Precision BioSciences Reports Clinical Program Updates for Its Allogeneic CAR T Pipeline

December 11, 2021

- Precision BioSciences is Simultaneously Advancing Development of PBCAR0191, as Potential First-in-Class, and PBCAR19B as Potential Best-in-Class CD19 Targeting Allogeneic CAR T Therapies

- High Response Rates to PBCAR0191 Observed in Heavily Treated Patients Who Relapsed Following Prior Autologous CAR T Therapy

- Company to Host Webcast and Conference Call Today at 7:30 PM ET

DURHAM, N.C.--(BUSINESS WIRE)--Dec. 11, 2021-- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage biotechnology company using its ARCUS® genome editing platform to develop allogeneic CAR T and *in vivo* gene editing therapies, today announced program updates across its allogeneic CAR T cell therapy pipeline, including updated data for its Phase 1/2a clinical study of PBCAR0191 with enhanced lymphodepletion (eLD)[1] presented at the 63rd American Society of Hematology (ASH) Annual Meeting.

“Precision’s clinical stage CAR T pipeline continues to generate promising data in lymphoma patients. We have recently observed a potential signal in patients who have relapsed following auto CAR T therapy and responded to treatment with PBCAR0191. This is a growing population of patients with the greatest need for new treatment options, and PBCAR0191 has the potential to be a first-in-class allogeneic CAR T product for this patient population,” said Michael Amoroso, Chief Executive Officer of Precision BioSciences. “In parallel, we are continuing to advance PBCAR19B, our immune evading stealth cell candidate, in a relapsed and/or refractory (R/R) patient population with non-Hodgkin’s lymphoma (NHL), in pursuit of a potential best-in-class CD19 targeting allogeneic product candidate.”

First-in-Class Approach: PBCAR0191

The updated data from the PBCAR0191 Phase 1/2a study included 22 (17 NHL, 5 B-ALL) heavily pre-treated R/R subjects with predominantly advanced or aggressive B-cell malignancies who were evaluable as of November 16, 2021. Evaluable subjects received a median 5 lines of prior treatment, including 27% (6/22) who previously received a CD19-directed autologous CAR T.

For patients that received treatment of PBCAR0191 following eLD as of November 16, 2021:

- PBCAR0191 showed no ≥ Grade 3 cytokine release syndrome (CRS), one Grade 3 immune effector cell-associated neurotoxicity syndrome (ICANS) with resolution to ≤ Grade 2 in 72 hours, no evidence of graft versus host disease and one infectious death at Day 54 deemed possibly related to treatment[2]
- PBCAR0191 yielded an overall response rate of 73% and a complete response rate of 59% using a 3 x 10^6 cells/kg cell dose
- Four responders among the 17 evaluable NHL subjects reached Day 180 durability assessment

Most notably, a potential signal for PBCAR0191 was observed among six subjects that previously received an autologous CAR T:

- 100% of these patients responded and 66% experienced a complete response at ≥ Day 28
- More than half of these patients had a longer duration of response on PBCAR0191 than with the prior autologous CAR T treatment

“Today, there are no FDA approved therapeutics for lymphoma patients who have relapsed following auto-CAR T therapy. PBCAR0191 has the potential to be developed as a salvage treatment for this growing population with high unmet need, and we are actively enrolling additional patients in this relapse setting to further validate this observed activity,” said Bijal Shah, M.D., Associate Professor, Malignant Hematology Department, H. Lee Moffitt Cancer Center and Research Institute.

Best-in-Class Approach: PBCAR19B Immune Evading Stealth Cell

The Phase 1 clinical study of PBCAR19B is actively enrolling subjects with R/R NHL. Flat doses of PBCAR19B CAR T cells following standard lymphodepletion (sLD)[3] are administered starting at Dose Level 1 (2.7×10^8 CAR T cells). The company has dosed the first three subjects at Dose Level 1.

“In parallel to our development with PBCAR0191, we are continuing to enroll patients in the PBCAR19B clinical trial and expect to share initial results for this program in mid-2022,” said Alan List M.D., Chief Medical Officer of Precision BioSciences. “Unique attributes of ARCUS designed to make complex gene edits in a single step may allow PBCAR19B to achieve a best-in-class allogeneic product profile to potentially displace CD19 directed autologous CAR T.”

PBCAR19B is a novel immune-evading stealth cell candidate employing a single-gene edit to knock-down beta-2 microglobulin designed for evading T

cell rejection, while also inserting an HLA-E transgene to further evade rejection from natural killer cells. Precision BioSciences' CAR T cells are the only allogeneic CAR T cells in human clinical trials made with a single gene editing step designed to specifically avoid the potentially deleterious effects of making multiple edits to T cells.

PBCAR269A Phase 1/2a Program Update

PBCAR269A is an investigational allogeneic CAR T immunotherapy targeting B-cell maturation antigen for the treatment of R/R multiple myeloma. The following has been observed among 14 patients that have been evaluated for clinical activity and safety across four dose levels of PBCAR269A[4] monotherapy following sLD:

- No Grade ≥ 3 CRS or ICANS
- Dose-dependent increase in PBCAR269A peak expansion

Overall, PBCAR269A monotherapy response observed in the Phase 1/2a trial was not comparable with autologous CAR T profiles. Therefore, Precision is continuing to enroll subjects with PBCAR269A in combination with nirogacestat, a gamma secretase inhibitor developed by SpringWorks Therapeutics, in pursuit of a potential therapeutic index comparable with or better than autologous CAR T. Initial clinical data from the combination cohort is expected to be presented in mid-2022.

The Company's balance of cash and cash equivalents was approximately $152 million as of November 30, 2021. The Company continues to expect that existing cash and cash equivalents, expected operational receipts, and available credit will be sufficient to fund its operating expenses and capital expenditure requirements into 2023.

Company-Hosted Webcast and Conference Call Information

Precision will host a conference call and webcast today, Saturday, December 11, 2021 at 7:30 PM ET. This event is not an official program of the ASH annual meeting. 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 1178837. Participants may access the live webcast, and accompanying presentation materials, as well as the archived webcast on Precision's website in the Investors section under Events & Presentations: https://investor.precisionbiosciences.com/events-and-presentations.

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 editing candidates designed 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 the expected timing of clinical updates and interim data reports related to PBCAR0191, PBCAR19B, PBCAR269A monotherapy and PBCAR269A in combination with nirogacestat, statements regarding our clinical development pipeline and the potential clinical benefit of our product candidates. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "target," "mission," "goal," "may," "will," "would," "potential," "project," "predict," "contemplate," 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 subjects; 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021, 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 page of our website under Events and Presentations 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.

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[1] Enhanced Lymphodepletion (eLD) = Fludarabine (30 mg/m^2/day × 4 days) and cyclophosphamide (1000 mg/m^2/day × 3 days)

[2] One death among subjects in ongoing complete response deemed possibly related to treatment by investigator (as previously disclosed); three deaths among subjects in ongoing complete response deemed unrelated to treatment

[3] Standard Lymphodepletion (sLD) = Fludarabine (30 mg/m^2/day × 3 days) and cyclophosphamide (1000 mg/m^2/day × 3 days)

[4] Dose Level 1= 0.6×10^6 cells/kg; Dose Level 2 = 2×10^6 cells/kg; Dose Level 3 = 6×10^6 cells/kg; Dose Level 4 = 960 x10^6 cells flat dose

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Investor Contact:
Alex Kelly
Chief Financial Officer
Alex.Kelly@precisionbiosciences.com

Media Contact:
Maurissa Messier
Senior Director, Corporate Communications
Maurissa.Messier@precisionbiosciences.com

Source: Precision BioSciences, Inc.