Codexis Doses First Subjects in Phase 1a Trial of CDX-6114

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Triggers $4 million milestone payment under strategic collaboration with Nestlé Health Science

REDWOOD CITY, Calif., July 09, 2018 (GLOBE NEWSWIRE) -- Codexis, Inc. (NASDAQ:CDXS), a leading protein engineering company, announces that it has dosed the first subjects in a first-in-human Phase 1a dose-escalation trial with CDX-6114, its orally administered enzyme therapeutic being developed for the management of phenylketonuria (PKU). The initiation of the trial triggers a $4 million milestone payment to Codexis from Nestlé Health Science under their strategic collaboration announced in October 2017.

This randomized, double-blind, placebo-controlled Phase 1a trial is intended to evaluate the safety and tolerability of CDX-6114 in up to 32 healthy volunteers, with up to four cohorts receiving a single dose of CDX-6114 at increasingly higher dose levels. Codexis also expects to generate valuable pharmacology data from this study, which will support the future development of the drug candidate. The company expects to report topline results from the Phase 1a trial in the fourth quarter of 2018.

“Initiation of this clinical trial is a major milestone in the development of CDX-6114 for the management of the orphan metabolic disorder PKU. CDX-6114 is the first biotherapeutic discovered using our CodeEvolver® protein engineering platform to enter human studies,” said Codexis President and CEO John Nicols. “Commencement of this clinical trial further validates our biotherapeutics strategy as PKU is the lead program in our pipeline, which focuses generally on the discovery and development of novel enzyme drug candidates for the treatment of rare diseases.”

“PKU is caused by the deficiency or absence of the natural enzyme for the metabolism of phenylalanine, and can lead to intellectual disability, seizures and cognitive and behavioral disabilities,” he added. “Physicians have been able to test for PKU for more than 50 years, yet treatment options have been limited primarily to dietary management. CDX-6114 is an orally dosed, GI-stable therapeutic enzyme developed to compensate for the missing natural enzyme.”

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, 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, life-long diet that is low in phenylalanine and supplement their diet with a synthetic phenylalanine-free formula to provide sufficient nutrients. Maintaining a strict, life-long diet is a challenge for individuals with PKU. There are an estimated 50,000 people with PKU in the developed world.

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, including Codexis’ expectation of receiving a $4 million milestone payment from Nestlé Health Science as a result of commencing the Phase 1a study, Codexis’ expectation of completing the Phase 1a trial and reporting top line results in the fourth quarter of 2018, and Codexis’ belief that the commencement of this clinical trial further validates our biotherapeutics discovery and development strategy. 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; Codexis’ dependence on a limited number of products and customers in its biocatalysis business; potential adverse effects to Codexis’ business if its customers’ pharmaceutical or food products are not received well in the markets; risks, uncertainties and costs associated with the successful development of biotherapeutic candidates, including obtaining development partners for its biotherapeutic programs and progressing such programs to clinical trials and regulatory approvals; Codexis’ ability to develop and commercialize new products for the biocatalysis markets; Codexis’ dependence on a limited number of contract manufacturers for large-scale production of its enzymes; Codexis’ ability to deploy its technology platform in new market spaces, including the fine chemicals, therapeutics and in vitro molecular diagnostics markets; Codexis’ ability to comply with the terms of its credit facility and its associated debt service obligations; Codexis’ need for additional capital in the future in order to expand its business or to adjust for market conditions or strategic considerations, which may involve Codexis entering into equity offerings, debt financings, credit facilities and/or strategic collaborations; Codexis’ dependence on key personnel; Codexis’ ability to establish and maintain adequate protection for intellectual property, trade secrets and other proprietary rights covering its technologies; and any claims by third parties that Codexis is infringing their intellectual property rights or other proprietary rights. 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 16, 2018 and Form 10-Q filed May 10, 2018, including under the caption “Risk Factors” and in Codexis’ other current and 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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