production of its enzymes. 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 15, 2018 and Quarterly Report on Form 10-Q filed

November 9, 2018, 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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