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# Codexis Announces Several Key Presentations from its Gene Therapy Programs at 19th Annual WORLDSymposium™

REDWOOD CITY, Calif., Feb. 22, 2023 (GLOBE NEWSWIRE) -- Codexis, Inc. (NASDAQ: CDXS), a leading enzyme engineering company, today highlights several key presentations from its gene therapy programs from [19<sup>th</sup> Annual WORLDSymposium™](#), taking place from February 22-26, 2023, in Orlando, Florida.

Notably, preclinical data in Fabry disease using its engineered transgene is being presented by its partner Takeda Pharmaceutical Company Limited (Takeda). This program is part of Codexis' Strategic Collaboration and License Agreement with Takeda, under which Codexis leverages its CodeEvolver® protein engineering platform to generate novel gene sequences encoding enzyme variants that are tailored to enhance efficacy by increasing activity, stability, and cellular uptake. Takeda is combining these improved transgenes with its gene therapy capabilities to develop novel product candidates for the treatment of rare genetic disorders. As part of the partnership, Codexis has engineered a unique  $\alpha$ -galactosidase A ( $\alpha$ -GLA) protein variant that may enable Takeda to address the limitations of existing standards of care in Fabry disease.

“Our strategic collaboration with Takeda allows us to demonstrate our platform’s leading enzyme engineering capabilities in the context of gene therapy,” said Stephen Dilly, MBBS, Ph.D., President and Chief Executive Officer of Codexis. “Using our CodeEvolver® platform to iterate upon naturally occurring enzymes, we are engineering an  $\alpha$ -GLA protein variant with enhanced stability and reduced immunogenicity to potentially overcome the challenges historically associated with gene therapy approaches for Fabry disease. Our ability to tailor enzymes with specific, desirable characteristics and improved expression profiles pairs nicely with Takeda’s gene therapy expertise as we continue working to address the high unmet need in rare genetic disorders.”

Fabry disease is a rare lysosomal storage disorder in which the body cannot efficiently break down lipids into smaller components. The disease stems from a deficiency in  $\alpha$ -GLA. Low levels of  $\alpha$ -GLA activity result in the accumulation of globotriaosylceramide (Gb3) in the lysosomes of various tissues, which can eventually negatively impact organs, including the heart, kidney, peripheral nervous system, skin, and gastrointestinal (GI) tract. Patients suffer from symptoms such as pain, fatigue, and renal and cardiac disease. While enzyme replacement therapy (ERT) is available for Fabry disease, treatment efficacy is routinely compromised by the short *in vivo* half-life and the development of anti-drug antibodies.

Takeda’s poster presentation, titled, “Preventing Fabry disease progression in a symptomatic mouse model with a recombinant adeno-associated virus (rAAV) based gene

therapy,” highlights its rAAV-based gene therapy candidate for the potential treatment of Fabry disease. The gene therapy candidate is being developed to encode the codon optimized, CodeEvolver® engineered α-GLA enzyme, which is designed to have improved serum and lysosomal stability and a predicted reduced immunogenicity.

Codexis is also presenting two abstracts highlighting its gene therapy program in GM1 Gangliosidosis (GM1) at *WORLDSymposium™*. Similar to the Fabry disease program, these data demonstrate the promise of Codexis’ CodeEvolver® platform to engineer an optimized enzyme for administration as a transgene in gene therapy to potentially slow and/or reverse GM1 disease progression. The posters, “An engineered β-galactosidase with improved stability and cross-correction for the potential treatment of GM1 Gangliosidosis via AAV gene therapy” and “In vitro modeling of GM1 Gangliosidosis using iPSC-derived cellular and organoid CNS models” will be available on the *WORLDSymposium™* OnDemand platform and are also available on the Company’s website at [www.codexis.com/resources](http://www.codexis.com/resources).

## **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](http://www.codexis.com).

## **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “suggest,” “target,” “on track,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. All statements other than statements of historical facts contained in this press release are forward-looking statements. Such forward-looking statements include, but are not limited to, statements regarding the efficacy of Takeda’s product candidate and whether such product candidate will be able to address the limitations of existing standards of care; and the promise of Codexis’ CodeEvolver® platform to engineer an optimized enzyme for administration as a transgene in gene therapy. 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, including, but not limited to,

the development of Takeda's product candidate for the treatment of Fabry disease being subject to a collaboration agreement that could be terminated; Codexis and or its partners being unable to obtain regulatory approval for their product candidates given the lengthy, time consuming and inherently unpredictable nature of such approval processes; clinical trials being difficult to design and implement, expensive, time-consuming and thus involving 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; and market and economic conditions negatively impacting Codexis or its partners' business and financial condition. Additional information about factors that could materially affect actual results can be found in Codexis' Annual Report on Form 10-K to be filed with the Securities and Exchange Commission (SEC) on or about February 24, 2023, 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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