

# Atara Biotherapeutics Announces Fourth Quarter and Full Year 2023 Financial Results and Operational Progress

Tab-cel® U.S. BLA on Track for Submission in Q2 2024 Following Positive Pre-BLA Meeting

Allogeneic CAR T Pipeline Expands Into Autoimmune Disease With Plans to Initiate an ATA3219 Lupus Nephritis Study in H2 2024, and Initial Clinical Data Expected H1 2025

ATA3219 NHL Study Enrolling With Initial Clinical Data Expected in Q4 2024

Cash Runway Into 2027 Enables Key Pipeline Readouts

THOUSAND OAKS, Calif.--(BUSINESS WIRE)-- <u>Atara Biotherapeutics</u>, <u>Inc.</u> (Nasdaq: ATRA), a leader in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform to develop transformative therapies for patients with cancer and autoimmune diseases, today reported financial results for the fourth quarter and full year 2023, recent business highlights, and key upcoming milestones for 2024.

"We are expanding Atara's proven EBV T-cell platform into allogeneic CAR T therapy for both oncology and autoimmune disease," said Pascal Touchon, President and Chief Executive Officer of Atara. "This includes strong momentum for our lead CAR T program, ATA3219, which is positioned to deliver near-term clinical data for both non-Hodgkin's lymphoma and lupus nephritis. We also are focused on submitting our BLA for tab-cel in the second quarter, the progress of which triggers financial milestones and sales royalty opportunities in our partnership with Pierre Fabre."

### Tabelecleucel (tab-cel<sup>®</sup> or Ebvallo<sup>™</sup>) for Post-Transplant Lymphoproliferative Disease (PTLD)

- Atara recently held a positive pre-BLA meeting with the U.S. Food and Drug Administration (FDA) that supports its plan to submit the tab-cel relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) Biologics License Application (BLA) in Q2 2024
- Data from the pivotal Phase 3 ALLELE study of tab-cel were published in *The Lancet Oncology* and showed a significant 51.2% objective response rate (ORR) and 23.0-month median duration of response in relapsed or refractory EBV+ PTLD subjects. Tab-cel was well tolerated with no events of graft-versus-host disease related to tab-cel
- Positive new data presented at the 2023 ESMO-IO meeting from the actively enrolling, multicohort Phase 2 EBVision trial with a pooled analysis demonstrated a 77.8% ORR in 18 central nervous system (CNS) EBV+ PTLD subjects including front line EBV+ PTLD
- Atara and Pierre Fabre Laboratories closed the expanded global partnership in

- December 2023 for the development, manufacturing, and commercialization rights of tab-cel in the United States and all remaining markets
- Atara received approximately \$27 million in cash upfront at the closing of the deal.
   Under the agreement, Atara has the potential to receive up to \$640 million in additional payments and significant double-digit tiered royalties on net sales, including up to \$100 million in potential regulatory milestones through BLA approval
  - Atara expects to receive \$20 million of these regulatory milestones in April based on the recent positive pre-BLA meeting, another \$20 million in connection with BLA acceptance, and the remaining \$60 million in potential regulatory milestones in connection with BLA approval
- In addition, Pierre Fabre Laboratories will reimburse Atara for tab-cel regulatory and development costs through BLA approval, and purchase tab-cel inventory manufactured through BLA transfer

#### ATA3219: CD19 Program in Lupus Nephritis

- Investigational New Drug (IND) application cleared for the use of ATA3219 as a monotherapy for the treatment of systemic lupus erythematosus (SLE) with kidney involvement (lupus nephritis [LN])
- Atara plans to initiate a Phase 1 LN study in H2 2024 with initial clinical data anticipated H1 2025
- The Phase 1 open-label, dose-escalation study is designed to evaluate safety, preliminary efficacy, pharmacokinetics, and biomarkers of a single dose of ATA3219 administered to LN subjects refractory to one or more lines of treatment. Subjects will receive lymphodepletion (LD) treatment followed by ATA3219 at a dose of 40, 80, or 160 x 10<sup>6</sup> CAR+ T cells. Each dose level is designed to enroll 3-6 patients
- In vitro data demonstrated the CD19 antigen-specific functional activity of ATA3219 and CAR-mediated activity against B cells from SLE patients. ATA3219 led to nearcomplete CD19-specific B-cell depletion compared to controls. These preclinical data were submitted as part of a late-breaking abstract which was accepted for poster presentation at the upcoming International Society for Cell & Gene Therapy meeting held May 29-June 1, 2024

#### ATA3219: CD19 Program in Non-Hodgkin's Lymphoma (NHL)

- Atara initiated enrollment of a multi-center, Phase 1 open-label, dose-escalation clinical trial of ATA3219 in NHL, including large B-cell lymphomas, follicular lymphoma, and mantle cell lymphoma, with initial clinical data anticipated in Q4 2024
- Study designed to evaluate safety, preliminary efficacy, pharmacokinetics, and biomarkers. Subjects will receive LD treatment followed by ATA3219 at a dose of 40, 80, 240, or 480 x 10<sup>6</sup> CAR+ T cells. Each dose level is designed to enroll 3-6 patients
- Preclinical data previously presented demonstrated superior in vivo persistence and CD19-specific anti-tumor efficacy compared to an autologous CD19 CAR T benchmark with no observed toxicity or alloreactivity

#### ATA3431: CD19/CD20 Program for B-Cell Malignancies

 Preclinical data presented at ASH 2023 demonstrated early evidence of potent antitumor activity, long-term persistence, and superior tumor growth inhibition

- compared to an autologous CD19/CD20 CAR T benchmark
- Dual CD19 and CD20 targeting designed to address CD19 escape and tumor variability and may provide additional efficacy in lymphoma
- Atara is progressing toward an IND submission in 2025

#### Fourth Quarter and Full Year 2023 Financial Results

- Cash, cash equivalents and short-term investments as of December 31, 2023 totaled \$51.7 million, as compared to \$102.4 million as of September 30, 2023 and \$242.8 million as of December 31, 2022
- Net cash used in operating activities was \$50.4 million and \$193.0 million for the fourth quarter and fiscal year 2023, as compared to \$56.9 million and \$270.4 million in the same periods in 2022
- Atara reported net losses of \$60.5 million, or \$0.56 per share, and \$276.1 million, or \$2.61 per share, for the fourth quarter and fiscal year 2023, respectively, as compared to \$74.6 million, or \$0.72 per share, and \$228.3 million, or \$2.24 per share, for the same periods in 2022
- Total costs and operating expenses include non-cash stock-based compensation, depreciation and amortization expenses of \$11.1 million and \$50.2 million for the fourth quarter and fiscal year 2023, respectively, as compared to \$12.6 million and \$59.5 million for the same periods in 2022
- Total costs and operating expenses include restructuring expense of \$6.7 million for the fourth quarter and fiscal year 2023 related to the reduction in force Atara announced in November 2023 and which reduced its headcount at that time by approximately 30%. This reduction in force was substantially completed in December 2023
- Atara announced an additional reduction in force in January 2024 that further reduced its headcount by approximately 25% to approximately 170 employees
- Research and development expenses were \$49.6 million and \$224.8 million for the fourth quarter and fiscal year 2023, respectively, as compared to \$62.5 million and \$272.5 million for the same periods in 2022
  - Research and development expenses include \$5.8 million and \$26.5 million of non-cash stock-based compensation expenses for the fourth quarter and fiscal year 2023, respectively, as compared to \$7.0 million and \$31.4 million for the same periods in 2022
- General and administrative expenses were \$11.5 million and \$50.9 million for the fourth quarter and fiscal year 2023, respectively, as compared to \$13.2 million and \$71.6 million for the same periods in 2022
  - General and administrative expenses include \$4.1 million and \$18.9 million of non-cash stock-based compensation expenses for the fourth quarter and fiscal year 2023, respectively, as compared to \$4.4 million and \$22.5 million for the same periods in 2022

#### 2024 Outlook and Cash Runway

 The cash, cash equivalents and short-term investments of \$51.7 million as of December 31, 2023 does not include the approximately \$27 million received in January 2024 from Pierre Fabre Laboratories from the closing of the expanded global partnership, the approximately \$15 million in proceeds from the issuance of pre-funded warrants received in the Company's January 2024 registered direct offering, or the approximately \$10 million in proceeds from the Company's at-the-market facility (ATM) received in Q1 2024. The cash, cash equivalents and short-term investments as of December 31, 2023, together with these amounts results in a pro-forma December 31, 2023 cash balance of approximately \$104 million

- In addition, Atara expects to achieve \$40 million of the \$100 million in total potential regulatory milestones by BLA acceptance
  - Atara expects to receive \$20 million of these regulatory milestones in April based on the recent positive pre-BLA meeting, another \$20 million in connection with BLA acceptance, and the remaining \$60 million in potential regulatory milestones in connection with BLA approval
- Atara expects full year 2024 operating expenses to decrease by approximately 35% year-over-year, with the large majority of the reduction beginning in Q2 2024 and continuing for the remainder of the year
- Atara expects that cash, cash equivalents and short-term investments as of December 31, 2023, plus the proceeds received in Q1 2024 as outlined above from:
  - Closing of the expanded global partnership with Pierre Fabre Laboratories;
  - Issuance of pre-funded warrants; and
  - The Company's ATM program;
  - When combined with certain anticipated payments from Pierre Fabre contingent upon the successful filing and approval of the tab-cel BLA, and operating efficiencies resulting from completed workforce reductions, and the planned transition of substantially all activities relating to tab-cel at the time of the BLA transfer to Pierre Fabre, in total will enable funding of planned operations into 2027

#### **About ATA3219**

ATA3219 combines the natural biology of unedited T cells with the benefits of an allogeneic therapy. It consists of allogeneic Epstein-Barr virus (EBV)-sensitized T cells that express a CD19 CAR construct for the treatment of CD19+ relapsed or refractory B-cell malignancies, including B-cell non-Hodgkin's lymphoma and B-cell mediated autoimmune diseases including systemic lupus erythematosus (SLE) with kidney involvement (lupus nephritis [LN]). ATA3219 has been optimized to offer a potential best-in-class profile, featuring off-the-shelf availability. It incorporates multiple clinically validated technologies including a modified CD3 $\zeta$  signaling domain (1XX) that optimizes expansion and mitigates exhaustion, enrichment during manufacturing for a less differentiated phenotype for robust expansion and persistence and retains the endogenous T-cell receptor without gene editing as a key survival signal for T cells contributing to persistence.

#### **About ATA3431**

ATA3431 is an allogeneic, bispecific CAR directed against CD20 and CD19, built on Atara's EBV T-cell platform. The design consists of a tandem CD20-CD19 design, with binders oriented to optimize potency. Dual targets address the limitations of single antigen loss and tumor variability. ATA3431 features a novel 1XX costimulatory domain, memory phenotype, and retained, unedited T-cell receptor. Preclinical data have demonstrated early evidence of antitumor activity, long-term persistence, and superior tumor growth inhibition compared to an autologous CD19/CD20 CAR T benchmark.

#### **Next-Generation Allogeneic CAR T Approach**

Atara is focused on applying Epstein-Barr virus (EBV) T-cell biology, featuring experience in over 600 patients treated with allogeneic EBV T cells, and novel chimeric antigen receptor (CAR) technologies to meet the current limitations of autologous and allogeneic CAR therapies head-on by advancing a potential best-in-class CAR T pipeline in oncology and autoimmune disease. Unlike gene-edited approaches aimed at inactivating T-cell receptor (TCR) function to reduce the risk for graft-vs-host disease, Atara's allogeneic platform maintains expression of the native EBV TCR that promote in vivo functional persistence while also demonstrating inherently low alloreactivity due to their recognition of defined viral antigens and partial human leukocyte antigen (HLA) matching. A molecular toolkit of clinically-validated technologies—including the 1XX costimulatory domain designed for better cell fitness and less exhaustion while maintaining stemness—offers a differentiated approach to addressing significant unmet need with the next generation CAR T.

#### About Atara Biotherapeutics, Inc.

Atara is harnessing the natural power of the immune system to develop off-the-shelf cell therapies for difficult-to-treat cancers and autoimmune conditions that can be rapidly delivered to patients from inventory. With cutting-edge science and differentiated approach, Atara is the first company in the world to receive regulatory approval of an allogeneic T-cell immunotherapy. Our advanced and versatile T-cell platform does not require T-cell receptor or HLA gene editing and forms the basis of a diverse portfolio of investigational therapies that target EBV, the root cause of certain diseases, in addition to next-generation AlloCAR-Ts designed for best-in-class opportunities across a broad range of hematological malignancies and B-cell driven autoimmune diseases. Atara is headquartered in Southern California. For more information, visit <u>atarabio.com</u> and follow <u>@Atarabio</u> on <u>X</u> and <u>LinkedIn</u>.

#### **Forward-Looking Statements**

This press release contains or may imply "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. For example, forward-looking statements include statements regarding: (1) the development, timing and progress of tab-cel<sup>®</sup>, including a potential BLA, the potential characteristics and benefits of tab-cel<sup>®</sup>, and the progress and results of, and prospects for, the expanded global partnership with Pierre Fabre Laboratories involving tab-cel<sup>®</sup>, and the potential financial benefits to Atara as a result of the expanded global partnership with Pierre Fabre Laboratories, including any payments thereunder; (2) the development, timing and progress of Atara's AlloCAR-T programs (including ATA3219 and ATA3431), including the timing of the start of any clinical trials, and the safety and efficacy of product candidates emerging from such programs; (3) Atara's cash runway, receipt of potential milestone payments, and operating expenses, including Atara's ability to fund its planned operations into 2027; and (4) Atara's planned transition of substantially all activities relating to tab-cel at the time of the BLA transfer to Pierre Fabre and the timing thereof. Because such statements deal with future events and are based on Atara's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including, without limitation, risks and uncertainties associated with the costly and timeconsuming pharmaceutical product development process and the uncertainty of clinical success; the COVID-19 pandemic and the wars in Ukraine and the Middle East, which may significantly impact (i) our business, research, clinical development plans and operations, including our operations in Southern California and Denver and at our clinical trial sites, as well as the business or operations of our third-party manufacturer, contract research organizations or other third parties with whom we conduct business, (ii) our ability to access capital, and (iii) the value of our common stock; the sufficiency of Atara's cash resources and need for additional capital; and other risks and uncertainties affecting Atara's and its development programs, including those discussed in Atara's filings with the Securities and Exchange Commission, including in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's most recently filed periodic reports on Form 10-K and Form 10-Q and subsequent filings and in the documents incorporated by reference therein. Except as otherwise required by law, Atara disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events or circumstances or otherwise.

#### **Financials**

## ATARA BIOTHERAPEUTICS, INC. Consolidated Balance Sheets (Unaudited) (In thousands)

				December 31, 2022
Assets				
Current assets:				
Cash and cash equivalents	\$	25,841	\$	92,942
Short-term investments		25,884		149,877
Restricted cash		146		146
Accounts receivable		34,108		40,221
Inventories		9,706		1,586
Other current assets		6,184		10,308
Total current assets		101,869		295,080
Property and equipment, net		3,856		6,300
Operating lease assets		54,935		68,022
Other assets		4,844		7,018
Total assets	\$	165,504	\$	376,420
Liabilities and stockholders' equity (deficit)				
Current liabilities:				
Accounts payable	\$	3,684	\$	6,871
Accrued compensation		11,519		17,659
Accrued research and development expenses		17,364		24,992
Deferred revenue		77,833		8,000
Other current liabilities		31,826		21,394
Total current liabilities		142,226		78,916
Deferred revenue - long-term		37,562		77,000
Operating lease liabilities - long-term		45,693		58,064
Liability related to the sale of future revenues - long-term		34,623		30,236
Other long-term liabilities		4,631		5,564
Total liabilities	\$	264,735	\$	249,780
Stockholders' (deficit) equity:				
Common stock		11		10
Additional paid-in capital		1,870,112		1,821,721
Accumulated other comprehensive loss		(204)		(2,067)
Accumulated deficit		(1,969,150 <sub>)</sub>		(1,693,024 <sub>)</sub>
Total stockholders' (deficit) equity		(99,231 <sub>)</sub>		126,640
Total liabilities and stockholders' (deficit) equity	<u>\$</u>	165,504	\$	376,420

#### ATARA BIOTHERAPEUTICS, INC.

#### Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(In thousands, except per share amounts)

	Three Months Ended December 31,			Twelve Months Ended December 31,			
		2023		2022	 2023		2022
Commercialization revenue	\$	4,189	\$	_	\$ 7,886	\$	_
License and collaboration revenue		63		221	687		63,573
Total revenue		4,252		221	8,573		63,573
Costs and operating expenses:							
Cost of commercialization revenue		3,160		_	8,886		_
Research and development expenses		49,600		62,515	224,785		272,533
General and administrative expenses		11,454		13,245	50,908		71,553
Total costs and operating expenses		64,214		75,760	284,579		344,086
Loss from operations		(59,962)	_	(75,539)	(276,006)		(280,513)
Gain on sale of ATOM Facility		` <u> </u>		<u> </u>			50,237
Interest and other income, net		(477 <sub>)</sub>		969	(105 <sub>)</sub>		1,986
Total other income (expense), net	-	(477)		969	(105)		52,223
Loss before provision for income taxes		(60,439)		(74,570)	(276,111)		(228,290)
Provision for income taxes		11		2	15		12
Net loss	\$	(60,450)	\$	(74,572)	\$ (276,126)	\$	(228,302)
Other comprehensive gain (loss):							
Unrealized gain (loss) on available-for-sale securities		367		892	1,863		(1,699 <sub>)</sub>
Comprehensive loss	\$	(60,083)	\$	(73,680)	\$ (274,263)	\$	(230,001)
Basic and diluted net loss per common share	\$	(0.56)	\$	(0.72)	\$ (2.61)	\$	(2.24)
Basic and diluted weighted-average shares outstanding		108,135		103,178	105,912		101,990

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