November 8, 2023

Adaptimmune Reports Third Quarter Financial Results and Business Update

Afami-cel: overall survival for people with synovial sarcoma who received afami-cel is superior to historic controls (CTOS 2023); BLA submission on track to complete in Q4 this year

SURPASS Phase 1 trial: 75% response rate in ovarian, urothelial, and head & neck cancers in patients with ≤ 3 prior lines of therapy (ESMO 2023)

SURPASS trial plans: Phase 1 trial focused on head & neck and bladder cancers in earlier line treatment settings; Phase 2 SURPASS-3 trial initiated for platinum resistant ovarian cancer

Lete-cel: 40% (18/45) of people with synovial sarcoma or MRCLS had clinical responses with lete-cel, by independent review[1]; primary efficacy endpoint requires 16/60 patients have responses (CTOS 2023)

Pipeline update: Gavo-cel and TC-510 programs terminated based on review of data

Financial: Cash runway confirmed into early 2026

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

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - November 8, 2023) - Adaptimmune Therapeutics plc (NASDAQ: ADAP), a leader in cell therapy to treat cancer, today reported financial results for the third quarter ended September 30, 2023 and provided a business update.

Adrian Rawcliffe, Adaptimmune's Chief Executive Officer: "Adaptimmune has been transformed in 2023. Our hat trick of data at ESMO and CTOS sets us up for commercial transition. We will submit the afami-cel BLA and recover lete-cel this quarter and update on our sarcoma plans in the new year."

Afami-cel - on track to be Adaptimmune's first commercial product for the treatment of synovial sarcoma

BLA update

Adaptimmune's rolling BLA submission for afami-cel is on track for completion in Q4 2023. Adaptimmune has completed submission of the preclinical module (Q4 2022) and the clinical module (Q1 2023).

Adaptimmune and FDA discussed and agreed on the planned content of the BLA, including the CMC dossier, last year. All validation activities required for the CMC dossier have been completed and the last section of the BLA rolling submission is currently being finalized.

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.

Cohort 2 of the SPEARHEAD-1 trial has completed recruitment and has an overall response rate nearly identical to Cohort 1 (data will be reported when follow-up is mature). The Company has agreed a plan with the FDA that data from Cohort 2 will serve as confirmatory evidence for full approval. Cohort 3 is ongoing to provide patient access to afami-cel in the interim.

Data presentation at CTOS (link to presentation HERE, press release HERE)

Adaptimmune reported better outcomes for people with synovial sarcoma who received afami-cel compared to historical control from the pivotal SPEARHEAD-1 trial (NCT04044768) for people with synovial sarcoma

- People with synovial sarcoma in the pivotal SPEARHEAD-1 trial had advanced metastatic disease and were heavily pre-treated having received a median of 3 prior lines of systemic therapy (range: 1-12)
- ~39% of patients who received afami-cel in the pivotal SPEARHEAD-1 trial had clinical responses with a median duration of response of ~12 months (CTOS 2022)
- Median overall survival (mOS) was ~17 months in SPEARHEAD-1 compared to historical mOS of <12 months for people with synovial sarcoma who received two or more prior lines of therapy[2]
- 70% of people with advanced synovial sarcoma who respond to afami-cel are alive two years post-treatment
- The length of time to next treatment, or treatment-free intervals, has a strong correlation with overall survival in metastatic sarcoma and the historical median time to next treatment is approximately 6, 3, or 2 months after two, three, or four lines of prior systemic therapy, respectively.[3]
- In the SPEARHEAD-1 trial, outcomes compare favorably to historical control data after a single dose of afami-cel. Patients had encouraging treatment-free intervals and the median time to next treatment was ~7 months overall and ~17 months among patients with a RECISTv1.1 response.
- Toxicities include cytokine release syndrome and reversible hematologic toxicities, in line with previous findings indicating an acceptable safety profile.

ADP-A2M4CD8 - Adaptimmune's next-generation product with responses in multiple solid tumor indications

Initiated the Phase 2 SURPASS-3 trial (NCT05601752) as monotherapy and in combination with the checkpoint inhibitor nivolumab for platinum resistant ovarian cancer. This trial has the potential to become registrational. ADP-A2M4CD8 has been granted FDA RMAT designation for treatment of patients with platinum resistant ovarian cancer.

The Phase 1 SURPASS trial is now focused on bladder and head & neck cancers in earlier treatment settings as monotherapy and in combination with the checkpoint inhibitor pembrolizumab.

Data presentation at ESMO (link to presentation HERE)

Clinical data demonstrate efficacy signals supporting further development in ovarian, urothelial, and head & neck cancers. As of the data cut-off, there were 46 evaluable patients who received ADP-A2M4CD8 monotherapy, and 10 who received ADP-A2M4CD8 in combination with nivolumab Phase 1 SURPASS clinical trial (NCT04044859).

- 35% (16/46) response rate in the ADP-A2M4CD8 monotherapy cohort with ~5 months median duration of response in heavily pre-treated patients across a broad range of solid tumors
- 50% (13/26) response rate in patients with ovarian, urothelial, and head & neck cancers
- 75% (9/12) response rate in ovarian, urothelial, and head & neck cancers in patients who received three or fewer prior lines of therapy
- Acceptable benefit-to-risk profile with ADP-A2M4CD8 next-generation monotherapy and in combination with the checkpoint inhibitor nivolumab across multiple solid tumor indications

Additional clinical pipeline updates
Lete-cel for the treatment of synovial sarcoma and myxoid/round cell liposarcoma (MRCLS)

Lete-cel is an engineered T-cell therapy targeted against NY-ESO-1 that is being investigated for the treatment of synovial sarcoma or MRCLS in the pivotal IGNYTE-ESO (NCT03967223) trial in patients who received prior anthracycline treatment. Data were recently disclosed (linked HERE). Adaptimmune is evaluating the path forward for this product and will provide an update in Q1 2024.

- 18/45 (40%) (99.6% CI: 20.3%, 62.3%) people with synovial sarcoma or MRCLS had RECISTv1.1 responses by independent review with two complete responses and 16 partial responses. The pre-defined success criteria for this planned interim analysis required at least 14 responders out of 45 patients and the primary endpoint for efficacy will require 16 responders out of 60 patients by independent review.
- Duration of Response (DoR) is still being followed in 9/18 (50%) of responders. The median duration of response was 10.6 months (95% CI: 3.3, NE). The duration of response ranged from 1.18+ to 16.6+ months and 12 out of 18 patients were censored for this analysis.
- Overall, the safety profile of lete-cel was acceptable, including CRS and reversible hematologic toxicities
- Substudy 1 was designed to explore the feasibility, efficacy, and safety of lete-cel in the first line setting for treatment-naïve patients with metastatic or unresectable synovial sarcoma or MRCLS. Of the five evaluable patients in the substudy, one exhibited a complete response, with an additional three partial responses, yielding an overall response rate of 80% (4/5) by investigator assessment.

Gavo-cel Phase 2 trial and TC-510 Phase 1 trial terminated

Adaptimmune has performed a risk benefit analysis, considering safety and efficacy data, and the Company's overall pipeline. Adaptimmune does not see a path forward to further develop the gavo-cel or TC-510 programs.

- **Gavo-cel**: Phase 2 trial data had an ORR of 11% (2/18) overall; 10% (1/10) in ovarian cancer; and, 12.5% (1/8) in mesothelioma (data cut August 2023)
- **TC-510:** one partial response in mesothelioma out of 5 patients treated (3 mesothelioma, 1 ovarian, 1 pancreatic); high incidence of cytokine release syndrome (CRS) and Grade 3 pneumonitis

Preclinical pipeline

- Company advancing preclinical development of its engineered TCR targeting PRAME (ADP-600)
- Preclinical program targeting CD70 using the Company's TRuC® platform (ADP-520) also ongoing
- Partnered programs with Genentech continue with the allogeneic pipeline

Other corporate news

- Dr. Karen Chagin joined Adaptimmune as Senior Vice President of Early-Stage Development
- Effective November 1, 2023, Kristen M. Hege, M.D. joined the Adaptimmune Board of Directors and Elliott Sigal, M.D., Ph.D. stood down from the Board

Financial Results for the three and nine months ended September 30, 2023

- **Cash / liquidity position:** As of September 30, 2023, Adaptimmune had cash and cash equivalents of $90.1 million and Total Liquidity[4] of $161.7 million, compared to $108.0 million and $204.6 million, respectively, as of December 31, 2022.
- **Revenue**: Revenue for the three and nine months ended September 30, 2023, was $7.3 million and $60.1 million, respectively, compared to $7.0 million and $16.1 million for the same periods in 2022. Revenue has increased in the nine months to September 30, 2023, compared to the same period in 2022 primarily due to the termination of the Astellas collaboration, resulting in the remaining deferred income for the collaboration being recognized as revenue in March 2023.
- **Research and development (R&D) expenses:** R&D expenses for the three and nine months ended September 30, 2023, were $37.8 million and $93.3 million, respectively, compared to $33.2 million and $104.7 million for the same periods in 2022. R&D expenses in the three months ended September 30, 2023 increased due to a decrease in offsetting reimbursements receivable for research and development tax and expenditure credits. R&D expenses in the nine months ended September 30, 2023 decreased due to a decrease in the average number of employees engaged in research and development, decreases in subcontracted expenditures, a decrease in share-based compensation expenses and a decrease in in-process research and development costs, which was partially offset by 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 three and nine months ended September 30, 2023, were $16.2 million and $56.6 million, respectively, compared to $16.8 million and $48.2 million for the same periods in 2022. G&A expenses in the nine months ended September 30, 2023 increased due to restructuring and charges recognised in the first quarter of 2023, an increase in other corporate costs due to an increase in accounting, legal and professional fees incurred

in relation to the TCR^2 Therapeutics, Inc merger agreement and severance and other related costs for former TCR^2 Therapeutics leadership, offset by a decrease in share-based compensation expenses.
- **Gain on bargain purchase:** a $22.0 million gain on bargain purchase was recognised in the nine months ended September 30, 2023, from the strategic combination with TCR^2 Therapeutics, Inc, with a $0.1 million remeasurement reducing the gain recognized in the three months ended September 30, 2023.
- **Net loss:** Net loss attributable to holders of the Company's ordinary shares for the three and nine months ended September 30, 2023, was $45.6 million and $66.0 million, respectively ($(0.03) and $(0.06) per ordinary share), compared to $41.4 million and $136.2 million, respectively ($(0.04) and $(0.14) per ordinary share), for the same periods in 2022.

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 payments under the Termination and Transfer Agreement with GSK, will fund the Company's current operations into early 2026, as further detailed in the Company's Quarterly Report on Form 10-Q for the third quarter ended September 30, 2023, to be filed with the Securities and Exchange Commission following this earnings release.

Webcast Information

The Company will host a live webcast to provide additional details at 8:00 a.m. EST (1:00 p.m. GMT) today, November 8, 2023. A live webcast of the conference call and replay can be accessed at https://www.gowebcasting.com/12932. Call in information is as follows: 1-800-806-5484 (US or Canada) or +1 416-340-2217 (International and additional options available HERE). Participant passcode 5420265#.

About Adaptimmune

Adaptimmune is a clinical-stage biopharmaceutical company focused on designing, developing, and delivering cell therapies to transform the lives of people with cancer. The Company's unique engineered T-cell receptor (TCR) platform enables the engineering of T-cells to target and destroy cancers across multiple solid tumor types.

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, 2022, our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and 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 thousands):

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 90,059	$ 108,033
Marketable securities - available-for-sale debt securities	71,669	96,572
Total Liquidity	**$ 161,728**	**$ 204,605**

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 September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenue	**$ 7,319**	**$ 7,007**	**$ 60,050**	**$ 16,120**
Operating expenses				
Research and development	(37,788)	(33,182)	(93,301)	(104,674)
General and administrative	(16,164)	(16,815)	(56,634)	(48,169)
Total operating expenses	**(53,952)**	**(49,997)**	**(149,935)**	**(152,843)**
Operating loss	**(46,633)**	**(42,990)**	**(89,885)**	**(136,723)**
Interest income	2,149	324	4,368	1,019
Gain on bargain purchase	(106)	—	22,049	—
Other income (expense), net	(324)	1,644	(494)	1,001
Loss before income tax expense	**(44,914)**	**(41,022)**	**(63,962)**	**(134,703)**
Income tax expense	(687)	(399)	(1,992)	(1,503)
Net loss attributable to ordinary shareholders	**$ (45,601)**	**$ (41,421)**	**$ (65,954)**	**$ (136,206)**
Net loss per ordinary share				
Basic and diluted	**$ (0.03)**	**$ (0.04)**	**$ (0.06)**	**$ (0.14)**

Weighted average shares outstanding:				
Basic and diluted	1,357,849,656	980,791,114	1,153,791,567	961,354,122

Condensed Consolidated Balance Sheets
(unaudited, in thousands, except share data)

	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 90,059	$ 108,033
Marketable securities - available-for-sale debt securities	71,669	96,572
Accounts receivable, net of allowance for expected credit losses of $0 and $0	789	7,435
Other current assets and prepaid expenses	56,851	43,330
Total current assets	**219,368**	**255,370**
Restricted cash	3,013	1,569
Operating lease right-of-use assets, net of accumulated amortization of $11,930 and $9,470	21,302	18,019
Property, plant and equipment, net of accumulated depreciation of $42,543 and $38,588	52,571	53,516
Intangible assets, net of accumulated amortization of $5,008 and $4,676	384	442
Total assets	$ **296,638**	$ **328,916**
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 13,922	$ 4,753
Operating lease liabilities, current	5,081	2,728
Accrued expenses and other current liabilities	26,831	31,215
Restructuring provision	-	2,285
Deferred revenue, current	29,312	23,520
Total current liabilities	**75,146**	**64,501**
Operating lease liabilities, non-current	20,520	20,349
Deferred revenue, non-current	111,487	160,892
Other liabilities, non-current	1,356	1,296
Total liabilities	**208,509**	**247,038**
Stockholders' equity		
Common stock - Ordinary shares par value £0.001, 1,702,760,280 authorized and 1,361,595,036 issued and outstanding (2022: 1,282,773,750 authorized and 987,109,890 issued and outstanding)	1,863	1,399

Additional paid in capital	1,061,420	990,656
Accumulated other comprehensive gain/(loss)	102	(875)
Accumulated deficit	(975,256)	(909,302)
Total stockholders' equity	**88,129**	**81,878**
Total liabilities and stockholders' equity	**$ 296,638**	**$ 328,916**

Condensed Consolidated Cash Flow Statement
(unaudited, in thousands)

	Nine months ended September 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (65,954)	$ (136,206)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6,647	4,009
Amortization	322	629
Gain on bargain purchase	(22,049)	—
Share-based compensation expense	8,692	14,294
Unrealized foreign exchange losses/(gains)	709	(2,501)
(Accretion)/amortization on available-for-sale debt securities	(1,595)	2,165
Other	253	765
Changes in operating assets and liabilities:		
Increase in receivables and other operating assets	(709)	(29,778)
(Decrease)/increase in payables and other current liabilities	(7,792)	15,200
Decrease in deferred revenue	(44,728)	(12,388)
Net cash used in operating activities	**(126,204)**	**(143,811)**
Cash flows from investing activities		
Acquisition of property, plant and equipment	(3,854)	(26,081)
Acquisition of intangible assets	(199)	(231)
Cash from acquisition of TCR2 Therapeutics Inc.	45,264	—
Maturity or redemption of marketable securities	139,243	136,694
Investment in marketable securities	(73,026)	(42,197)
Other	913	—
Net cash provided by investing activities	**108,341**	**68,185**
Cash flows from financing activities		
Proceeds from issuance of common stock from offerings, net of commissions and issuance costs	623	11,422
Proceeds from exercise of stock options	183	42
Net cash provided by financing activities	**806**	**11,464**

Effect of currency exchange rate changes on cash, cash equivalents and restricted cash	527	(6,791)
Net decrease in cash, cash equivalents and restricted cash	(16,530)	(70,953)
Cash, cash equivalents and restricted cash at start of period	109,602	151,666
Cash, cash equivalents and restricted cash at end of period	**$ 93,072**	**$ 80,713**

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[1] Substudy 2 in patients who received prior anthracycline treatment; responses for primary efficacy endpoint by independent review

[2] Carroll C, et al. Future Oncology; NOTE: patients in SPEARHEAD-1 were heavily pre-treated having received a median of 3 prior lines of systemic therapy (range: 1-12) (CTOS 2023)

[3] Savina M, et al. BMC Med. 2017;15(78)

[4] 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

To view the source version of this press release, please visit https://www.newsfilecorp.com/release/186549

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