March 14, 2022

Adaptimmune Reports Fourth Quarter and Full Year 2021 Financial Results and Business Update

- SPEARHEAD-1 met its primary endpoint - planning for afami-cel BLA submission in Q4 2022 for people with synovial sarcoma -

- Moving to late-phase development with ADP-A2M4CD8: SURPASS-2 initiated in esophageal and EGJ cancers; initiating SURPASS-3 in ovarian cancer in 2022 -

- Allogeneic platform on-track for planned IND submission in 2023 for first product targeting MAGE-A4 -

- Started our strategic collaboration for allogeneic T-cell therapies with Genentech - $150 million upfront payment received -

- Scaling up autologous patient supply at Navy Yard facility and construction underway of a dedicated allogeneic cell manufacturing facility in the UK -

- Appointed Cintia Piccina as Chief Commercial Officer -

- Financial guidance confirmed: funded into early 2024 -

- Conference call to be held today at 8:30 a.m. EDT (12:30 p.m. GMT) -

PHILADELPHIA and OXFORDSHIRE, United Kingdom, March 14, 2022 (GLOBE NEWSWIRE) -- 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, 2021, and provided a business update.

“We are focused on four things in 2022: filing our first BLA, building our MAGE-A4 franchise, scaling up our manufacturing capabilities, and making progress with our allogeneic platform,” said Adrian Rawcliffe, Adaptimmune’s Chief Executive Officer. “Last year, we delivered major milestones of our ‘2-2-5-2’ strategic plan. SPEARHEAD-1 met its primary endpoint and we identified further indications for late-stage development with our next-gen SPEAR T-cells targeting MAGE-A4. Furthermore, not only did we enter a strategic collaboration with Genentech, but we also made tremendous progress with our wholly owned allogeneic therapy targeting MAGE-A4, which is on-track for an IND in 2023.”

Progress with the Company’s “2-2-5-2” strategic plan to be delivered by 2025
“2” marketed SPEAR T-cell products targeting MAGE-A4

Roadmap to BLA submission for afami-cel[1] in 2022 (first-generation product targeting MAGE-A4)

- Advanced/metastatic synovial sarcoma is a rare and clinically challenging disease, with no clear standard of care after progression following chemotherapy, with reported response rates with second line therapies of 18% or lower
- SPEARHEAD-1 has met its primary endpoint[2]
- As of the data cut-off of September 1, 2021 (CTOS), the overall response rate (ORR) per Independent Review was 34% (36% in patients with synovial sarcoma and 25% for patients with myxoid/ round cell liposarcoma [MRCLS])
- Afami-cel continues to show a favorable benefit:risk profile with more than 100 patients treated to date across multiple trials
- Cohort 1 of the SPEARHEAD-1 trial has completed, and treatment in Cohort 2 initiated in 2021
- Pediatric plans agreed with regulatory agencies
- Adaptimmune is commencing preparation of the BLA and targeting a BLA submission to the US Food and Drug Administration (FDA) in Q4 2022

Further indications for late-stage clinical development for SPEAR T-cells targeting MAGE-A4

- Initiated recruitment in the Phase 2 SURPASS-2 trial for people with esophageal and esophagogastric junction (EGJ) cancers
- Initiating the Phase 2 SURPASS-3 trial for people with ovarian cancer in 2022

"2" additional BLAs for SPEAR T-cell products targeting MAGE-A4
Phase 1 SURPASS trial with next-generation ADP-A2M4CD8 SPEAR T-cells targeting MAGE-A4

- Overall response rate of 36% with a complete response in ovarian cancer, and partial responses in ovarian, head and neck, EGJ, bladder, and synovial sarcoma cancers (ESMO 2021)
- Most patients experienced antitumor activity with a disease control rate of 86% (ESMO 2021)
- The benefit:risk profile of ADP-A2M4CD8 cell therapy remains favorable
- The SURPASS trial continues to enroll, focusing on people with gastroesophageal, head and neck, lung, bladder, and ovarian cancers
- Combination with a checkpoint inhibitor to be started this year
- Data confirmed preclinical observations that the enhanced TCR interaction in ADP-A2M4CD8 results in a more potent product (SITC 2021)

Other clinical updates

- Closed enrollment in the SPEARHEAD-2 trial investigating afami-cel in combination with a checkpoint inhibitor for people with head and neck cancer in 2021
- Presented data from the radiation sub-study of the completed Phase 1 trial with afami-cel (SITC 2021), which closed to enrollment in 2021
- Reported clinical benefit to people with liver cancer from the Phase 1 ADP-A2AFP trial (ILCA 2021)
    - This trial closed to screening in 2021
    - The Company continues to focus development on new cell therapies to target liver cancer

"5" autologous products in the clinic

Preclinical pipeline update

- Filed a clinical trial application (CTA) for tumor-infiltrating lymphocytes (TILs) incorporating IL-7 (a potent stimulator of T-cell proliferation and survival) in collaboration with the Center for Cancer Immune Therapy (CCIT, a leading TIL center) in Denmark, with the intent to initiate a single-center clinical trial in 2022
- Planning to initiate a Phase 1 trial in multiple indications with a new next-generation SPEAR T-cell targeting MAGE-A4, being developed in collaboration with Noile-Immune Biotech Inc., that incorporates IL-7 and CCL19 (to increase migration of SPEAR T-cells into tumors)
- Adaptimmune continues to develop TCRs to additional HLAs and new targets, as well as further next-generation approaches

"2" allogeneic products in the clinic

Allogeneic pipeline update

- Wholly owned allogeneic platform on track for planned IND submission in 2023 for first product targeting MAGE-A4
- Announced a strategic collaboration with Genentech to research, develop, and commercialize allogeneic T-cell therapies
    - Collaboration covers the research and development of "off-the-shelf" cell therapies for up to five shared cancer targets and the development of a novel allogeneic personalized cell therapy platform
    - Adaptimmune received $150 million upfront payment under the terms of the agreement
- First preclinical data presented from the Company's mesothelin HLA-independent TCR (HiT) program, which is being co-developed with Astellas, demonstrating antigen-specific tumor cell killing *in vitro* and complete tumor regression in an animal model (ASGCT 2021).
- The animal model also demonstrated that Adaptimmune's HiT T-cells targeting mesothelin outperformed a comparator TRuC construct (ASGCT 2021)
- Second target nominated for allogeneic product development in collaboration with Astellas

Patient supply

- To date, Adaptimmune has successfully manufactured hundreds of autologous batches in-house at its Navy Yard facility (Philadelphia, PA) across multiple products and tumor types
- Work underway at Navy Yard to scale up GMP manufacturing to meet commercial and clinical trial patient supply demands
- Started construction of a new cell manufacturing facility dedicated to allogeneic therapies in the UK, planned to be opened later this year
- Continued improvement of manufacturing processes including addition of an AKT inhibitor (AKTi). Data demonstrate that addition of AKTi during the *ex vivo* T-cell expansion phase of manufacturing provides further proliferative potential and enhanced memory phenotype of next-gen SPEAR T-cells (SITC 2021)

Corporate

- The Company appointed Cintia Piccina as its Chief Commercial Officer

Financial Results for the fourth quarter and year ended December 31, 2021

- **Cash / liquidity position:** As of December 31, 2021, Adaptimmune had cash and cash equivalents of $149.9 million and Total Liquidity[3] of $369.6 million, compared to $56.9 million and $368.2 million, respectively, as of December 31, 2020.
- **Revenue**: Revenue for the fourth quarter and year ended December 31, 2021 was $1.4 million and $6.1 million, respectively, compared to $1.5 million and $4.0 million for the same periods in 2020. Revenue for the year ended December 31, 2021 has increased primarily due to an increase in development activities under our collaboration arrangements.
- **Research and development (R&D) expenses:** R&D expenses for the fourth quarter and year ended December 31, 2021 were $29.5 million and $111.1 million, respectively, compared to $25.8 million and $91.6 million for the same periods in 2020. R&D expenses increased due to an increase in the number of employees engaged in research and development, increases in subcontracted expenditures, and an increase in share-based compensation costs. These increases were partially 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 fourth quarter and year ended December 31, 2021 were $14.8 million and $57.3 million, respectively, compared to $13.2 million and $45.8 million for the same periods in 2020 due to increases in employee-related costs, share-based compensation expense, and professional fees.
- **Net loss:** Net loss attributable to holders of the Company's ordinary shares for the fourth quarter and year ended December 31, 2021 was $38.8 million and $158.1 million respectively ($(0.04) and $(0.17) per ordinary share), compared to $36.6 million and $130.1 million ($(0.04) and $(0.15) per ordinary share) for the same periods in 2020.

Financial Guidance

The Company believes that its existing cash, cash equivalents and marketable securities, together with the upfront and 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 Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission prior to this earnings release.

Conference Call Information

The Company will host a live teleconference and webcast to provide additional details at 8:30 a.m. EDT (12:30 p.m. GMT) today, March 14, 2022. The live webcast of the conference call will be available via the Events page of Adaptimmune's corporate website at www.adaptimmune.com. An archive will be available after the call at the same address. To participate in the live conference call, if preferred, please dial (833) 652-5917 (US or Canada) or +1 (430) 775-1624 (International). After placing the call, please ask to be joined into the Adaptimmune conference call and provide the confirmation code (1343635).

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 (SEC) on March 14, 2022 and our other SEC filings. 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, 2021	December 31, 2020
Cash and cash equivalents	$ 149,948	$ 56,882
Marketable securities - available-for-sale debt securities	219,632	311,335
Total Liquidity	**$ 369,580**	**$ 368,217**

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 December 31,		Year ended December 31,	
	2021	2020	2021	2020
Development revenue	1,417	1,502	6,149	1,122
Revenue	**$ 1,417**	**$ 1,502**	**$ 6,149**	**$ 3,958**
Operating expenses				
Research and development	(29,505)	(25,777)	(111,090)	(91,568)

General and administrative	(14,776)	(13,238)	(57,305)	(45,795)
Total operating expenses	**(44,281)**	**(39,015)**	**(168,395)**	**(137,363)**
Operating loss	**(42,864)**	**(37,513)**	**(162,246)**	**(133,405)**
Interest income	179	538	1,095	2,313
Other income (expense), net	4,036	414	3,852	1,162
Loss before income tax expense	**(38,649)**	**(36,561)**	**(157,299)**	**(129,930)**
Income tax expense	(210)	(52)	(791)	(162)
Net loss attributable to ordinary shareholders	**$ (38,859)**	**$ (36,613)**	**$ (158,090)**	**$ (130,092)**
Net loss per ordinary share				
Basic and diluted	**$ (0.04)**	**$ (0.04)**	**$ (0.17)**	**$ (0.15)**
Weighted average shares outstanding:				
Basic and diluted	937,328,712	928,676,161	934,833,017	854,783,763

Condensed Consolidated Balance Sheets

(unaudited, in thousands, except share data)

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 149,948	$ 56,882
Marketable securities - available-for-sale debt securities	219,632	311,335
Accounts receivable, net of allowance for doubtful accounts of $0 and $0	752	139
Other current assets and prepaid expenses	45,126	29,796
Total current assets	**415,458**	**398,152**
Restricted cash	1,718	4,602
Operating lease right-of-use assets, net of accumulated amortization	20,875	18,880
Property, plant and equipment, net of accumulated depreciation of $36,253 (2020: $31,097)	30,494	27,778
Intangible assets, net of accumulated amortization	1,000	1,730
Total assets	$ **469,545**	$ **451,142**
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 8,113	$ 6,389
Operating lease liabilities, current	2,320	2,773
Accrued expenses and other accrued liabilities	29,909	27,079
Deferred revenue, current	22,199	2,832
Total current liabilities	**62,541**	**39,073**
Operating lease liabilities, non-current	23,148	20,938
Deferred revenue, non-current	177,223	49,260
Other liabilities, non-current	673	644
Total liabilities	**263,585**	**109,915**
Stockholders' equity		
Common stock - Ordinary shares par value £0.001, 1,240,853,520 authorized and 937,547,934 issued and outstanding (2020: 1,038,249,630 authorized and 928,754,958 issued and outstanding)	1,337	1,325
Additional paid in capital	959,611	935,706
Accumulated other comprehensive loss	(11,142)	(10,048)
Accumulated deficit	(743,846)	(585,756)
Total stockholders' equity	**205,960**	**341,227**
Total liabilities and stockholders' equity	$ **469,545**	$ **451,142**

Condensed Consolidated Cash Flow Statement
(unaudited, in thousands)

	Year ended December 31, 2021	Year ended December 31, 2020
Cash flows from operating activities		
Net loss	$ (158,090)	$ (130,092)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,630	6,627
Amortization	937	967
Share-based compensation expense	20,629	10,414
Unrealized foreign exchange gains/(losses)	540	(1,333)
Amortization/(accretion) on available-for-sale debt securities	5,276	3,836
Other	1,173	(55)
Changes in operating assets and liabilities:		
(Increase)/decrease in receivables and other operating assets	(19,358)	1,747
Decrease/(increase) in non-current operating assets	—	2,458
Increase in payables and other current liabilities	4,207	3,867
Increase in deferred revenue	149,785	47,973
Net cash provided by/(used in) operating activities	**10,729**	**(53,591)**
Cash flows from investing activities		
Acquisition of property, plant and equipment	(8,574)	(2,341)
Acquisition of intangible assets	(207)	(565)
Maturity or redemption of marketable securities	224,343	105,022
Investment in marketable securities	(139,762)	(381,040)
Net cash provided by/(used in) investing activities	**75,800**	**(278,924)**
Cash flows from financing activities		
Proceeds from issuance of common stock from offerings, net of commissions and issuance costs	2,529	334,388
Proceeds from exercise of stock options	759	5,663
Net cash provided by financing activities	**3,288**	**340,051**
Effect of currency exchange rate changes on cash, cash equivalents and restricted cash	365	(960)
Net increase/(decrease) in cash, cash equivalents and restricted cash	90,182	6,576
Cash, cash equivalents and restricted cash at start of period	61,484	54,908
Cash, cash equivalents and restricted cash at end of period	$ **151,666**	$ **61,484**

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[1] Afamitresgene autoleucel “afami-cel” (formerly ADP-A2M4)

[2] The primary endpoint is evaluated using a one-sided exact-based Clopper-Pearson 97.5% confidence interval (CI). Because the lower bound of the CI exceeds the response rate reported with historical second line therapy(ies) (18%), the trial has met the pre-specified threshold for demonstrating efficacy.

[3] 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

Source: Adaptimmune Therapeutics plc