

Adaptimmune Reports Second-Quarter Financial Results and Business Update

- Reaffirming financial guidance; Company funded into early 2024 -
- ASCO data confirms afami-cel potential for synovial sarcoma; BLA submission on-track for Q4 2022 -
- Update from signal-finding Phase 1 SURPASS trial at the September ESMO 2022 Congress -
- Quarterly call to be held today, August 4, 2022, at 8:00 a.m. EDT (1:00 p.m. BST) -

Philadelphia, Pennsylvania, and Oxford, United Kingdom--(Newsfile Corp. - August 4, 2022) - Adaptimmune Therapeutics plc (NASDAQ: ADAP), a leader in cell therapy to treat cancer, today reported financial results for the second quarter ended June 30, 2022 and provided a business update. For the three months ended June 30, 2022, Revenue was \$5.5 million, Total Operating Expenses (Research and Development and General and Administrative) were \$49.3 million, and Net Loss was \$44.5 million.

"We continue to demonstrate progress with our focus areas for 2022: submitting our BLA for afami-cel, building a MAGE-A4 franchise, scaling up manufacturing capabilities, and advancing our allogeneic platform, pipeline and collaborations," said Adrian Rawcliffe, Adaptimmune's Chief Executive Officer. "The data presented at ASCO further confirm the potential of afami-cel for the initial indication of synovial sarcoma with the BLA submission on-track for Q4 this year. To support commercialization of afami-cel and other products both near- and longer-term, we are investing in focused but scalable operational infrastructure to set us up for success. At the same time, we are carefully monitoring market conditions. We will continue to prudently manage expenses and stop or delay non-core activities."

Adaptimmune's first potential commercial product, afami-cel, supported by positive data readouts

Biologics License Application (BLA) submission for afami-cel on track for Q4 2022

Adaptimmune is preparing its BLA and continues to target submission to the U.S. Food and Drug Administration (FDA) in the fourth-quarter 2022 for the treatment of synovial sarcoma. This BLA is supported by data from Cohort 1 of the pivotal trial SPEARHEAD-1, which met its primary endpoint for efficacy. In addition, the Company has the following progress updates:

- Miltenyi Biotec vector facility released for cGMP manufacture
- Vector and T-cell product characterization nearing completion
- Method validation for commercial T-cell lot release assays (including potency assays) in progress

- Vector process performance qualification (PPQ) initiated
- Pre-market approval (PMA) for the companion diagnostic is on-track to be submitted simultaneously with BLA

Afami-cel presentation at ASCO 2022 - responses reported across all patient subgroups

As <u>reported in June</u>, data based on pooled analyses of characteristics associated with clinical responses (per investigator assessment) from both Cohort 1 of the SPEARHEAD-1 trial, as well as the Phase 1 trial of afami-cel in patients with advanced synovial sarcoma or myxoid/round cell liposarcoma (MRCLS), were presented at the American Society for Clinical Oncology (ASCO)

- Overall response rate was 36% in heavily pre-treated patients across both types of sarcomas (41% in synovial sarcoma and 10% for MRCLS), with a median duration of response of 52 weeks
- Patients who responded to afami-cel had longer progression-free survival (median 58 weeks) compared to non-responders (median 12 weeks)
- Responses occurred across all clinical subgroups, with greater response rates associated with lower baseline tumor burden, fewer prior lines of therapy, and higher MAGE-A4 expression
- Benefit:risk profile of afami-cel has been favorable, to date

Potential of next-gen MAGE-A4 targeted cell therapy in multiple solid tumors

Phase 1 signal-finding SURPASS trial update at ESMO in September

- The purpose of the next-generation ADP-A2M4CD8 program is to improve the potency of Adaptimmune's first-generation product targeting MAGE-A4, afami-cel, to achieve meaningful clinical responses beyond sarcoma
- ADP-A2M4CD8 is being investigated in the SURPASS family of trials
- Last year, at the European Society for Medical Oncology (ESMO) 2021 Congress, <u>Adaptimmune reported</u> data from 22 evaluable patients with confirmed responses in ovarian, head and neck, esophagogastric junction, and bladder cancers from the Phase 1 signal-finding SURPASS trial, with this next-generation cell therapy
- Based on positive signals in gastroesophageal cancers in the Phase 1 SURPASS trial, Adaptimmune initiated a Phase 2 SURPASS-2 trial last year
- The Company plans to initiate an additional Phase 2 trial, SURPASS-3, this year for people with ovarian cancer, based on positive signals from the SURPASS Phase 1 trial
- On September 10, 2022 at 15:45 CET, Dr. David Hong from the MD Anderson Cancer Center, will present a data update from the Phase 1 signal-finding SURPASS trial at the ESMO 2022 Congress
- Data at ESMO will include 44 patients who received ADP-A2M4CD8 and 43 patients will be evaluable for efficacy (as of the data cut-off date of August 01, 2022)
- On September 9th, the Company will host a live virtual event from 8 a.m. to 9 a.m. EDT to discuss the ESMO data and its SURPASS family of trials

Corporate and other news

 Adaptimmune has implemented rigorous cost containment measures to enable delivery against its four key focus areas: submitting the BLA for afami-cel, building its

- MAGE-A4 franchise, scaling up manufacturing capabilities, and progressing the allogeneic platform
- To prioritize near- and mid-term value creation from its MAGE-A4 franchise, including the BLA submission for afami-cel and the SURPASS family of trials, Adaptimmune will delay submission of an IND for its new next-generation cell therapy ADP-A2M4N7X19, which it is developing in collaboration with Noile-Immune. Core preclinical activities will continue.
- Construction is underway to increase the Company's cGMP manufacturing space at its Navy Yard site in Philadelphia, PA to support current clinical trials and future commercial products
- A dedicated allogeneic manufacturing facility in the United Kingdom is nearing completion, which will support the IND planned for 2023 for Adaptimmune's wholly owned allogeneic cell therapy targeting MAGE-A4

Financial Results for the three and six months ended June 30, 2022

- Cash / liquidity position: As of June 30, 2022, Adaptimmune had cash and cash equivalents of \$97.8 million and Total Liquidity^[1] of \$258.1 million, compared to \$149.9 million and \$369.6 million, respectively, as of December 31, 2021.
- Revenue: Revenue for the three and six months ended June 30, 2022 was \$5.5 million and \$9.1 million, respectively, compared to \$3.1 million and \$3.5 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.
- Research and development (R&D) expenses: R&D expenses for the three and six months ended June 30, 2022 were \$34.7 million and \$71.5 million, respectively, compared to \$28.9 million and \$53.4 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 increases in in-process research and development costs. These were offset by an increase in reimbursements receivable for research and development tax and expenditure credits.
- **General and administrative (G&A) expenses:** G&A expenses for the three and six months ended June 30, 2022 were \$14.6 million and \$31.4 million, respectively, compared to \$13.5 million and \$27.4 million for the same periods in 2021 due to increases in employee-related costs and other corporate costs.
- **Net loss**: Net loss attributable to holders of the Company's ordinary shares for the three and six months ended June 30, 2022 was \$44.5 million and \$94.8 million, respectively (\$(0.05) and \$(0.10) per ordinary share), compared to \$39.1 million and \$76.8 million, respectively (\$(0.04) and \$(0.08) 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, will fund the Company's current operations into early 2024, as further detailed in the Company's Quarterly Report on Form 10-Q for the three and six months ended June 30, 2022, to be filed with the Securities and Exchange Commission

following this earnings release.

Conference Call Information

The Company will host a live teleconference and webcast to provide additional details at 8:00 a.m. EDT (1:00 p.m. BST) today, August 4, 2022. A live webcast of the conference call and replay can be accessed at https://www.gowebcasting.com/12004. Call in information is as follows: (800)-952-5114 (US or Canada) or +1 (416)-406-0743 (International and additional options available HERE). After placing the call, please ask to be joined into the Adaptimmune conference call and provide the confirmation code (5869059).

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, 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 millions):

	Jı	une 30,	December 31,		
	2022			2021	
Cash and cash equivalents	\$	97,811	\$	149,948	
Marketable securities - available-for-sale debt securities		160,278		219,632	
Total Liquidity	\$	258,089	\$	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			Six months ended				
	_	June 30,			June 3		∍ 30,	
		2022		2021		2022		2021
Revenue	\$	5,538	\$	3,095	\$	9,113	\$	3,529
Operating expenses								
Research and development		(34,740)		(28,868)		(71,492)		(53,374)
General and administrative		(14,550)		(13,539)		(31,354)		(27,356)
Total operating expenses		(49,290)		(42,407)		(102,846)		(80,730)
Operating loss		(43,752)		(39,312)		(93,733)		(77,201)
Interest income		357		266		695		691
Other income (expense), net		(655)		54		(643)		53
Loss before income tax expense		(44,050)		(38,992)		(93,681)		(76,457)
Income tax expense		(470)		(76)		(1,104)		(374)
Net loss attributable to ordinary shareholders	\$	(44,520)	\$	(39,068)	\$	(94,785)	\$	(76,831)
Net loss per ordinary share								
Basic and diluted	\$	(0.05)	\$	(0.04)	\$	(0.10)	\$	(80.0)
Weighted average shares outstanding:								
Basic and diluted	9	62,794,072	9	34,228,095	Ś	951,474,546	ξ	32,667,125

Condensed Consolidated Balance Sheets

(unaudited, in thousands, except share data)

	June 30, 2022		December 31, 2021	
Assets		_		·
Current assets				
Cash and cash equivalents	\$	97,811	\$	149,948
Marketable securities - available-for-sale debt securities		160,278		219,632
Accounts receivable, net of allowance for doubtful accounts of \$0 and \$0		2,382		752
Other current assets and prepaid expenses	_	60,694	_	45,126
Total current assets		321,165	_	415,458
Restricted cash		1,713		1,718
Operating lease right-of-use assets, net of accumulated amortization		19,380		20,875
Property, plant and equipment, net of accumulated depreciation of \$36,073 and \$36,253		45,400		30,494
Intangible assets, net of accumulated amortization of \$4,287 and \$4,051	_	612	_	1,000
Total assets	\$	388,270	\$	469,545

Liabilities and stockholders' equity			
Current liabilities			
Accounts payable	\$	15,991	\$ 8,113
Operating lease liabilities, current		2,557	2,320
Accrued expenses and other current liabilities		32,616	29,909
Deferred revenue, current		22,468	22,199
Total current liabilities		73,632	 62,541
Operating lease liabilities, non-current		21,635	23,148
Deferred revenue, non-current		150,437	177,223
Other liabilities, non-current		649	673
Total liabilities		246,353	 263,585
Stockholders' equity			
Common stock - Ordinary shares par value £0.001, 1,282,773,750 authorized and 976,759,524 issued and outstanding (2021: 1,240,853,520 authorized and 937,547,934 issued	ł		
and outstanding)		1,387	1,337
Additional paid in capital		980,204	959,611
Accumulated other comprehensive loss		(1,043)	(11,142)
Accumulated deficit		(838,631)	(743,846)
Total stockholders' equity		141,917	 205,960

388,270

469,545

Condensed Consolidated Cash Flow Statement

(unaudited, in thousands)

Total liabilities and stockholders' equity

	Six months ended June 30,			
		2022		2021
Cash flows from operating activities				_
Net loss	\$	(94,785)	\$	(76,831)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation		2,728		2,879
Amortization		419		-
Share-based compensation expense		10,631		10,783
Unrealized foreign exchange gains		(108)		(267)
Amortization on available-for-sale debt securities		1,636		2,884
Other		585		1,401
Changes in operating assets and liabilities:				
Increase in receivables and other operating assets		(22,898)		(21,457)
Increase in payables and other current liabilities		12,898		663
(Decrease)/ increase in deferred revenue		(6,758)		1,946
Net cash used in operating activities		(95,652)		(77,999)
Cash flows from investing activities				
Acquisition of property, plant and equipment		(16,074)		(2,924)
Acquisition of intangible assets		-		(143)
Maturity or redemption of marketable securities		97,605		154,465
Investment in marketable securities		(42,197)		(81,958)
Net cash provided by investing activities		39,334		69,440

Cash flows from financing activities

Proceeds from issuance of common stock from offerings, net of commissions and issuance costs	9,976	2,519
Proceeds from exercise of stock options	36	578
Net cash provided by financing activities	 10,012	 3,097
Effect of currency exchange rate changes on cash, cash equivalents and restricted		
cash	 (5,836)	(937)
Net decrease in cash, cash equivalents and restricted cash	 (52,142)	 (6,399)
Cash, cash equivalents and restricted cash at start of period	151,666	61,484
Cash, cash equivalents and restricted cash at end of period	\$ 99,524	\$ 55,085

Adaptimmune Contact

Investor and Media Relations

Juli P. Miller, Ph.D. - VP, Corporate Affairs and Investor Relations

T: +1 215 825 9310 M: +1 215 460 8920

Juli.Miller@adaptimmune.com

^[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



To view the source version of this press release, please visit https://www.newsfilecorp.com/release/132727

SOURCE Adaptimmune Therapeutics PLC