



Precision BioSciences Announces Two Oral Presentations Highlighting Updated Interim Data from Lead PBCAR0191 CAR T Immunotherapy for Relapsed and Refractory B-cell Malignancies at the 63rd Annual Meeting of the American Society of Hematology

November 4, 2021 at 9:01 AM EDT

- *Enhanced Lymphodepletion Improved Overall Response Rate and Complete Response Rate Compared to Standard Lymphodepletion in Heavily Pretreated NHL and B-ALL Subjects with a Median of ~6 Prior Lines of Therapy*

- *Clinically Significant Activity in Subjects Previously Treated with Autologous CD19 Directed CAR T*

- *In B-ALL Subjects Enhanced Lymphodepletion or Higher Doses of PBCAR0191 Resulted in High Complete Response Rates Allowing the Potential to Bridge to Allogeneic Stem Cell Transplant*

- *Data Presented at ASH will be Updated to Include Subjects with >28 Day Follow up as of October 10, 2021*

DURHAM, N.C.--(BUSINESS WIRE)--Nov. 4, 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 that investigators involved with the Phase 1/2a study of PBCAR0191 in Relapsed/Refractory (R/R) non-Hodgkin's lymphoma (NHL) and B-cell acute lymphoblastic leukemia (B-ALL), will present new data during two oral presentations at the 63rd Annual Meeting of the American Society of Hematology (ASH) taking place December 11-14, 2021.

"We are encouraged by the response rates seen in this heavily pre-treated patient population, and that a treatment strategy with enhanced lymphodepletion mitigated PBCAR0191 rejection and improved peak CAR T cell expansion and persistence, compared to standard lymphodepletion, with predictable toxicity," said Alan List, MD, Chief Medical Officer of Precision BioSciences. "We look forward to sharing additional patient outcome, durability, and safety data for PBCAR0191 at the American Society of Hematology Annual Meeting."

The abstracts accepted by the ASH are now available at www.hematology.org, and will be presented during the following oral presentation sessions:

Session Name: 626, Abstract #302. Aggressive Lymphomas Prospective Therapeutic Trials: Challenging Populations

Oral Presentation Title: Allogeneic CAR-T PBCAR0191 with Intensified Lymphodepletion is Highly Active in Subjects with Relapsed/Refractory B-cell Malignancies

Presenting Author: Bijal Shah, M.D., Moffitt Cancer Center

Date/Time: Saturday, December 11, 2021 at 4:15 PM ET

Location: Georgia World Congress Center, B401-B402

Session Name: 704, Abstract #650 Cellular Immunotherapies: Allogeneic CARs and CARs for T Cell Lymphomas

Oral Presentation Title: Preliminary Safety and Efficacy of PBCAR0191, an Allogeneic 'Off-the-Shelf' CD19-Directed CAR-T for Patients with Relapsed/Refractory (R/R) CD19+ B-ALL

Presenting Author: Nitin Jain, M.D., The University of Texas MD Anderson Cancer Center

Date/Time: Monday, December 13, 2021 at 10:45 AM ET

Location: Georgia World Congress Center, Sidney Marcus Auditorium

Published abstracts report on key interim clinical evaluations of CD19+ NHL or B-ALL subjects treated with PBCAR0191.

Abstract #302: For 21 subjects with Relapsed/Refractory (R/R) B-cell malignancies (16 NHL, 5 B-ALL) who received PBCAR0191 following enhanced lymphodepletion¹ as of July 1, 2021:

- PBCAR0191 demonstrated a safety profile with no Grade 3 CRS, one Grade 3 self-limited ICANS, no evidence of GvHD, and one infectious death at Day 54, deemed possibly related to treatment.
- 83% (15/18) of evaluable subjects experienced a complete response (CR) rate or complete remission with incomplete marrow recovery (CRI); 62% (8/13) of NHL subjects and 80% (4/5) of B-ALL subjects, respectively.
- 20% (3/15) of responders demonstrated durability of response greater than 6 months, with 3 additional responders not yet having reached a 6-month evaluation threshold.
- Compared to standard lymphodepletion², enhanced lymphodepletion mitigated PBCAR0191 rejection to markedly improve peak CAR T cell expansion and persistence with area under the curve increasing 80-fold.
- Among 6 subjects who progressed following prior CD19 CAR therapy (5 NHL, 1 B-ALL), the overall response rate was 83% (5/6) with 67% (4/6) achieving a CR, including an ongoing MRD negative CR in a B-ALL subject of >6 months.

Abstract #650: For 15 subjects with R/R B-cell acute lymphoblastic leukemia including 11 subjects who received PBCAR0191 Dose Level 3/4a³ and 4

subjects who received PBCAR0191 Dose Level 4b⁴ as of August 2, 2021:

- PBCAR0191 demonstrated a safety profile with no cases of GvHD, no Grade ≥ 3 CRS, and one case of Grade 3 ICANS, which resolved within 48 hours.
- For subjects who received either Dose Level 3/4a following enhanced lymphodepletion or Dose Level 4b following standard lymphodepletion, 78% (7/9) achieved a high CR or CRi rate; 56% (5/9) maintained the CR at day 28 or later potentially securing an adequate window to bridge to allogeneic stem cell transplant.
- Use of enhanced lymphodepletion or higher doses of PBCAR0191 resulted in substantial improvements in peak CAR T cell expansion and area under the curve.

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 our clinical development pipeline and interim data announcements. 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," "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 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 June 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 & 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 eLD = Fludarabine (30 mg/m²/day for 4 days) and cyclophosphamide (1000 mg/m²/day for 3 days)

² sLD = Fludarabine (30 mg/m²/day for 3 days) and cyclophosphamide (500 mg/m²/day for 3 days)

³ 3 x 10 cells/kg or equivalent following either standard or enhanced lymphodepletion

⁴ Flat dose of 5 x 10 cells following standard lymphodepletion

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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.