



Adaptimmune Reports Fourth Quarter / Full Year 2019 Financial Results and Business Update

February 27, 2020

- Compelling data in synovial sarcoma in the Phase 1 trial, and continued momentum in the Phase 2 SPEARHEAD-1 trial with goal to launch ADP-A2M4 for sarcoma in 2022 -

- Encouraging demonstration of the potential of SPEAR T-cell platform in four new solid tumor indications -

- Co-development and co-commercialization agreement with Astellas to develop stem-cell derived 'off-the-shelf' CAR-T and TCR T-cell therapies -

PHILADELPHIA and OXFORDSHIRE, United Kingdom, Feb. 27, 2020 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in cell therapy to treat cancer, today reported financial results for the fourth quarter and year ended December 31, 2019, and provided a business update.

"The last 12 months have been transformative. We reported responses in five different solid tumors, confirming that our SPEAR T-cell platform can treat a wide range of cancers. We also validated the potential of our allogeneic platform by demonstrating that we can generate functional T-cells from stem cells, and by signing our first major strategic deal in five years with Astellas," said Adrian Rawcliffe, Adaptimmune's Chief Executive Officer. "With our passionate and skilled teams, and our world class capabilities, we are developing our cell therapy pipeline for a range of tumor indications, aiming to launch our first product in 2022 for people with sarcoma."

Responses in five solid tumor indications demonstrate SPEAR T-cell potential to treat cancer

Based on compelling response data in synovial sarcoma from the Phase 1 trial announced in May of last year, and updated at ESMO and CTOS, the Phase 2 SPEARHEAD-1 trial was initiated with ADP-A2M4 in synovial sarcoma and myxoid/ round cell liposarcoma (MRCLS). The product was granted Orphan Drug Designation, for the treatment of soft tissue sarcomas, and Regenerative Medicine Advanced Therapy designation, for synovial sarcoma, by the US FDA. The Company aims to launch ADP-A2M4 for sarcoma in 2022.

In January of this year, partial responses in liver, melanoma, gastro-esophageal junction, and head and neck cancers were reported. These early data in multiple indications demonstrate the potential of Adaptimmune's SPEAR T-cell platform across multiple targets and a range of solid tumors. Further updated data will be presented at upcoming medical / scientific meetings.

Partnerships to develop next-generation and off-the-shelf cell therapies

In January of this year, a co-development and co-commercialization agreement with Astellas, through its wholly owned subsidiary Universal Cells, Inc., was announced for stem-cell derived allogeneic CAR-T and TCR T-cell therapies. The Company has received an upfront payment of \$50 million under the agreement and is entitled to receive research funding of up to \$7.5 million per year.

This agreement covers the co-development and co-commercialization of up to three T-cell therapies and leverages Astellas' Universal Donor Cell Platform and Adaptimmune's stem-cell derived allogeneic T-cell platform. This new collaboration may encompass both CAR-T and TCR T-cell approaches, including Adaptimmune's novel HLA-independent TCR ("HiT") platform.

In 2019, Adaptimmune announced agreements with Alpine Immune Sciences and Noile-Immune to develop further next-generation products.

Leadership, manufacturing and financial updates strengthen fully integrated cell therapy company position

Adrian Rawcliffe assumed the role of Chief Executive Officer effective September 1, 2019 and John Lunger became Chief Patient Supply Officer effective August 1, 2019. In January 2020, a series of changes to the R&D leadership were announced, including the appointment of Elliot Norry as Chief Medical Officer. These leadership changes strengthen the scientific and clinical organization from early to late stage and accelerate the application of translational science learnings to therapeutic candidates and trials, as Adaptimmune becomes a late-stage cell therapy company aiming to launch a commercial product in 2022.

Adaptimmune's in-house cell manufacturing facility located at the Navy Yard in Philadelphia, PA, is achieving a 25-day processing time for production of SPEAR T-cells. 95% of patient batches manufactured in 2019 met manufacturing criteria set for those batches. The Navy Yard facility was approved as a manufacturing source for a number of the Company's clinical trials in Europe. The Company also produced its first GMP batch of lentiviral vector using an in-house, proprietary suspension process at its dedicated manufacturing space within the Cell and Gene Therapy Catapult Manufacturing Centre at Stevenage, UK.

Finally, on January 24, 2020, the Company closed an underwritten public offering of 21,000,000 American Depository Shares (ADSs) which, together with the full exercise by the underwriters on February 7, 2020 of their option to purchase an additional 3,150,000 ADSs, generated net proceeds of approximately \$89.8 million. Following the agreement with Astellas and the public offering of ADSs described above, the Company is funded into 2H 2021.

Planned 2020 milestones

First Half of 2020

- Full summary of the ADP-A2M4 Phase 1 trial at a medical conference
- Safety update on Cohorts 1 and 2 of the ADP-A2AFP Phase 1 trial at a medical conference
- Update on Cohort 3 of the ADP-A2AFP Phase 1 trial at a medical conference
- Initiation of PD1 / PDL1 inhibitor combination trial with ADP-A2M4 in head & neck cancer
- Data update from allogeneic program at a scientific meeting

Second Half of 2020

- 12-month durability data from patients with synovial sarcoma from the ADP-A2M4 Phase 1 trial at a medical conference
- Updates on dose escalation cohorts from the SURPASS trial at medical conferences
- Update on the ADP-A2M4 Phase 1 radiation sub-study at a medical conference
- Update on the ADP-A2AFP expansion cohort at a medical conference

Financial Results for the fourth quarter and year ended December 31, 2019

- **Cash / liquidity position:** As of December 31, 2019, Adaptimmune had cash and cash equivalents of \$50.4 million and Total Liquidity¹ of \$89.5 million.
- **Revenue:** Revenue for the fourth quarter and year ended December 31, 2019 were \$0.7 million and \$1.1 million compared to \$1.5 million and \$59.5 million for the same periods of 2018. The revenue recognized for the year ended December 31, 2019 is due to development work on the third target program under the GSK Collaboration and License Agreement. Revenue for the year ended December 31, 2018 included \$39.1 million of license revenue and \$20.4 million of development revenue due to the performance under the NY-ESO transition program and the PRAME development plan, which were completed in 2018.
- **Research and development (“R&D”) expenses:** R&D expenses for the fourth quarter and year ended December 31, 2019 were \$20.4 million and \$97.5 million, compared to \$22.8 million and \$98.3 million for the same periods of 2018. The decrease in R&D expenses for the year ended December 31, 2019 was driven by a reduction in subcontracted expenses and clinical trial costs following the transfer of NY-ESO to GSK in 2018 and a decrease in share-based compensation expenditure, offset by recognition of accrued purchase commitments for clinical materials and payments for in-process research and development (following collaborations with Alpine Immune Sciences, Inc. and Noile-Immune Biotech, Inc.).
- **General and administrative (“G&A”) expenses:** G&A expenses for the fourth quarter and year ended December 31, 2019 were \$10.7 million and \$43.4 million, compared to \$10.8 million and \$43.6 million for the same periods of 2018.
- **Net loss:** Net loss attributable to holders of the Company’s ordinary shares for the fourth quarter and year ended December 31, 2019 was \$29.4 million and \$137.2 million (\$0.22 per ordinary share) compared to \$36.2 million and \$95.5 million (\$0.16 per ordinary share) in the same periods of 2018.

Financial Guidance

The Company believes that its existing cash and cash equivalents and marketable securities, Total Liquidity, together with the net proceeds received from the underwritten public offering in January 2020, the additional net proceeds generated from the exercise in full of the underwriters’ option in February 2020 and the upfront payment received under its agreement with Astellas in January 2020, will fund the Company’s current operating plan into the second half of 2021.

Conference Call Information

The Company will host a live teleconference and webcast to provide additional details at 8:00 a.m. EST (1:00 p.m. GMT) today, February 27, 2020. 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 (U.S. 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 (6083408).

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 Quarterly Report on Form 10-Q filed with the SEC on November 6, 2019, 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 is the total of cash and cash equivalents and marketable securities. Each of these components appears in the Company’s Consolidated Balance Sheet. The U.S. GAAP financial measure most directly comparable to Total Liquidity is cash and cash equivalents as reported in the Company’s Consolidated Financial Statements, which reconciles to Total Liquidity as follows (unaudited):

	December 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 50,412	\$ 68,379
Marketable securities	39,130	136,755

Total Liquidity

\$ 89,542

\$ 205,134

The Company believes that the presentation of Total Liquidity provides useful information to investors because management reviews Total Liquidity as part of its management of overall liquidity, financial flexibility, capital structure and leverage. The definition of Total Liquidity includes marketable securities, which are highly liquid and available to use in our current operations.

Consolidated Statement of Operations

(unaudited, in thousands, except per share data)

	Three months ended		Year ended	
	December 31,		December 31,	
	2019	2018	2019	2018
Revenue	\$ 728	\$ 1,479	\$ 1,122	\$ 59,505
Operating expenses				
Research and development (including losses accrued on firm purchase commitments of \$-, \$-, \$5,000 and \$-)	(20,354)	(22,769)	(97,501)	(98,269)
General and administrative	(10,729)	(10,816)	(43,391)	(43,601)
Total operating expenses	(31,083)	(33,585)	(140,892)	(141,870)
Operating loss	(30,355)	(32,106)	(139,770)	(82,365)
Interest income	448	1,044	2,772	2,849
Other income (expense), net	631	(4,976)	75	(15,501)
Loss before income taxes	(29,276)	(36,038)	(136,923)	(95,017)
Income taxes	(88)	(135)	(242)	(497)
Net loss	\$ (29,364)	\$ (36,173)	\$ (137,165)	\$ (95,514)
Net loss per ordinary share				
Basic and diluted	\$ (0.05)	\$ (0.06)	\$ (0.22)	\$ (0.16)
Weighted average shares outstanding:				
Basic and diluted	630,994,079	627,429,277	629,805,218	584,338,942

Consolidated Balance Sheets

(unaudited, in thousands)

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	\$ 50,412	\$ 68,379
Marketable securities - available-for-sale debt securities	39,130	136,755
Accounts receivable, net of allowance for doubtful accounts of \$0 and \$0	—	192
Other current assets and prepaid expenses (including current portion of clinical materials)	30,947	25,769
Total current assets	120,489	231,095

Restricted cash	4,496	4,097	
Clinical materials	2,503	3,953	
Operating lease right-of-use assets, net of accumulated amortization	20,789	—	
Property, plant and equipment, net of accumulated depreciation of \$23,649 (2018: \$15,924)	31,068	36,118	
Intangibles, net of accumulated amortization	2,198	1,473	
Total assets	\$ 181,543	\$ 276,736	
Liabilities and stockholders' equity			
Current liabilities			
Accounts payable	6,357	4,083	
Operating lease liabilities, current	2,493	—	
Accrued expenses and other accrued liabilities	23,363	20,354	
Deferred revenue	2,128	—	
Total current liabilities	34,341	24,437	
Operating lease liabilities, non-current	22,966	—	
Other liabilities, non-current	598	5,414	
Total liabilities	57,905	29,851	
Stockholders' equity			
Common stock - Ordinary shares par value £0.001, 785,857,300 authorized and 631,003,568 issued and outstanding (2018: 701,103,126 authorized and 627,454,270 issued and outstanding)	943	939	
Additional paid in capital	585,623	574,208	
Accumulated other comprehensive loss	(7,264) (9,763)
Accumulated deficit	(455,664) (318,499)
Total stockholders' equity	123,638	246,885	
Total liabilities and stockholders' equity	\$ 181,543	\$ 276,736	

Consolidated Cash Flow Statement
(unaudited, in thousands)

	Year ended December 31, 2019		Year ended December 31, 2018	
Cash flows from operating activities				
Net loss	\$ (137,165)	\$ (95,514)
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>				
Depreciation	7,172		7,188	
Amortization	838		622	
Share-based compensation expense	11,053		16,202	
Realized (gain) loss on available-for-sale debt securities	(13)	2,473)
Unrealized foreign exchange losses	1,076		9,747	
Other	(185)	237)
<i>Changes in operating assets and liabilities:</i>				
Increase in receivables and other operating assets	(1,436)	(5,162)
(Increase) decrease in non-current operating assets	(1,450)	742)
Increase (decrease) in payables and deferred revenue	7,603		(40,923)
Net cash used in operating activities	(112,507)	(104,388)
Cash flows from investing activities				
Acquisition of property, plant and equipment	(1,592)	(3,910)
Acquisition of intangibles	(1,482)	(798)
Maturity or redemption of marketable securities	125,303		138,038	
Investment in marketable securities	(27,284)	(150,787)
Net cash provided by (used in) investing activities	94,945		(17,457)
Cash flows from financing activities				
Proceeds from issuance of common stock, net of issuance costs of \$0 and \$347	—		99,653	
Proceeds from exercise of stock options	366		3,037	
Net cash provided by financing activities	366		102,690	
Effect of currency exchange rate changes on cash, cash equivalents and restricted cash	(372)	3,335)
Net decrease in cash and cash equivalents	(17,568)	(15,820)
Cash, cash equivalents and restricted cash at start of period	72,476		88,296	
Cash, cash equivalents and restricted cash at end of period	\$ 54,908		\$ 72,476	

Adaptimmune Contacts:

Media Relations:

Sébastien Desprez — VP, Communications and Investor Relations

T: +44 1235 430 583

M: +44 7718 453 176

Sebastien.Desprez@adaptimmune.com

Investor Relations:

Juli P. Miller, Ph.D. — Senior Director, 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.



Source: Adaptimmune Therapeutics plc