Precision BioSciences Provides Update on Allogeneic CAR T Programs and Regulatory Path Forward

May 31, 2023

Azer-Cel Safety Profile was Significantly Improved Compared to Prior Cohorts in Patients Dosed Using Optimized Product at Lower Intensity Lymphodepletion; No Grade 3 or Greater Allogeneic CAR T Related Adverse Events Were Observed

Azer-Cel Achieved 83% Overall Response Rate (ORR), 61% Complete Response (CR) Rate with 55% Durable Response Greater Than or Equal to Six Months Among Evaluable CAR T Relapsed Subjects (n=18)

Upcoming Azer-Cel Meeting with FDA in June to Align on Potential Phase 2 Study in CAR T Relapsed Diffuse Large B-cell Lymphoma (DLBCL); Focus on Trial Design, Size, and Endpoints

PBCAR19B Stealth Cell Proof of Concept Achieved; Designed to Enable Expansion and Persistence by Delaying Host Rejection Through Immune Cloaking

PBCAR19B Stealth Cell Achieved 71% ORR with No Grade 3 or Greater Allogeneic CAR T Related Adverse Events; Most Compelling Signal in Third Line DLBCL (n=5) with 80% ORR and 60% CR (MRD-)

Company to Host Webcast and Conference Call Today at 8:30 AM ET

DURHAM, N.C.--(BUSINESS WIRE)--May 31, 2023-- Precision BioSciences, Inc. (Nasdaq: DTIL) a clinical stage gene editing company developing ARCUS®-based *in vivo* gene editing and *ex vivo* allogeneic CAR T therapies, today announced program updates across its allogeneic CAR T pipeline. The Company highlighted new interim clinical data for its lead candidate, azercabtagene zapreleucel (azer-cel), as a potential first-in-class allogeneic CD19 CAR T for the growing CAR T relapsed patient population with DLBCL. The Company also provided the first clinical update on PBCAR19B stealth cell, which is in development as a potential best-in-class allogeneic CAR T therapy for patients with relapsed or refractory (r/r) non-Hodgkin lymphoma (NHL), with primary focus on DLBCL.

“Over the last two years, we have pursued a deliberate, multi-faceted approach in the development of our CAR T programs with the aim of bringing off-the-shelf therapies to patients. In the process, we have built one of the most extensive data packages for an allogeneic product, with the goal of tailoring azer-cel for patients who have relapsed following autologous CAR T treatment,” said Michael Amoroso, Chief Executive Officer at Precision BioSciences. “With the updated clinical data presented today, including safety, efficacy, and durability, we believe we have identified the recommended azer-cel dosing regimen to discuss in a clinical meeting with the U.S. Food and Drug Administration (FDA) to align on next steps.”

Mr. Amoroso continued, “In addition to azer-cel, we are also advancing our CD19-targeted program, PBCAR19B stealth cell, which incorporates an immune cloaking approach designed to allow greater CAR T expansion and persistence. Last year, we applied platform-wide manufacturing optimizations using ARCUS for CAR T insertion for both of our clinical candidates. We believe the optimized stealth cell product resulted in preliminary efficacy and safety on par with autologous CAR T in the r/r DLBCL setting. The interim data highlighted today supports further investigation of the stealth cell product candidate in DLBCL patients. Looking ahead, we will continue to evaluate the durability of response in the stealth cell patients and seek potential partnerships in this larger, earlier line setting.”

Azer-cel as a Potential First-in Class Allogeneic CAR T Product Candidate for CD19+ CAR T Relapsed Patients

As of May 30, 2023, we observed continued high response rates with an acceptable safety profile in r/r NHL patients. Among all evaluable subjects (n=61), ORR was 58% with 41% achieving a CR, across all doses and lymphodepletion regimen.

- Activity was most compelling among the azer-cel treated subjects who had relapsed following autologous CAR T therapy (n=18); ORR was achieved in 83% of subjects and 61% achieved CR.
- In CAR T relapsed evaluable subjects (n=11), 55% had ongoing durable responses for ≥ 6-months.
- In the most recent CAR T relapsed cohort receiving optimized Dose Level 4b with FluCy750[1] (n=5), 60% ORR was achieved, and 66% of evaluable patients achieved a full molecular remission (MRD-) which may be predictive of durability.
- No Grade 3 or greater cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), infection or graft versus host disease was observed in the most recent cohort.

“Azer-cel continues to demonstrate promising results in DLBCL patients who relapsed following CAR T, and we are encouraged by the high overall response rates with molecular remissions in this patient setting,” said Alan List, M.D., Chief Medical Officer at Precision BioSciences. “Based on this dataset, azer-cel has the potential to improve outcomes in this large and growing population with high unmet need. Also based on these results, a clinical meeting with the FDA has been scheduled in June to discuss next steps for azer-cel in the CAR T relapsed setting. We look forward to providing updates on the path forward in the near future.”

PBCAR19B Stealth Cell as a Potential Best-in Class Allogeneic CAR T Product Candidate for Earlier Line CAR T Naïve CD19+ DLBCL

PBCAR19B is Precision's anti-CD19 targeting allogeneic CAR T candidate designed to evade immune rejection by host T cell and NK cells with a single ARCUS gene edit to insert a CD19 CAR transgene, knock-down beta-2 microglobulin, and insert an HLA-E transgene. The treatment goal of this program is to potentially displace autologous CAR T in the 2nd line DLBCL setting.

As of May 30, 2023, in Phase 1 results we observed an acceptable safety profile with high overall response rates among all evaluable subjects with evidence of molecular remission (MRD-) and preliminary durability at Dose Level 2 (540 million cells)[2].

- Out of seven evaluable subjects at Dose Level 2, five with DLBCL and two with mantle cell lymphoma, PBCAR19B achieved 71% ORR and 43% CR rate.
- In DLBCL patients, ORR was achieved in 80% of subjects and 60% achieved a CR (MRD-).
- No Grade 3 or greater cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), infection or graft versus host disease was observed.
- PBCAR19B stealth cell achieved proof of concept and appeared to be effective in delaying recovery of host T- and NK-cells.
- PBCAR19B stealth cell dosed at 540M cells + FluCy750 has been established as the dosing regimen for further investigation in DLBCL patients.

"We are impressed with our PBCAR19B stealth cell construct which appeared to delay host rejection through immune cloaking. Stealth cell achieved a high response rate, especially in DLBCL subjects with a high frequency of MRD- complete responses, and acceptable safety with our improved manufacturing process at Dose Level 2 in the Phase 1 study," said Dr. List. "The next steps for stealth cell will be to await further durability data and seek thoughtful partnership for ongoing development in the earlier line DLBCL setting."

Company-Hosted Webcast and Conference Call Information

Precision will host a conference call and webcast today, May 31, 2023, at 8:30 AM ET. The dial-in conference call number is (800) 715-9871 and the conference ID number for the call is 4729500. 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 precise and versatile genome editing platform that was designed with therapeutic safety, delivery, and control in mind. Using ARCUS, the Company's pipeline consists of several *in vivo* gene editing candidates designed to cure genetic and infectious diseases where no adequate treatments exist and multiple *ex vivo* clinical candidates. 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 clinical development and expected efficacy and benefit of our product candidates, the expected timing of updates regarding our allogenic CAR T and in vivo programs, the expected timing of regulatory processes, expectations about our operational initiatives and business strategy, expectations around partnership opportunities, and expectations about achievement of key milestones. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "approach," "believe," "contemplate," "could," "estimate," "expect," "goal," "intend," "look," "may," "mission," "plan," "possible," "potential," "predict," "project," "pursue," "should," "target," "will," "would," 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. These statements are neither promises nor guarantees, but involve 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; the risk that other genome-editing technologies may provide significant advantages over our ARCUS technology; our dependence on our ARCUS technology; the initiation, cost, timing, progress, achievement of milestones and results of research and development activities and preclinical and clinical studies; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, and biotechnology fields; our or our collaborators' ability to identify, develop and commercialize product candidates; pending and potential product 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 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; our ability to obtain orphan drug designation or fast track designation for our product candidates or to realize the expected benefits of these designations; 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; the rate and degree of market acceptance of any of our product candidates; our ability to effectively manage the growth of our operations; our ability to attract, retain, and motivate executives and personnel; effects of system failures and security breaches; insurance expenses and exposure to uninsured liabilities; effects of tax rules; effects of the COVID-19 pandemic and variants thereof, or any pandemic, epidemic, or outbreak of an infectious disease; 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; effects of natural and manmade disasters, public health emergencies and other natural catastrophic events; effects of sustained inflation, supply chain disruptions and major central bank policy actions; market and economic conditions; risks related to ownership of our common stock, including fluctuations in our stock price, and other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023, 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 SEC Filings 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] Dose Level 4b = 500×10^6 (flat dose). FluCy750 lymphodepletion = fludarabine 30 mg/m^2 × 3 days + cyclophosphamide 750 mg/m^2 × 3 days.

[2] Dose Level 2 = 540×10^6 (flat dose) with FluCy750 lymphodepletion (fludarabine 30 mg/m^2 × 3 days + cyclophosphamide 750 mg/m^2 × 3 days).

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