Intellia Therapeutics and Kyverna Therapeutics Announce Collaboration to Develop Next-Generation Allogeneic T-Cell Therapy for Autoimmune Diseases

January 5, 2022

- *Intellia grants Kyverna exclusive rights to its differentiated allogeneic cell engineering platform for the development of KYV-201, a next-generation CD19 CAR T-cell therapy to treat autoimmune diseases*

- *Kyverna to lead and fund preclinical and clinical development; Intellia to receive option to co-develop and co-promote with lead U.S. commercialization rights*

CAMBRIDGE, Mass. and EMERYVILLE, Calif., Jan. 05, 2022 (GLOBE NEWSWIRE) -- Intellia Therapeutics, Inc. (NASDAQ:NTLA), a leading clinical-stage genome editing company focused on developing curative therapeutics leveraging CRISPR-based technologies, and Kyverna Therapeutics, a cell therapy company engineering a new class of therapies for autoimmune and inflammatory diseases, today announced a licensing and collaboration agreement for the development of an allogeneic CD19 chimeric antigen receptor (CAR) T-cell therapy for the treatment of a variety of B cell-mediated autoimmune diseases.

As part of the agreement, Intellia granted Kyverna rights to use its proprietary *ex vivo* CRISPR/Cas9-based allogeneic platform for the development of KYV-201, a next-generation CD19 CAR T-cell investigational candidate for the treatment of select autoimmune diseases. In exchange, Intellia received an equity stake in Kyverna and made an additional investment in Kyverna. Kyverna will lead and fund preclinical and clinical development for KYV-201. Intellia will be eligible to receive certain development and commercial milestone payments, as well as low-to-mid-single-digit royalties on potential future sales. Intellia may also exercise an option to lead U.S. commercialization for KYV-201 under a co-development and co-commercialization agreement. If Intellia chooses to co-develop and co-commercialize KYV-201, it will pay an opt-in fee and share in 50 percent of development costs and future sales revenue from commercializing KYV-201 in the U.S. Kyverna retains all rights outside of the U.S., and Intellia will receive low-to-mid-single-digit royalties on net sales generated outside of the U.S.

“Intellia has built a novel CRISPR/Cas9-based allogeneic platform with the goal of developing safer and more effective therapies for a host of diseases. We are excited to license our allogeneic cell engineering platform to Kyverna, for the development of a new autoimmune disease therapeutic product for patients,” said Intellia President and Chief Executive Officer John Leonard, M.D. “Today’s announcement is another example of our strategy to fully leverage the power of our genome editing technology to address diseases that are inadequately treated with existing medicines. While our core focus remains on advancing therapies within our own research and clinical pipeline, we recognize that our proprietary technology can have additional impact when we strategically partner with others who possess complementary capabilities.”

Preclinically, CD19-targeted CAR T-cell therapies have demonstrated striking efficacy through deep B-cell depletion in disease models in both blood and tissues in disease models, supporting the promise of a transformative therapy for patients living with B-cell driven autoimmune diseases.[1] Through an announced agreement with the National Institutes of Health (NIH), Kyverna is the exclusive worldwide licensee of a novel clinical-stage anti-CD19 CAR T construct for use in both autologous and allogeneic CAR T-cell therapies to address autoimmune diseases. Designed to improve the tolerability profile of conventional CD19 CAR Ts, this construct combines a fully human anti-CD19 CAR with costimulatory domains engineered to minimize cytokine release and to improve clinical tolerability,[2] as observed in a Phase 1/2 clinical study conducted by the NIH in 20 patients with B-cell malignancies. Recognizing the favorable characteristics as highly desirable for the treatment of autoimmune diseases, Kyverna, through its collaboration with Intellia, plans to develop the construct in the CRISPR/Cas9-engineered allogeneic CD19 CAR T KYV-201 for use in B-cell mediated autoimmune diseases.

“The partnership with Intellia will allow us to develop our next-generation fully human CD19 CAR T construct in an allogeneic setting. The improved tolerability profile observed in the NIH trial for this construct, combined with the off-the-shelf allogeneic approach enabled by Intellia’s CRISPR/Cas9 technology, holds great promise for patients with autoimmunity,” said Kyverna President and Chief Executive Officer Dominic Borie, M.D., Ph.D. “We believe that these two points, together with the anticipated transformative efficacy, may enable outpatient administration and support access for patients with B cell-driven autoimmune diseases.”

About Intellia Therapeutics
Intellia Therapeutics, a leading clinical-stage genome editing company, is developing novel, potentially curative therapeutics using CRISPR-based technologies. To fully realize the transformative potential of CRISPR-based technologies, Intellia is pursuing two primary approaches. The company’s *in vivo* programs use intravenously administered CRISPR as the therapy, in which proprietary delivery technology enables highly precise editing of disease-causing genes directly within specific target tissues. Intellia’s *ex vivo* programs use CRISPR to create the therapy by using engineered human cells to treat cancer and autoimmune diseases. Intellia’s deep scientific, technical and clinical development experience, along with its robust intellectual property portfolio, have enabled the company to take a leadership role in harnessing the full potential of genome editing to create new classes of genetic medicine. Learn more at intelliatx.com. Follow us on Twitter @intelliatweets.

About Kyverna Therapeutics
Kyverna Therapeutics is a cell therapy company engineering a new class of therapies for autoimmune and inflammatory diseases. The Kyverna therapeutic platform combines advanced T-cell engineering and synthetic biology technologies to suppress or eliminate the autoreactive immune cells

at the origin of autoimmune and inflammatory diseases. In addition to developing next-generation chimeric antigen receptor T-cell (CAR T) therapies in both autologous and allogeneic settings, Kyverna is creating synReg T cells, a synthetic version of Regulatory T cells (Tregs), powerful natural immune cells that control immune homeostasis through multiple immunosuppressive mechanisms. By offering more than one mechanism for taming autoimmunity, Kyverna is positioned to transform how autoimmune diseases are treated. For more information, please visit https://kyvernatx.com.

Intellia Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, express or implied statements regarding Intellia's beliefs and expectations regarding: its strategy, business plans and focus; its ability to quickly and efficiently realize the scope and potential of its genome editing technology; its ability to maintain, expand and maximize its intellectual property portfolio and pipeline as well as accelerate clinical validation for its platform; the therapeutic value and development potential of CRISPR/Cas9 gene editing technologies and therapies; its ability to combine its CRISPR genome editing platform with Kyverna's CD19 CAR T-cell therapy expertise to create successful therapeutic products; and the expected strategic benefits of any current or future collaborations.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events, and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks related to Intellia's ability to protect and maintain its intellectual property portfolio; risks related to Intellia's relationship with third parties, including its licensors and licensees; risks related to the ability of Intellia's licensors to protect and maintain their intellectual property position; uncertainties related to the authorization, initiation and conduct of studies and other development requirements for the new company's product candidates; the risk that any one or more of the collaboration product candidates (including KYV-201) will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies; and the risk that Intellia's collaboration with Kyverna or its other collaborations will not continue or will not be successful. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Intellia's most recent annual report on Form 10-K and quarterly report on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in Intellia's other filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release represent Intellia's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Intellia explicitly disclaims any obligation to update any forward-looking statements, except as required by law.

Contacts:

For Intellia:

Investors:
Ian Karp
Senior Vice President, Investor Relations and Corporate Communications
+1-857-449-4175
ian.karp@intelliatx.com

Lina Li
Director, Investor Relations
+1-857-706-1612
lina.li@intelliatx.com

Media:
Matt Crenson
Ten Bridge Communications
+1-917-640-7930
media@intelliatx.com
mcrenson@tenbridgecommunications.com

For Kyverna:

Ryan Jones
media@kyvernatx.com

Kathy Vincent
Greig Communications, Inc.
kathy@greigcommunications.com

1. Kansal R et al. Sustained B cell depletion by CD19-targeted CAR T cells is a highly effective treatment for murine lupus. Sci. Transl. Med. 2019; 11(482):eaav1648
2. Brudno J et al. Safety and feasibility of anti-CD19 CAR T cells with fully human binding domains in patients with B-cell lymphoma. Nat. Medicine 2020;26:270-280.

Source: Intellia Therapeutics, Inc.