



## Precision BioSciences Presents Analysis of Azer-Cel, Allogeneic CAR T Product Attributes Related to In Vivo Pharmacokinetics, Pharmacodynamics, and Clinical Outcomes at 2022 American Society of Hematology Annual Meeting

December 10, 2022 at 10:00 AM EST

- Cryopreserved, Post-thaw CAR T Cell Composition and Effective CAR T Cell Dose are Predictive for Response to Treatment with Azer-cel

- Peak CAR T Expansion, a Key Determinant of Durable Response, Strongly Correlated with Effective CAR T Dose

DURHAM, N.C.--(BUSINESS WIRE)--Dec. 10, 2022-- Precision BioSciences (Nasdaq: DTIL), a clinical stage gene editing company developing ARCUS®-based *ex vivo* allogeneic CAR T and *in vivo* gene editing therapies, today presented a novel, product-attributes analysis of its lead CD19 allogeneic CAR T candidate, Azercabtagene Zapreleucel (azer-cel; PBCAR0191) that shows a relationship between CAR T cell composition and effective cell dose with pharmacokinetics, pharmacodynamics, and clinical outcomes. Data from this analysis, [Effective Cell Dose and Functional Attributes of Azercabtagene Zapreleucel \(azer-cel; PBCAR0191\) Associated with Allogeneic CAR T-Cell Safety and Efficacy in Patients with Relapsed/Refractory B-Cell Lymphoma](#), were presented today during a poster session at the American Society of Hematology Annual Meeting.

"Autologous CAR T therapy remains one of the most promising approaches in the treatment of hematological malignancies. However, 30-60% of high-grade non-Hodgkin Lymphoma (NHL) patients relapse after treatment and, for a proportion of patients, an effective autologous product cannot be manufactured<sup>1</sup>," said Caron A. Jacobson, M.D., azer-cel clinical trial investigator and Medical Director for the Immune Effector Cell Therapy Program at Dana-Farber Cancer Institute. "Unlike autologous CAR T cell therapy, all allogeneic CAR T products are cryopreserved, which may alter the effective dose and composition of the post-thaw product. In this analysis, azer-cel cellular attributes were interrogated in the post-thaw product for possible relationship to *in vivo* pharmacokinetics, pharmacodynamics, and clinical outcomes for 44 subjects with NHL across multiple azer-cel dose levels and lymphodepletion regimens. The analysis found that CAR T expansion, a key determinant of durable response, strongly correlated with non-apoptotic CAR T cell dose."

Azer-cel is an investigational allogeneic anti-CD19 CAR T candidate currently in a Phase 1/2a clinical trial of adult subjects with relapsed or refractory NHL, who relapsed following treatment with an autologous CAR T.

"This is the first analysis of an allogeneic anti-CD19 CAR T product to examine the relationships between allogeneic CAR T cell composition, cell dose, and lymphodepletion with pharmacokinetics, pharmacodynamics, and clinical outcomes," said Alan List, M.D., Chief Medical Officer, Precision BioSciences. "These results indicate that the post-thaw CAR T product composition drives *in vivo* cell expansion potential and CAR T-related adverse events. We are continuing to use this information in real time, applying optimizations across our first- and second-generation allogeneic CAR T platforms with the goal of improving those attributes and characteristics that drive predictability, reliability, and performance of CAR T cell therapy."

The analysis also showed that CD4:CD8 ratio strongly correlated with *in vivo* CD4<sup>+</sup> CAR T cell expansion. Similar to data reported in autologous CAR T studies, differentiated CD4<sup>+</sup> CAR T cell dose correlated with Grade 3 or greater neurotoxicity. This was particularly observed in a subset of patients that were both CAR T relapsed and conditioned with an intensified lymphodepletion treatment regimen.

### 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 multiple *ex vivo* "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](http://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, expected efficacy and benefit of our product candidates and programs, optimizations and improvements across our allogeneic CAR T platforms, and expectations about our operational initiatives and our business strategy. 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," "promise," "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. 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 studies and clinical trials; 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 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 COVID-19 pandemic and variants thereof, 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, 2022, 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](http://www.sec.gov) and the Investors page of our website under SEC Filings at [investor.precisionbiosciences.com](http://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.

<sup>i</sup> Gena Kanas, Wenzhen Ge, Ruben G. W. Quek, Katie Keeven, Knar Nersesyan & Jon E. Arnason (2022) Epidemiology of diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) in the United States and Western Europe: population-level projections for 2020–2025, *Leukemia & Lymphoma*, 63:1, 54-63, DOI: 10.1080/10428194.2021.1975188



View source version on [businesswire.com](https://www.businesswire.com/news/home/20221210005005/en/): <https://www.businesswire.com/news/home/20221210005005/en/>

**Investor Contact:**

Mei Burris  
Director, Investor Relations and Finance  
[Mei.Burris@precisionbiosciences.com](mailto:Mei.Burris@precisionbiosciences.com)

**Media Contact:**

Maurissa Messier  
Senior Director, Corporate Communications  
[Maurissa.Messier@precisionbiosciences.com](mailto:Maurissa.Messier@precisionbiosciences.com)

Source: Precision BioSciences, Inc.