

Adaptimmune Reports Fourth-Quarter and Full Year Financial Results and Business Update

BLA submission initiated for afami-cel, with aim to complete in mid-2023; afami-cel has the potential to be the first marketed engineered TCR T-cell therapy for a solid tumor

52% (13/25) response rate in ovarian, bladder and head & neck cancers in the Phase 1 SURPASS trial with next-generation MAGE-A4 product; 75% (9/12) response rate amongst patients with these tumor types who received \leq 3 prior lines of therapy

Adaptimmune will advance its wholly owned optimized PRAME TCR to be IND-ready in 2023

Strategic combination to create a preeminent cell therapy company for solid tumors announced earlier today

Webcast to be held today, March 6, 2023, at 8:00 a.m. EST (1:00 p.m. GMT)

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - March 6, 2023) - Adaptimmune Therapeutics plc (NASDAQ: ADAP), a leader in cell therapy to treat cancer, today reported financial results for the fourth quarter and full year ended December 31, 2022 and provided a business update.

Adrian Rawcliffe, Adaptimmune's Chief Executive Officer: "The last twelve months have seen immense progress in autologous cell therapies for people with cancer. CAR-T therapies have established autologous T-cell therapy as viable businesses within the broader cell and gene therapy market, which has annual sales exceeding three billion dollars. Our progress with T-cell therapies in solid tumors is truly exciting, as solid tumors account for nearly 90% of all adult cancers. I think 2023 will be a breakout year for T-cell therapies to address the broader cancer market, with Adaptimmune at the forefront."

Adaptimmune's first potential commercial product, afami-cel, for the treatment of synovial sarcoma

Adaptimmune initiated its BLA submission to the U.S. Food and Drug Administration (FDA) in the fourth-quarter 2022 and is on track to complete the BLA in mid-2023. This BLA is supported by data from Cohort 1 of the pivotal trial SPEARHEAD-1, which met its primary endpoint for efficacy. The Company has Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA for afami-cel for the treatment of synovial sarcoma.

As reported in November 2022, data presented at the Connective Tissue Oncology Society (CTOS) annual meeting indicate continued clinical responses with an acceptable safety profile in heavily pre-treated patients with late-stage synovial sarcoma after a single dose of

afami-cel.

- Overall response rate was 39% in heavily pre-treated patients with synovial sarcoma, with a median duration of response of ~12 months
- Afami-cel shown to drive tumor infiltration of activated and proliferative cytotoxic ("killer") T-cells into tumors which likely contributes to antitumor responses.
- Benefit:risk profile of afami-cel has been favorable, to date

Potential of next-gen MAGE-A4 TCR T-cell therapy (ADP-A2M4CD8) in multiple solid tumors

- The following results were reported from 43 evaluable patients the Phase 1 SURPASS trial at the beginning of the year in heavily pre-treated patients with late-stage cancers after a single dose of ADP-A2M4CD8
 - 37% overall response rate across multiple solid tumors
 - 52% response rate in the focus indications of ovarian, bladder and head & neck cancers
 - 75% response rate in these focus indications amongst patients who received ≤ 3 prior lines of therapy
- The Company is initiating a Phase 2 trial, SURPASS-3, in 1H 2023 for people with ovarian cancer.
 - SURPASS-3 will be conducted in patients with platinum resistant ovarian cancer who have received ≤ 4 prior lines of therapy; ADP-A2M4CD8 will be investigated as monotherapy and also combined with the checkpoint inhibitor nivolumab.
 - SURPASS-3, which could become registrational, is supported by RMAT designation from the FDA and is being developed in collaboration with The GOG Foundation, Inc.
- Adaptimmune is initiating two new cohorts in the Phase 1 SURPASS trial, combining ADP-A2M4CD8 with the checkpoint inhibitor pembrolizumab in 1) the second line treatment setting for bladder cancer and 2) in the first line treatment setting for head & neck cancer.
- As announced last year, the Company has closed the SURPASS-2 trial in gastroesophageal cancers to further enrollment

Preclinical pipeline update

- Last year, the Company announced that it will gain full control of the late-stage preclinical optimized PRAME TCR as well as the NY-ESO cell therapy program; discussions with GSK to finalize termination and transfer terms remain ongoing
- The Company aims for the PRAME program to be IND-ready in 2023

- Adaptimmune will continue to focus on its MAGE-A4 franchise while determining the optimal development path for complementary PRAME and NY-ESO programs
- Partnered programs with Genentech continue with the allogeneic pipeline and the Company is also advancing its own wholly owned allogeneic programs
- Last year, the Company took the decision to change the cell line being used to develop its MAGE-A4 allogeneic cell therapy. This change was due to the presence of a chromosomal abnormality in the original cell line and will delay the timing of the first allogeneic IND submission to 2025. This original cell line is not used in any of the Company's partnered programs.

Corporate and other news

- Adaptimmune announced a strategic combination with TCR² Therapeutics Inc. earlier today (please refer to separate press release dated March 6, 2023). As a result, and following the closing of the transaction, it is anticipated that the combined company's cash runway will extend into early 2026.
- Adaptimmune and Universal Cells have agreed to terminate the Collaboration and License Agreement dated January 13, 2020 under which the parties agreed to codevelop certain allogeneic cell therapies. Termination is effective as of March 6, 2023. Termination does not impact the development of our allogeneic cell lines for our internal allogeneic programs or for our collaboration with Genentech Inc.
- Completed the majority of the expenditure on two capital projects to prepare manufacturing network for the next phase of growth.
 - Additional cleanroom space in the manufacturing facility at the Navy Yard in Philadelphia, PA for future commercial launch of afami-cel
 - Construction of a dedicated allogeneic manufacturing facility in the United Kingdom (co-located with its UK research headquarters) to supply future allogeneic products.
- Completed restructuring with a reduction in headcount of approximately 25%.
- In connection with the Company's restructuring, Cintia Piccina separated from the Company as its Chief Commercial Officer effective March 5, 2023. Ms. Piccina remains engaged with Adaptimmune on a consultancy basis.

Financial Results for the fourth quarter and year ended December 31, 2022

- Cash / liquidity position: As of December 31, 2022, Adaptimmune had cash and cash equivalents of \$108.0 million and Total Liquidity of \$204.6 million, compared to \$149.9 million and \$369.6 million, respectively, as of December 31, 2021.
- **Revenue**: Revenue for the fourth quarter and year ended December 31, 2022 was \$11.0 million and \$27.1 million, respectively, compared to \$1.4 million and \$6.1 million for the same periods in 2021. Revenue has increased primarily due to an increase in development activities under our collaboration arrangements, in particular due to

development activities under the Genentech Strategic Collaboration and License Agreement, which become effective in October 2021. Revenue also increased due to a \$6 million payment receivable from GSK as a result of the termination and amendment to the GSK Collaboration and License Agreement.

- Research and development (R&D) expenses: R&D expenses for the fourth quarter
 and year ended December 31, 2022 were \$23.1 million and \$127.7 million,
 respectively, compared to \$29.5 million and \$111.1 million for the same periods in
 2021. R&D expenses increased due to an increase in the average number of
 employees engaged in research and development, increases in subcontracted
 expenditures and a decrease in offsetting reimbursements receivable for research and
 development tax and expenditure credits.
- General and administrative (G&A) expenses: G&A expenses for the fourth quarter and year ended December 31, 2022 were \$15.2 million and \$63.4 million, respectively, compared to \$14.8 million and \$57.3 million for the same periods in 2021 due to increases in employee-related costs and other corporate costs and restructuring charges.
- **Net loss:** Net loss attributable to holders of the Company's ordinary shares for the fourth quarter and year ended December 31, 2022 was \$29.3 million and \$165.5 million, respectively (\$(0.03) and \$(0.17) per ordinary share), compared to \$38.9 million and \$158.1 million, respectively (\$(0.04) and \$(0.17) per ordinary share), for the same periods in 2021.

Financial Guidance

The Company believes that its existing cash, cash equivalents and marketable securities, together with the additional payments under the Strategic Collaboration and License Agreement with Genentech and reductions in the Company's operating costs as a result of the restructuring of the Company that is expected to be completed in the first quarter of 2023, will fund the Company's current operations into early 2025, as further detailed in the Company's Quarterly Report on Form 10-K for the fourth quarter and year ended December 31, 2022, to be filed with the Securities and Exchange Commission following this earnings release.

On March 6, 2023 the Company announced entry into a merger agreement under which the Company will combine with TCR² Therapeutics Inc in an all-stock transaction. Following the closing of the transaction, we currently estimate that the cash runway of the combined company will extend into early 2026.

Webcast Information

The Company will host a live webcast to provide additional details at 8:00 a.m. EDT (1:00 p.m. GMT) today, March 6, 2023. A live webcast of the conference call and replay can be accessed at https://api.newsfilecorp.com/redirect/e4WKKsxwna. Call in information is as follows: (800)-319-4610 (US or Canada) or +1 (416)-915-3239 (International and additional options available HERE). Callers should dial in 5-10 minutes prior to the scheduled start time and simply ask to join the Adaptimmune call.

About Adaptimmune

Adaptimmune is a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapy products for people with cancer. The Company's unique SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform enables the engineering of T-cells to target and destroy cancer across multiple solid tumors.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). These forward-looking statements involve certain risks and uncertainties. Such risks and uncertainties could cause our actual results to differ materially from those indicated by such forward-looking statements, and include, without limitation: the success, cost and timing of our product development activities and clinical trials and our ability to successfully advance our TCR therapeutic candidates through the regulatory and commercialization processes. For a further description of the risks and uncertainties that could cause our actual results to differ materially from those expressed in these forward-looking statements, as well as risks relating to our business in general, we refer you to our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2021 filed on March 14, 2022, Current Reports on Form 8-K, and our other filings with the Securities and Exchange Commission. The forward-looking statements contained in this press release speak only as of the date the statements were made and we do not undertake any obligation to update such forward-looking statements to reflect subsequent events or circumstances.

Total Liquidity (a non-GAAP financial measure)

Total Liquidity (a non-GAAP financial measure) is the total of cash and cash equivalents and marketable securities (available-for-sale debt securities). Each of these components appears separately in the condensed consolidated balance sheet. The U.S. GAAP financial measure most directly comparable to Total Liquidity is cash and cash equivalents as reported in the condensed consolidated financial statements, which reconciles to Total Liquidity as follows (in millions):

	December 31,		December 31,		
		2022		2021	
Cash and cash equivalents	\$	108,033	\$	149,948	
Marketable securities - available-for-sale debt securities		96,572		219,632	
Total Liquidity	\$	204,605	\$	369,580	

The Company believes that the presentation of Total Liquidity provides useful information to investors because management reviews Total Liquidity as part of its assessment of overall solvency and liquidity, financial flexibility, capital position and leverage.

Condensed Consolidated Statement of Operations

(unaudited, in thousands, except per share data)

Three months ended	Year ended
December 31,	December 31,

	 2022		2021	2022		2021	
Development revenue	11,028		1,417		27,148		6,149
Revenue	\$ 11,028	\$	1,417	\$	27,148	\$	6,149
Operating expenses							
Research and development	(23,052)		(29,505)		(127,726)		(111,090)
General and administrative	(15,218)		(14,776)		(63,387)		(57,305)
Total operating expenses	 (38,270)		(44,281)		(191,113)		(168,395)
Operating loss	 (27,242)		(42,864)		(163,965)		(162,246)
Interest income	523		179		1,542		1,095
Other (expense) income, net	(1,537)		4,036		(536)		3,852
Loss before income tax expense	(28,256)		(38,649)		(162,959)		(157,299)
Income tax expense	(994)		(210)		(2,497)		(791)
Net loss attributable to ordinary shareholders	\$ (29,250)	<u>\$</u> _	(38,859	\$	(165,456)	<u>\$</u> _	(158,090)
Net loss per ordinary share							
Basic and diluted	\$ (0.03)	\$	(0.04)	\$	(0.17)	\$	(0.17)
Weighted average shares outstanding:							
Basic and diluted	984,715,238		937,328,712		967,242,403		934,833,017

Condensed Consolidated Balance Sheets

(unaudited, in thousands, except share data)

	December 31, 2022		December 31, 2021	
Assets				
Current assets				
Cash and cash equivalents	\$	108,033	\$	149,948
Marketable securities - available-for-sale debt securities		96,572		219,632
Accounts receivable, net of allowance for doubtful accounts of \$0 and \$0		7,435		752
Other current assets and prepaid expenses		43,330		45,126
Total current assets		255,370		415,458
Restricted cash		1,569		1,718
Operating lease right-of-use assets, net of accumulated amortization of \$9,470 and \$7,253		18,019		20,875
Property, plant and equipment, net of accumulated depreciation of \$38,588 and \$36,253		53,516		30,494
Intangible assets, net of accumulated amortization of \$4,676 and \$4,051		442		1,000
Total assets	\$	328,916	\$	469,545
Liabilities and stockholders' equity				
Current liabilities				
Accounts payable	\$	4,753	\$	8,113
Operating lease liabilities, current		2,728		2,320
Accrued expenses and other current liabilities		31,215		29,909
Restructuring provision		2,285		-
Deferred revenue, current		23,520		22,199
Total current liabilities		64,501		62,541
Operating lease liabilities, non-current		20,349		23,148
Deferred revenue, non-current		160,892		177,223
Other liabilities, non-current		1,296		673

Total liabilities	247,038	263,585
Stockholders' equity		
Common stock - Ordinary shares par value £0.001, 1,282,773,750 authorized and 987,109,890 issued and outstanding (2021: 1,240,853,520 authorized and 937,547,934		
issued and outstanding)	1,399	1,337
Additional paid in capital	990,656	959,611
Accumulated other comprehensive loss	(875)	(11,142)
Accumulated deficit	(909,302)	(743,846)
Total stockholders' equity	81,878	205,960
Total liabilities and stockholders' equity	\$ 328,916 \$	469,545

Condensed Consolidated Cash Flow Statement

(unaudited, in thousands)

	Year ended December 31, 2022		Year ended December 31, 2021	
Cash flows from operating activities				
Net loss	\$	(165,456)	\$	(158,090)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation		5,266		5,630
Amortization		809		937
Share-based compensation expense		18,240		20,629
Unrealized foreign exchange (gains)/losses		(2,438)		540
Amortization on available-for-sale debt securities		2,525		5,276
Other		816		1,173
Changes in operating assets and liabilities:				
(Increase)/decrease in receivables and other operating assets		(9,813)		(19,358)
Increase in payables and other current liabilities		4,408		4,207
Increase in deferred revenue		3,874		149,785
Net cash (used in)/provided by operating activities		(141,769)		10,729
Cash flows from investing activities				
Acquisition of property, plant and equipment		(29,496)		(8,574)
Acquisition of intangible assets		(244)		(207)
Maturity or redemption of marketable securities		166,994		224,343
Investment in marketable securities		(48,117)		(139,762)
Net cash provided by/(used in) investing activities		89,137		75,800
Cash flows from financing activities				
Proceeds from issuance of common stock from offerings, net of commissions and issuance costs		12,817		2,529
Proceeds from exercise of stock options		12,617 50		759
Net cash provided by financing activities		12,867		3,288
Effect of currency exchange rate changes on cash, cash equivalents and restricted				
cash		(2,299)		365
Net (decrease)/increase in cash, cash equivalents and restricted cash		(42,064)		90,182
Cash, cash equivalents and restricted cash at start of period		151,666		61,484
Cash, cash equivalents and restricted cash at end of period	\$	109,602	\$	151,666

Supplemental cash flow information

Interest received	\$ 5,149 \$	7,765
Amortization on available-for-sale debt securities	(2,525)	(5,276)
Income taxes paid	630	535

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¹ Total liquidity is a non-GAAP financial measure, which is explained and reconciled to the most directly comparable financial measures prepared in accordance with GAAP below



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