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# Codexis Announces Results of Phase 1a Clinical Trial with CDX-6114

## **CDX-6114 meets safety and tolerability endpoints**

REDWOOD CITY, Calif., Nov. 08, 2018 (GLOBE NEWSWIRE) -- Codexis, Inc. (NASDAQ: CDXS), a leading protein engineering company, announces top-line results from its Phase 1a single ascending-dose study in healthy volunteers with CDX-6114, its orally administered enzyme candidate for the potential treatment of the metabolic disorder phenylketonuria (PKU). All of the defined study endpoints were met.

The randomized, double-blind, placebo-controlled Phase 1a study evaluated the safety and tolerability of CDX-6114 in 32 healthy volunteers evenly divided into four cohorts. Each cohort was administered a single dose of CDX-6114 at increasingly higher dose levels. CDX-6114 was well tolerated at all four dose levels with no serious adverse events (SAEs) or GI-related symptoms observed. In addition, a dose-dependent pharmacodynamic response was observed, and an initial readout on pharmacokinetics was obtained with no evidence of systemic exposure.

"We have reached a key milestone for the company with the completion of our first ever clinical study on a novel biotherapeutic candidate developed using our CodeEvolver<sup>®</sup> protein engineering platform," said Codexis President and CEO John Nicols. "We are encouraged by the outcomes of this trial which, in addition to demonstrating safety and tolerability across the entire dose range, generated valuable pharmacology data to support and guide the continuing clinical development of this biotherapeutic candidate."

## **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<sup>®</sup> 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](http://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' expectations regarding continuing clinical development of CDX-6114. 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: the uncertainties inherent in research and the clinical development process, including risks, uncertainties and costs associated with the successful development of biotherapeutic candidates, including obtaining development partners for Codexis' unpartnered biotherapeutic programs and progressing such programs to clinical trials and regulatory approvals; Codexis' dependence on its collaborator Nestlé Health Science for the successful development and commercialization of CDX-6114; Codexis' dependence on a limited number of contract manufacturers for large-scale production of its enzymes; 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 15, 2018 and Quarterly Report on Form 10-Q filed August 8, 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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