

Adaptimmune Reports Fourth Quarter / Full Year 2020 Financial Results and Business Update

- Outlined strategy to build integrated cell therapy company and the Company's "2-2-5-2" five-year core value drivers -
 - Reported compelling durable responses in patients with synovial sarcoma, and initial responses in lung, head and neck, liver, esophagogastric junction, and melanoma cancers confirming potential of SPEAR T-cells for solid tumors -
- Completed enrollment of SPEARHEAD-1 clinical trial, to support planned BLA filing and commercialization in 2022 for ADP-A2M4 for people with synovial sarcoma -
 - Initiating Phase 2 trial (SURPASS-2) with ADP-A2M4CD8 in esophageal and esophagogastric junction cancers in 1H 2021 -
- Demonstrated killing of cancer cells with T-cells derived from the Company's allogeneic platform. MAGE-A4 and mesothelin to be first allogeneic programs into the clinic -
 - Financial guidance confirmed: funded into early 2023 -

PHILADELPHIA and OXFORDSHIRE, United Kingdom, Feb. 25, 2021 (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, 2020, and provided a business update.

"We are building the cell therapy company of the future for people with cancer. With our '2-2-5-2' by 2025 strategic plan, we will deliver value with marketed SPEAR T-cell products starting with ADP-A2M4 for people with synovial sarcoma," said Adrian Rawcliffe, Adaptimmune's Chief Executive Officer. "We completed enrollment in our SPEARHEAD-1 trial in approximately 12 months to support our first BLA, which is strong evidence of our ability to execute rapidly. We are focusing the SURPASS trial, using our next-generation ADP-A2M4CD8 product, on lung, gastroesophageal, head and neck, and bladder cancers to identify new indications to take forward to late-stage development."

Planned 2021 data updates¹

- SPEARHEAD-1 trial with ADP-A2M4 for people with synovial sarcoma
 - June: preliminary data at American Society of Clinical Oncology (ASCO)
 - November: full update at Connective Tissue Oncology Society (CTOS)
- SURPASS Phase 1 trial with ADP-A2M4CD8 (next-generation product targeting MAGE-A4)
 - September: update at European Society for Medical Oncology (ESMO)

- Additional clinical updates
 - September: update at International Liver Cancer Association (ILCA) conference for ADP-A2AFP Phase 1 trial for people with liver cancer
 - October: update at American Society for Radiation Oncology (ASTRO) for radiation sub-study of the ADP-A2M4 Phase 1 trial²
 - November: ADP-A2M4 translational data update at Society for Immunotherapy of Cancer (SITC)

“2-2-5-2” by 2025 strategic plan

At an Investor Day held in November 2020, the Company outlined its “2-2-5-2” by 2025 strategic plan encompassing:

“2” - Two marketed products targeting MAGE-A4

Estimated potential addressable population in tumor types with significant MAGE-A4 expression, factored for HLA-A2³, is ~39,000 patients per year in the US and EU

Durable responses in synovial sarcoma – on track to file a Biologics License Application (BLA) for ADP-A2M4 in 2022

- The first commercial opportunity for SPEAR T-cells targeting MAGE-A4 will be in synovial sarcoma with plans to file a BLA in the US in 2022
- In 2020, the Company received positive endorsements from regulatory authorities with Regenerative Medicine Advanced Therapy (RMAT) designation and Orphan Drug Designation (ODD) in the US, and access to Priority Medicines (PRIME) regulatory support and ODD in the EU
- Data from the Phase 1 trial with ADP-A2M4 ([presented at CTOS 2020](#))
 - In 16 patients with synovial sarcoma, there was an Overall Response Rate of 44% and a Disease Control Rate of 94%
 - Responses were durable with a median duration of response of 28 weeks with ongoing responses beyond 72 weeks in two patients (median overall survival had not been reached)
 - These data are considerably superior⁴ to response rates observed with available second line therapies in synovial sarcoma

SURPASS-2 in esophageal and esophagogastric junction (EGJ) cancers in 1H 2021

- The Company will initiate a Phase 2 trial, SURPASS-2, with ADP-A2M4CD8 (next-generation SPEAR T-cells targeting MAGE-A4 that co-express CD8 α intended to increase potency) for patients with esophageal or EGJ cancers in 1H 2021
- SURPASS-2 is supported by encouraging data from the Phase 1 SURPASS trial ([presented at SITC 2020](#)) with one confirmed partial response (PR) in a patient with EGJ cancer and tumor reductions in two additional patients (1 with esophageal and 1 with EGJ cancer)
- The trial will be conducted at multiple centers in North America and the EU, and is intended to enroll 45 people with esophageal or EGJ cancers to be treated with doses up to 10 billion SPEAR T-cells
- The Company also presented preclinical data at SITC 2020 indicating that AKT inhibition during the manufacture of SPEAR T-cells results in a more consistent expansion and phenotype of the final product. This process is currently being used for

the Phase 1 SURPASS trial.

“2” - Two additional BLAs for SPEAR T-cell products

- Adaptimmune’s Phase 1 SURPASS trial with ADP-A2M4CD8 continues to enroll patients, focusing on lung, gastroesophageal, head and neck, and bladder cancers – indications for which the Company has reported responses or signs of efficacy with its MAGE-A4 targeted products
- In 2020, Adaptimmune initiated SPEARHEAD-2 with its first-generation SPEAR T-cells targeting MAGE-A4 in combination with pembrolizumab for people with head and neck cancers
- The Phase 1 trial with ADP-A2AFP for people with liver cancer is ongoing. [As presented at ILC 2020](#), nine patients were treated as of the data cut-off and best responses were:
 - One patient with a complete response, one with stable disease (SD), and two with progressive disease (PD) among the four patients who received ~5 billion or more SPEAR T-cells
 - Five patients with SD who received doses of 100 million and 1 billion SPEAR T-cells in the first two dose cohorts

“5” - Five new autologous products in the clinic

- Adaptimmune has a deep preclinical pipeline from which it expects to bring five new products into the clinic.
- These include multiple possibilities for next-generation autologous SPEAR T-cells such as:
 - ADP-A2AFP SPEAR T-cells co-expressing CD8 α
 - ADP-A2M4 SPEAR T-cells co-expressing IL-7, IL-15, dnTGF β , and/ or PDE7
 - Enhancing SPEAR T-cells with IL-7 for proliferation and survival and CCL19 for migration into tumor in collaboration with Noile-Immune Biotech, Inc.
 - Enhancing SPEAR T-cells using transmembrane and surface immunoregulatory mechanisms with Alpine Immune Sciences, Inc.
- The Company is also developing new products, including:
 - Expanding into HLAs beyond HLA-A2 to increase the addressable patient population
 - HLA-independent TCR (HiT) candidates for multiple targets including GPC3
 - A new program for next-generation TILs co-expressing IL-7 in melanoma in collaboration with leading TIL therapy center ([CCIT, Denmark](#))

“2” - Two allogeneic products in the clinic

- In January 2020, [Adaptimmune announced](#) it had entered into an agreement to co-develop and co-commercialize stem-cell derived allogeneic cell therapies with Astellas
 - The first target nominated is a HiT targeting mesothelin
- [At ASGCT 2020](#), Adaptimmune presented data with evidence of its allogeneic platform demonstrating differentiation of functional T-cells from human-induced pluripotent stem cells (hiPSCs) that can kill MAGE-A4 expressing target cells *in vitro* –targeted to become the Company’s first allogeneic product in the clinic

Corporate updates from 2020

- Despite the impact of the COVID-19 pandemic on the biotechnology industry, Adaptimmune continued to see improved enrollment in its clinical trials
- In Q1, the Company received an upfront payment of \$50 million from Astellas. The Company is also entitled to receive research funding of up to \$7.5 million per collaboration target per year
- Underwritten public offering in Q1 generated net proceeds of approximately \$90 million
- Underwritten public offering in Q2 generated net proceeds of approximately \$244 million

Financial Results for the fourth quarter and year ended December 31, 2020

- **Cash / liquidity position:** As of December 31, 2020, Adaptimmune had cash and cash equivalents of \$56.9 million and Total Liquidity⁵ of \$368.2 million.
- **Revenue:** Revenue for the fourth quarter and year ended December 31, 2020 was \$1.5 million and \$4.0 million, respectively, compared to \$0.7 million and \$1.1 million for the same periods in 2019. The increase was due to revenue arising under the collaboration agreement with Astellas, which was entered into in January 2020.
- **Research and development (R&D) expenses:** R&D expenses for the fourth quarter and year ended December 31, 2020 were \$25.8 million and \$91.6 million, respectively, compared to \$20.4 million and \$97.5 million for the same periods in 2019. R&D expenses in the year ended December 31, 2019 included the accrual of a purchase commitment and higher costs for in-process research and development; excluding the impact of these, research and development expenses have increased as the Company progresses development of its cell therapies.
- **General and administrative (G&A) expenses:** G&A expenses for the fourth quarter and year ended December 31, 2020 were \$13.2 million and \$45.8 million, respectively, compared to \$10.7 million and \$43.4 million for the same periods in 2019. The increase in G&A expenses was due to an increase in general corporate costs, including professional fees and insurance.
- **Net loss:** Net loss attributable to holders of the Company's ordinary shares for the fourth quarter and year ended December 31, 2020 was \$36.6 million and \$130.1 million (\$0.15 per ordinary share), compared to \$29.4 million and \$137.2 million (\$0.22 per ordinary share) for the same periods in 2019.

Financial Guidance

The Company believes that its existing cash, cash equivalents and marketable securities will fund the Company's current operations into early 2023, as further detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, 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. EST (1:00 p.m. GMT) today, February 25, 2021. 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 (2099860).

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 5, 2020, 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 consolidated balance sheet. The US GAAP financial measure most directly comparable to Total Liquidity is cash and cash equivalents as reported in the consolidated financial statements, which reconciles to Total Liquidity as follows (in millions):

	December 31, 2020	December 31, 2019
Cash and cash equivalents	\$ 56,882	\$ 50,412
Marketable securities - available-for-sale debt securities	311,335	39,130
Total Liquidity	\$ 368,217	\$ 89,542

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 liquidity, financial flexibility, capital structure and leverage.

Consolidated Statement of Operations

(unaudited, in thousands, except per share data)

Three months ended

Year ended

	December 31,		December 31,	
	2020	2019	2020	2019
Revenue	1,502	728	3,958	1,122
Operating expenses				
Research and development (including losses accrued on firm purchase commitments of \$0, \$0, \$0 and \$5,000)	(25,777)	(20,354)	(91,568)	(97,501)
General and administrative	(13,238)	(10,729)	(45,795)	(43,391)
Total operating expenses	(39,015)	(31,083)	(137,363)	(140,892)
Operating loss	(37,513)	(30,355)	(133,405)	(139,770)
Interest income	538	448	2,313	2,772
Other income (expense), net	414	631	1,162	75
Loss before income taxes	(36,561)	(29,276)	(129,930)	(136,923)
Income taxes	(52)	(88)	(162)	(242)
Net loss attributable to ordinary shareholders	\$ (36,613)	\$ (29,364)	\$ (130,092)	\$ (137,165)
Net loss per ordinary share				
Basic and diluted	\$ (0.04)	\$ (0.05)	\$ (0.15)	\$ (0.22)
Weighted average shares outstanding:				
Basic and diluted	928,676,161	630,994,079	854,783,763	629,805,218

Consolidated Balance Sheets

(unaudited, in thousands, except share data)

	December 31, 2020	December 31, 2019
Assets		
Current assets		

Cash and cash equivalents	\$ 56,882	\$ 50,412
Marketable securities - available-for-sale debt securities	311,335	39,130
Accounts receivable, net of allowance for doubtful accounts of \$0 and \$0	139	—
Other current assets and prepaid expenses (including current portion of clinical materials)	29,796	30,947
Total current assets	398,152	120,489
Restricted cash	4,602	4,496
Clinical materials	—	2,503
Operating lease right-of-use assets, net of accumulated amortization	18,880	20,789
Property, plant and equipment, net of accumulated depreciation	27,778	31,068
Intangibles, net of accumulated amortization	1,730	2,198
Total assets	\$ 451,142	\$ 181,543
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 6,389	\$ 6,357
Operating lease liabilities, current	2,773	2,493
Accrued expenses and other accrued liabilities	27,079	23,363
Deferred revenue, current	2,832	2,128
Total current liabilities	39,073	34,341
Operating lease liabilities, non-current	20,938	22,966
Deferred revenue, non-current	49,260	—
Other liabilities, non-current	644	598
Total liabilities	109,915	57,905
Stockholders' equity		
Common stock - Ordinary shares par value £0.001, 1,038,249,630 authorized and 928,754,958 issued and outstanding (2019: 785,857,300 authorized and 631,003,568 issued and outstanding)	1,325	943
Additional paid in capital	935,706	585,623
Accumulated other comprehensive loss	(10,048)	(7,264)
Accumulated deficit	(585,756)	(455,664)
Total stockholders' equity	341,227	123,638
Total liabilities and stockholders' equity	\$ 451,142	\$ 181,543

Consolidated Cash Flow Statement
(unaudited, in thousands)

	Year ended December 31, 2020	Year ended December 31, 2019
Cash flows from operating activities		
Net loss	\$ (130,092)	\$ (137,165)
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>		
Depreciation	6,627	7,172
Amortization	967	838
Share-based compensation expense	10,414	11,053
Unrealized foreign exchange (gains) losses	(1,333)	1,076
Amortization (accretion) on available-for-sale debt securities	3,836	(185)
Other	(55)	(13)
<i>Changes in operating assets and liabilities:</i>		
Decrease (increase) in receivables and other operating assets	1,747	(1,436)
Decrease (increase) in non-current operating assets	2,458	(1,450)
Increase (decrease) in payables and other liabilities	3,867	5,508
Increase (decrease) in deferred revenue	47,973	2,095
Net cash used in operating activities	(53,591)	(112,507)
Cash flows from investing activities		
Acquisition of property, plant and equipment	(2,341)	(1,592)
Acquisition of intangibles	(565)	(1,482)
Maturity or redemption of marketable securities	105,022	125,303
Investment in marketable securities	(381,040)	(27,284)
Net cash (used in) provided by investing activities	(278,924)	94,945
Cash flows from financing activities		
Proceeds from issuance of shares in the January offering	78,616	—
Proceeds from issuance of shares upon exercise of the overallotment for the January Offering	11,938	—
Proceeds from issuance of shares in the June Offering	209,986	—
Proceeds from issuance of shares upon exercise of the overallotment for the June Offering	33,848	—
Proceeds from exercise of stock options	5,663	366
Net cash provided by financing activities	340,051	366
Effect of currency exchange rate changes on cash, cash equivalents and restricted cash	(960)	(372)

Net increase (decrease) in cash, cash equivalents and restricted cash	6,576	(17,568)
Cash, cash equivalents and restricted cash at start of period	54,908	72,476
Cash, cash equivalents and restricted cash at end of period	\$ 61,484	\$ 54,908

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¹ All data updates subject to congress acceptance

² The main portion of the ADP-A2M4 Phase 1 trial is closed for enrollment

³ Mortality figures based on American Cancer Society 2020 (US) and Global Can (EU) – synovial sarcoma data based on internal market research; MAGE-A4 expression ranges based on Adaptimmune samples and expression cut-off criteria of $\geq 30\%$ tumor cells at $\geq 2+$ intensity; HLA-A2 expression of 41% based on Adaptimmune samples (1,043 patient samples); serum AFP expression ranges based on internal samples (62 patients) and expression cut off $> 100\text{ng/mL}$

⁴ Pollack S, *et al. Cancer Medicine*. 2020; 9:4593–4602; Seto T, *et al Med. Sci*. 2019, 7, 48; van der Graaf WT, *et al. Lancet*, 379(9829), 1879-1886

⁵ 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