



Precision BioSciences and Tiziana Life Sciences Announce Exclusive License Agreement to Evaluate Foralumab, a Novel, Fully Human Anti-CD3 Monoclonal Antibody, in Conjunction with Allogeneic CAR T Candidates for Cancer Treatment

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Precision Gains Access to Tiziana's Anti-CD3 Antibody, Foralumab, to Evaluate as a Lymphodepletion Agent with its Allogeneic CAR T Portfolio

DURHAM, N.C., NEW YORK & LONDON--(BUSINESS WIRE)--Sep. 2, 2021-- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage biotechnology company developing allogeneic CAR T and *in vivo* gene correction therapies with its ARCUS® genome editing platform, and Tiziana Life Sciences plc (Nasdaq: TLSA / LSE: TILS), a clinical stage biotechnology company focused on innovative therapeutics for oncology, inflammation, and infectious diseases, today announced an exclusive license agreement to explore Tiziana's foralumab, a fully human anti-CD3 monoclonal antibody (mAb), as an agent to induce tolerance of allogeneic CAR T cells to potentially improve the clinical outcome of CAR T cell therapy.

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The Cluster of Differentiation (CD) 3 is a receptor on effector T cells and an anti-CD3 antibody, such as foralumab, has the potential to eliminate or tolerize patient effector T cells. Precision's manufacturing process, which uses ARCUS to knock out the TRAC gene and implements a CD3-depletion step, produces allogeneic CAR T candidates that are >99.9% CD3-negative. Thus, an anti-CD3 antibody, such as foralumab, might be used to enable the CAR T cells to expand, proliferate, and persist to maximize long term clinical benefits.

Under the terms of the agreement, Precision gains an exclusive license to use foralumab as a lymphodepletion agent in conjunction with its allogeneic CAR T therapeutics for the treatment of cancers. Precision will be responsible for the development, commercialization, and costs for use of foralumab, and Tiziana will receive upfront payment, certain milestone payments, and royalties for foralumab.

"We are building out an allogeneic CAR T platform with editing strategies and novel conditioning regimens, such as a lymphodepleting agent like foralumab, for a broad range of hematologic malignancies and solid tumors," said Alan List, M.D., Chief Medical Officer at Precision BioSciences. "By combining Precision's know-how in constructing novel CAR T products with novel conditioning regimens, we will explore this approach to potentially improve durability of clinical responses to our therapeutic platform."

"We're pleased to offer Precision the exclusive opportunity to explore foralumab, our fully human anti-CD3 monoclonal antibody, for use as a potential lymphodepletion strategy with their allogeneic CAR T programs," said Kunwar Shailubhai, Chief Executive Officer and Chief Scientific Officer of Tiziana Life Sciences. "While CAR T therapies have been clinically successful, relapse rates remain high, which continues to limit broad utility. We are impressed with Precision's novel approaches to CAR T development, offering the potential for a meaningful off-the-shelf solution. Further, given Precision's approach to manufacturing that produces CAR T cells virtually CD3-negative, we believe use of foralumab as a lymphodepletion or tolerizing agent has the potential, either alone or in combination with other co-stimulatory molecules, to improve the long-term success of CAR T in cancer treatment."

About Precision's Allogeneic CAR T Platform

Precision is advancing a pipeline of cell-phenotype optimized allogeneic CAR T therapies, leveraging fully scaled, proprietary manufacturing processes. The Company's allogeneic CAR T platform is designed to maximize the number of patients who can potentially benefit from CAR T therapy. Precision carefully selects high-quality T cells derived from healthy donors as starting material, then uses its ARCUS genome editing technology to modify the cells via a single-step engineering process. By inserting the CAR gene at the T cell receptor (TCR) locus, this process knocks in the CAR while knocking out the TCR, which is designed to create a consistent product that can be reliably and rapidly manufactured and is designed to prevent graft-versus-host disease. Precision optimizes its CAR T therapy candidates for immune cell expansion in the body by maintaining a high proportion of naive and central memory CAR T cells throughout the manufacturing process and in the final product.

About Foralumab

Foralumab (TZLS-401, formerly NI-0401), the only entirely human anti-CD3 mAb, shows reduced release of cytokines as compared to other anti-CD3 mAbs after IV administration in patients with Crohn's disease with decreases in the classic side effects of cytokine release syndrome and improves the overall safety profile of Foralumab. In a humanized mouse model (NOD/SCID IL2 γ c-/-), it was shown that while targeting the T cell receptor, orally administered Foralumab modulates immune responses of the T cells, enhances regulatory T-cells (Tregs) and thus provides therapeutic benefit in treating inflammatory and autoimmune diseases without the occurrence of potential adverse events usually associated with parenteral mAb therapy (Ogura M. et al., 2017 Clin Immunol 183, 240-246). Based on animal studies, the nasal and oral administration of Foralumab offers the potential for the immunotherapy of autoimmune and inflammatory diseases in a safe manner by the induction of Tregs.

About Precision BioSciences, Inc.

Precision BioSciences, Inc. is a clinical stage biotechnology company dedicated to improving life (DTIL) with its novel and proprietary ARCUS® genome editing platform. ARCUS is a highly specific and versatile genome editing platform that was designed with therapeutic safety, delivery, and control in mind. Using ARCUS, the Company's pipeline consists of multiple "off-the-shelf" CAR T immunotherapy clinical candidates and

several *in vivo* gene correction therapy candidates to cure genetic and infectious diseases where no adequate treatments exist. For more information about Precision BioSciences please visit www.precisionbiosciences.com.

About Tiziana Life Sciences plc

Tiziana Life Sciences plc is a dual listed (Nasdaq: TLSA & UK LSE: TILS) biotechnology company that focuses on the discovery and development of novel molecules to treat human diseases in oncology, inflammation and infectious diseases. In addition to Miliclib, the Company will be shortly initiating Phase 2 studies with orally administered Foralumab for Crohn's Disease and nasally administered Foralumab for progressive multiple sclerosis. Foralumab is the only fully human anti-CD3 monoclonal antibody ("mAb") in clinical development in the world. This Phase 2 compound has potential application in a wide range of autoimmune and inflammatory diseases, such as Crohn's Disease, multiple sclerosis, type-1 diabetes ("T1D"), inflammatory bowel disease ("IBD"), psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable. The Company is accelerating development of anti-Interleukin 6 receptor ("IL6R") mAb, a fully human monoclonal antibody for treatment of IL6-induced inflammation, especially for treatment of COVID-19 patients.

Precision Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the Company's agreement with Tiziana for the exploration, use, development or commercialization of foralumab as a lymphodepletion agent in conjunction with the Company's allogeneic CAR T therapeutics for the treatment of cancers and any future milestone or royalty payments thereunder. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "target," "mission," "may," "will," "would," "should," "could," "target," "project," "predict," "contemplate," "potential," or the negative thereof and similar words and expressions.

Forward-looking statements are based on management's current expectations, beliefs and assumptions and on information currently available to us. Such statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various important factors, including, but not limited to: our ability to become profitable; our ability to procure sufficient funding and requirements under our current debt instruments; our operating expenses and our ability to predict what those expenses will be; our limited operating history; the success of our programs and product candidates in which we expend our resources; our dependence on our ARCUS technology; the initiation, cost, timing, progress, achievement of milestones and results of research and development activities, preclinical or greenhouse studies and clinical or field trials; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, biotechnology and agricultural biotechnology fields; our or our collaborators' ability to identify, develop and commercialize product candidates; pending and potential liability lawsuits and penalties against us or our collaborators related to our technology and our product candidates; the U.S. and foreign regulatory landscape applicable to our and our collaborators' development of product candidates; our or our collaborators' ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; our or our collaborators' ability to advance product candidates into, and successfully design, implement and complete, clinical or field trials; potential manufacturing problems associated with the development or commercialization of any of our product candidates; our ability to achieve our anticipated operating efficiencies at our manufacturing facility; delays or difficulties in our and our collaborators' ability to enroll patients; if our product candidates do not work as intended or cause undesirable side effects; risks associated with applicable healthcare, data privacy and security regulations and our compliance therewith; the rate and degree of market acceptance of any of our product candidates; the success of our existing collaboration agreements, and our ability to enter into new collaboration arrangements; our current and future relationships with third parties including suppliers and manufacturers; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; potential litigation relating to infringement or misappropriation of intellectual property rights; our ability to effectively manage the growth of our operations; our ability to attract, retain, and motivate key scientific and management personnel; market and economic conditions; effects of natural and manmade disasters, public health emergencies and other natural catastrophic events effects of the outbreak of COVID-19, or any pandemic, epidemic or outbreak of an infectious disease; insurance expenses and exposure to uninsured liabilities; effects of tax rules; risks related to ownership of our common stock and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021, as any such factors may be updated from time to time in our other filings with the SEC, and accessible on the SEC's website at www.sec.gov and the Investors & Media page of our website at investor.precisionbiosciences.com.

All forward-looking statements speak only as of the date of this press release and, except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Tiziana Forward-Looking Statements

Certain statements made in this announcement are forward-looking statements. These forward-looking statements are not historical facts but rather are based on the Company's current expectations, estimates, and projections about its industry; its beliefs; and assumptions. Words such as 'anticipates,' 'expects,' 'intends,' 'plans,' 'believes,' 'seeks,' 'estimates,' and similar expressions are intended to identify forward-looking statements. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties, and other factors, some of which are beyond the Company's control, are difficult to predict, and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. The Company cautions security holders and prospective security holders not to place undue reliance on these forward-looking statements, which reflect the view of the Company only as of the date of this announcement. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. The Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances, or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.



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