Precision BioSciences Reacquires Global Rights to its Allogeneic CAR T Programs

April 15, 2021

- Precision Reacquires from Servier its Global Development and Commercialization Rights and Control of All Partnered CAR T Programs, Including PBCAR0191 and PBCAR19B Stealth Cell

- Servier Eligible to Receive Milestones and Royalties Based on Program Success

- Precision to Host Conference Call and Webcast Today at 5:00 p.m. ET

DURHAM, N.C.--(BUSINESS WIRE)--Apr. 15, 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, today announced it has entered into a Program Purchase Agreement to reacquire all global development and commercialization rights for all CAR T partnered programs covered under its Development and Commercial License Agreement with Servier. This includes its two clinical stage CD19-targeting allogeneic CAR T candidates, PBCAR0191 and PBCAR19B stealth cell, as well as four additional product targets.

“We are excited about the potential of our allogeneic CAR T pipeline to deliver off-the-shelf treatments for patients with cancer,” said Matt Kane, CEO and Co-Founder of Precision BioSciences. “We believe we are in a unique position with multiple near-term opportunities to achieve success with allogeneic CAR T cells targeting CD19. Our lead candidate, PBCAR0191, continues to look promising when paired with our enhanced lymphodepletion regimen, and our immune-evading PBCAR19B stealth cell candidate is poised to enter the clinic soon. We seized the opportunity to reacquire these two CD19 programs, as well as four additional targets that were selected by Servier in 2020 to regain global commercial rights and full control of our clinical programs, allowing us to focus our resources and enable rapid decision making.”

Under the terms of the Program Purchase Agreement, Servier will receive $1.25 million in cash and Precision has agreed to waive earned, but as-yet unpaid, milestones totaling $18.75 million that would have otherwise been payable to Precision. Servier is also eligible to receive milestones and low- to mid-single-digit royalties subject to product development achievement. With respect to products directed to CD19, Servier has certain rights of negotiation if Precision elects to re-partner the programs.

“Precision was a very good partner for us, and we continue to believe their proprietary, single-step cell engineering technology has the potential to open the door to an off-the-shelf approach for addressing cancer,” said Patrick Therasse, Deputy Head of R&D Oncology at Servier. “While we have made the strategic decision to refocus our R&D activities and we will no longer be taking an active role in the Precision programs, we continue to believe they have multiple opportunities, including the stealth cell approach, to benefit patients with hematologic malignancies and solid tumors, so we are pleased to be able to participate in the potential future success of these programs.”

Subsequent to Precision’s December 2020 interim Phase 1/2a study data update for PBCAR0191, enrollment in the study has continued, with a focus on dose level 3 (3×10^6 cells/kg) following enhanced lymphodepletion (eLD)[1]. Initial response rates are consistent with the high response rates reported by Precision in December 2020, and the safety profile continues to be acceptable. Precision intends to monitor the results for durability from this eLD regimen and report updated interim results by mid-2021.

By the end of May 2021, Precision expects to dose the first patient with PBCAR19B, its second CD19 allogeneic CAR T candidate that is engineered with Precision’s proprietary stealth cell technology. Although it has not finalized its full financial results for the first quarter ended March 31, 2021, Precision BioSciences had cash and cash equivalents of approximately $193 million as of March 31, 2021 and continues to expect that cash and cash equivalents, expected operational receipts, and available credit will allow the Company to continue its operations into 2023.

Company-Hosted Conference Call and Webcast Information

Precision's management team will host a conference call and webcast at 5:00 p.m. ET, Thursday, April 15, 2021 to discuss today’s announcement. The dial-in conference call numbers for domestic and international callers are (866) 996-7202 and (270) 215-9609, respectively. The conference ID number for the call is 8170529. Participants may access the live webcast and the accompanying presentation materials on Precision's website https://investor.precisionbiosciences.com/events-and-presentations in the Investors and Media section under Events and Presentations. An archived replay of the webcast will be available on Precision's website for approximately 30 days.

About PBCAR0191 (Clinical Trials Study Identifier: NCT03666000)

PBCAR0191 is an investigational allogeneic CAR T in a Phase 1/2a clinical trial for the treatment of patients with R/R NHL and R/R B-ALL. PBCAR0191 was designed using Precision BioSciences’ novel and proprietary ARCUS® genome editing platform. It has been granted Fast Track Designation by the FDA for the treatment of R/R B-ALL. Precision also holds Orphan Drug Designation from the FDA for this program in mantle cell lymphoma, an aggressive subtype of NHL.

In December 2020, Precision BioSciences reported positive interim results from this study, in which 27 patients with R/R NHL or R/R B-ALL were dosed with PBCAR0191 CAR T therapy and showed no graft versus host disease, no grade ≥ 3 cytokine release syndrome, and no grade ≥ 3 neurotoxicity. For those NHL and B-ALL patients dosed with PBCAR0191, when combined with eLD, objective response rates reached 83% (5/6).

About PBCAR19B (Clinical Trials Study Identifier: NCT04649112)

PBCAR19B is a next-generation, stealth cell candidate for patients with CD19-positive malignancies such as R/R NHL. PBCAR19B is designed to improve the persistence of allogeneic CAR T cells following infusion by reducing rejection by T cells and NK cells. In addition to the CAR gene, the PBCAR19B stealth cell vector carries a short hairpin RNA that suppresses expression of beta-2 microglobulin, a component of Class I Major Histocompatibility Complex (MHC) molecules found on the cell surface. Reducing or knocking-down Class I MHC expression on allogeneic CAR T cells has been shown to reduce CAR T cell killing by cytotoxic T cells. The PBCAR19B vector also carries an HLA-E gene intended to reduce rejection of CAR T cells by NK cells that can be stimulated as a result of reduced MHC molecule expression on the cell surface.

About Precision BioSciences, Inc.

Precision BioSciences, Inc. is a clinical stage biotechnology company dedicated to improving life (DTIL) with its wholly 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.

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 potential milestone payments under the purchase agreement with Servier, the expected timing of trials and results from clinical studies of CAR T product candidates and in vivo gene editing programs, and expectations regarding our liquidity, anticipated cash payments and our ability to fund operations. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "believe," "could," "eligible," "expect," "should," "plan," "intend," "estimate," "target," "mission," "goal," "may," "will," "would," "should," "could," "target," "potential," "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 and effects of restrictions thereunder; risks associated with raising additional capital; 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 limited ability or inability to assess the safety and efficacy of our product candidates; 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 obtain an adequate supply of T cells from qualified donors; our ability to achieve our anticipated operating efficiencies at our manufacturing facility; delays or difficulties in our and our collaborators' ability to enroll patients; changes in interim "top-line" and initial data that we announce or publish; if our product candidates do not work as intended or cause undesirable side effects; risks associated with applicable healthcare, data protection, 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 and reliance on 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 executives and personnel; market and economic conditions; effects of system failures and security breaches; 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 Annual Report on Form 10-K for the year ended December 31, 2020, as any such factors may be updated from time to time in our other filings with the SEC, which are 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 have no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

[1] Fludarabine (30 mg/m/day for 4 days) and cyclophosphamide (1000 mg/m^2/day for 3 days)

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