

# Adaptimmune Reports Fourth Quarter / Full Year 2018 Financial Results and Business Update

- On track for clinical data update from trials in multiple solid tumors at the Q1 2019 earnings update call in May -

- Completed initial safety cohorts for ADP-A2M10 (MAGE-A10) in lung and triple tumor studies as well as ADP-A2M4 (MAGE-A4) basket study -

- Treating patients in expansion phases of all ADP-A2M10 and ADP-A2M4 studies at target doses of 1 billion cells (with doses up to 10 billion cells) -
- Completed Cohort 1 for safety in ADP-A2AFP (AFP) study and treating patients in safety Cohort 2 at target doses of 1 billion cells -
- Significant progress in cell and vector manufacturing internally as well as with external partners-

- Guidance confirmed: funded through to late 2020

- Conference call to be held today at 8:00 a.m. EDT (1:00 p.m. GMT) -

PHILADELPHIA and OXFORD, United Kingdom, Feb. 27, 2019 (GLOBE NEWSWIRE) --Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, today reported financial results for the fourth quarter and year ended December 31, 2018 and provided a business update.

"2018 was a year of strong delivery across the portfolio with record numbers of patients treated in our clinical trials. We moved through the dose escalation portion of our studies with ADP-A2M4 and ADP-A2M10 and we are now treating patients in the expansion phases for both programs. Our third program, ADP-A2AFP, moved to the second dose cohort at target doses of 1 billion cells. We are very pleased to have observed an acceptable safety profile, thus far, with all three programs, showing no evidence of off-target toxicity or alloreactivity," said James Noble, Chief Executive Officer. "We are now able to devote our resources to these programs following the successful transition of NY-ESO to GSK."

"We made equally impressive progress in manufacturing with our in-house facility going from our first ever dose, at the beginning of 2018, to being able to produce target doses for up to 10 patients per month. In the UK, we started up our vector manufacturing that should begin to produce vector later this year. 2019 promises to be a significant year, with data emerging across our portfolio from May onwards. We look forward to reporting clinical data throughout the year," added James Noble.

#### **Clinical momentum**

Initial safety testing is complete in the triple tumor and non-small cell lung cancer (NSCLC) studies with ADP-A2M10, as well as the basket study with ADP-A2M4. All three studies are enrolling and treating patients with up to 10 billion cells in the expansion phases with no predetermined stagger between dosing required.

In 2018, the Safety Review Committee (SRC) endorsed dose escalation through Cohorts 1, 2, and 3 of these studies, after reviewing safety data from 16 patients treated in the ADP-A2M10 studies and nine patients in the ADP-A2M4 study.

In the hepatocellular carcinoma study with ADP-A2AFP, the SRC endorsed escalation to safety Cohort 2 to treat patients with a target dose of 1 billion cells.

To date, across all four studies, most adverse events have been consistent with those typically experienced by cancer patients undergoing cytotoxic chemotherapy or other cancer immunotherapies with no evidence of alloreactivity or toxicity related to off-target binding.

#### Building an integrated company

Since the opening of the Navy Yard facility in January 2018, Adaptimmune can now manufacture cells for up to 10 patients per month, and this is scalable to 100 patients per month without significant capital expenditure. Further, an additional 10 patients per month can be treated with cells produced at a third-party vendor HCATs. Both the Navy Yard and HCATs facilities are now able to routinely produce cells to meet target doses across a broad range of solid tumors. This capacity will allow Adaptimmune to service its existing and planned clinical trials.

With respect to vector, Adaptimmune is well supplied as its own vector manufacturing has completed its first engineering run with first production anticipated in 2019, as well as production in place at a third-party vendor. The vendor has already produced vector for ADP-A2M10, ADP-A2M4, ADP-A2AFP, and next generation SPEAR T-cells.

In light of the Company's increased clinical focus, Rafael Amado assumed the new role of President of R&D last year to bring the clinical and research functions under a single leadership, facilitating alignment and integration of all parts of the R&D structure.

The Company is working with more than 20 active clinical trial sites at leading cancer centers in the US, Canada, and the EU. In Europe, the infrastructure has been tested and has delivered the first doses to patients with additional patients being enrolled in the UK and Spain. Adaptimmune has also reached agreement on an expanded collaboration with MD Anderson Cancer Center (Houston, TX) to further enhance the Company's translational research capabilities.

While progressing studies with ADP-A2M10, ADP-A2M4, and ADP-A2AFP as well as planning for the next stage of clinical development, including potential registration trials, Adaptimmune continues to progress developing next generation SPEAR T-cells, new targets, other HLAs, and an off-the-shelf product.

Finally, Adaptimmune is funded through to late 2020, based on management's current estimates, with Total Liquidity<sup>1</sup> of \$205 million (including cash and cash equivalents of \$68 million) at year-end 2018.

#### 2018 Highlights Clinical progress with wholly-owned programs:

- ADP-A2M10 (MAGE-A10):
  - **January 2018**: The SRC endorsed escalation to Cohort 2 (1 billion target dose) in the ADP-A2M10 triple tumor and lung studies based on favorable safety data
  - ASCO: Poster presented at ASCO with initial safety data
  - **July:** SRC endorsed dose escalation to Cohort 3 in the NSCLC and triple tumor studies, and treating patients at target dose of 5 billion cells commenced
  - **ESMO:** Presentation of Cohorts 1 and 2 safety data showing dose proportionate persistence and expansion
  - **Q4**: Escalation to expansion phase allowing for doses up to 10 billion cells with no pre-determined stagger between patients for both studies
- ADP-A2M4 (MAGE-A4) Basket study:
  - ASCO: The SRC endorsed escalation to Cohort 2 based on favorable safety data in Cohort 1. Added synovial sarcoma and myxoid/round cell liposarcoma (MRCLS) indications for a total of nine solid tumors in this study
  - August: Dose escalation to Cohort 3
  - **ESMO**: Presentation of Cohorts 1 and 2 safety data showing dose appropriate persistence and expansion, and early, but transient, evidence of antitumor activity in one ovarian cancer patient
  - **Q4**: Escalation to expansion phase allowing for doses up to 10 billion cells with no pre-determined stagger between patients
- ADP-A2AFP (AFP) Hepatocellular carcinoma:
  - SRC endorsed escalation to Cohort 2 with target doses of 1 billion cells
- Clinical learnings
  - AACR 2018: Presented two posters with ADP-A2M10 and ADP-A2M4 preclinical data
  - **Q2:** Published study in Cancer Discovery indicating that NY-ESO SPEAR T-cells are long-lived, self-renewing, and capable of persistent anti-tumor effects
  - SITC: Updated data supporting further understanding of systemic and local immunity following NY-ESO treatment in synovial sarcoma, including the positive impact of a more intense pre-conditioning regimen with respect to SPEAR T-cell expansion and persistence; adjusted to a more intense pre-conditioning regimen in current trials as a result
  - Q4: Published paper in Hepatology "Tuning T-cell receptor affinity to optimize clinical risk-benefit when targeting α-fetoprotein (AFP) positive liver cancer," which details the development of the SPEAR T-cells targeting AFP

# Preclinical:

- Good progress with off-the-shelf product and presented progress to date at ASGCT 2018
- Developing multiple next generation approaches first candidate ready for IND submission in 2H 2019
- Investigated new targets and additional HLAs to be brought to the clinic beyond 2019
- Well-developed preclinical package including proprietary methods for predicting binding of a TCR to an off-target peptide utilizing alanine scanning processes. A licensing program is available to third parties wishing to use this patented method.

### Manufacturing:

- Routinely producing cell product at target doses across a broad range of solid tumor indications
- Navy Yard facility now capable of manufacturing cell product for up to 10 patients per month (scalable to 100 patients per year) with capacity for an additional 10 patients per month at a third-party supplier HCATs
- Implemented rapid sterility testing to decrease vein-to-vein time
- Routinely producing more than 5 billion cells to meet target doses
- Agreement with third-party vector manufacturer for commercial supply batches manufactured for ADP-A2M10, ADP-A2M4, ADP-A2AFP, and next generation SPEAR T-cells
- In-house suspension vector manufacturing capacity with an engineering run completed and first production expected in 2019

# NY-ESO Program (now transitioned to GSK):

- **Myxoid/round cell liposarcoma:** Initial responses observed in a second solid tumor indication with data presented at ASCO 2018 and updated at SITC 2018
- Agreement with GSK:
  - Completed transition of the NY-ESO SPEAR T-cell development program in August 2018
  - GSK assumed full responsibility for future research, development, and potential commercialization of NY-ESO now called GSK3377794 (GSK '794)
  - Adaptimmune received ~ \$27.5 million (~£21.2 million) in 2018 from GSK for completion of the transition

#### Other corporate news:

- Completed Registered Direct Offering, raising total net proceeds of ~\$100 million in September 2018
- Appointed John Furey as an independent Non-Executive Director, effective July 5, 2018, succeeding Dr. Peter Thompson

# Financial Results for the fourth quarter and year ended December 31, 2018

- **Cash / liquidity position:** As of December 31, 2018, Adaptimmune had cash and cash equivalents of \$68.4 million and Total Liquidity<sup>1</sup> of \$205.1 million.
- **Revenue:** Revenue represents the upfront and milestone payments, which are recognized as delivered services to GSK. Revenue for the fourth quarter and year ended December 31, 2018 were \$1.5 million and \$59.5 million compared to \$4.3 million and \$37.8 million for the same periods of 2017. Revenue in the year ended December 31, 2018 includes \$39.1 million of revenue for the license to NY-ESO, which commenced in September 2018.
- Research and development ("R&D") expenses: R&D expenses for the fourth quarter and year ended December 31, 2018 were \$22.8 million and \$98.3 million, compared to \$25.1 million and \$87.4 million for the same periods of 2017. The increase was primarily due to increased costs associated with clinical trials; costs of developing manufacturing capability in the Company's U.S. facility and increased personnel expenses.

- General and administrative ("G&A") expenses: G&A expenses for the fourth quarter and year ended December 31, 2018 were \$10.8 million and \$43.6 million, compared \$8.8 million and \$31.1 million for the same periods of 2017. The increase was primarily due to increased personnel costs consistent with our planned growth an increase in costs associated with supporting and maintaining our IT infrastructure.
- Net loss: Net loss attributable to holders of the Company's ordinary shares for the fourth quarter and year ended December 31, 2018 were \$36.2 million and \$95.5 million (\$(0.16) per ordinary share) compared to \$27.3 million and \$70.1 million (\$(0.13) per ordinary share) in the same periods of 2017.

<sup>1</sup> 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.

#### **Financial Guidance**

The Company believes that its existing cash and cash equivalents, short-term deposits and marketable securities, Total Liquidity, will fund the Company's current operating plan through to late 2020.

#### **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, 2019. 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 (9455267).

#### About Adaptimmune

Adaptimmune is a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapy products. The Company's unique SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform enables the engineering of T-cells to target and destroy cancer, including solid tumors. Adaptimmune is currently conducting clinical trials with SPEAR T-cells targeting MAGE-A4, MAGE-A10, and AFP across multiple solid tumor indications. The Company is located in Philadelphia, USA, and Abingdon, Oxfordshire and Stevenage, U.K. For more information, please visit <a href="http://www.adaptimmune.com">http://www.adaptimmune.com</a>.

#### **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 Securities and Exchange Commission (SEC) on November 6, 2018, 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, short-term deposits 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:

(in thousands) (unaudited)	December 31, 2018		December 31, 2017		
Cash and cash equivalents	\$	68,379	\$	84,043	
Marketable securities		136,755		124,218	
Total Liquidity	\$	205,134	\$	208,261	

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.

#### **Condensed Consolidated Statement of Operations**

(unaudited, in thousands, except per share data)

	Three months ended December 31,			Year ended December 31,				
		2018		2017	2018		2017	
Revenue	\$	1,479	\$	4,270	\$	59,505	\$	37,833
Operating expenses								
Research and development		(22,769)		(25,148)		(98,269)		(87,388)
General and administrative		(10,816)		(8,822)		(43,601)		(31,106)
Total operating expenses		(33,585)		(33,970)		(141,870)		(118,494 )
Operating loss		(32,106)		(29,700)	-	(82,365)		(80,661)
Interest income		1,044		779		2,849		2,230
Other income (expense), net		(4,976)		1,488		(15,501)		8,744
Loss before income taxes		(36,038)		(27,433)		(95,017)		(69,687)
Income taxes		(135)		170		(497)		(451)
Net loss	\$	(36,173 )	\$	(27,263)	S	(95,514)	\$	(70,138)
Net loss per ordinary share – Basic and diluted	\$	(0.06)	\$	(0.05)	\$	(0.16 )	\$	(0.13)
Weighted average shares outstanding – Basic and diluted		627,429,277		562,119,334		584,338,942		527,637,086

#### **Condensed Consolidated Balance Sheets**

(unaudited, in thousands)

	December 31, 2018		December 31, 2017		
Assets					
Current assets					
Cash and cash equivalents	\$	68,379	\$	84,043	
Marketable securities - available-for-sale debt securities		136,755		124,218	
Accounts receivable, net of allowance for doubtful accounts of \$- and \$-		192		206	
Other current assets and prepaid expenses (including current					
portion of clinical materials)		25,769		21,716	
Total current assets		231,095		230,183	
Restricted cash		4,097		4,253	
Clinical materials		3,953		4,695	
Property, plant and equipment, net		36,118		40,679	
Intangibles, net		1,473		1,337	
Total assets		276,736		281,147	
Liabilities and stockholders' equity Current liabilities Accounts payable		4,083 20,354		8,378 27,201	
Accrued expenses and other accrued liabilities Deferred revenue		20,354		,	
		-	·	38,735	
Total current liabilities		25,937		74,314	
Other liabilities, non-current		5,414		3,849	
Total liabilities		29,851		78,163	
Stockholders' equity					
Common stock - Ordinary shares par value £0.001, 701,103,126 authorized and 627,454,270 issued and outstanding (2017: 701,103,126 authorized and 562,119,334 issued and					
outstanding)		939		854	
Additional paid in capital		574,208		455,401	
Accumulated other comprehensive loss		(9,763)		(21,641)	
Accumulated deficit		(318,499)		(231,630)	
Total stockholders' equity		246,885		202,984	
Total liabilities and stockholders' equity	\$	276,736	\$	281,147	

# Condensed Consolidated Cash Flow Statement

(unaudited, in thousands)

	Year ended 2018	Decem	cember 31, 2017	
Cash flows from operating activities				
Net loss	\$ (95,514)	\$	(70,138)	
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	7,188		5,032	
Amortization	622		391	
Share-based compensation expense	16,202		10,804	
Realized loss on available-for-sale debt securities	2,473		646	
Unrealized foreign exchange losses (gains)	9,747		(8,599)	
Other	237		341	
Changes in operating assets and liabilities:				
Increase in receivables and other operating assets	(5,162)		(7,346)	
Decrease in non-current operating assets	742		2,115	
(Decrease) increase in payables and deferred revenue	 (40,923)		12,439	

Net cash used in operating activities	(104,388 )	(54,315 )
Cash flows from investing activities		
Acquisition of property, plant and equipment	(3,910)	(24,643)
Acquisition of intangibles	(798)	(369)
Proceeds from disposal of property, plant and equipment	_	550
Maturity of short-term deposits	_	40,625
Investment in short-term deposits	_	(18,000)
Maturity or redemption of marketable securities	138,038	29,090
Investment in marketable securities	(150,787)	(153,334)
Net cash (used in) provided by investing activities	(17,457 )	(126,081 )
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	99,653	103,167
Proceeds from exercise of stock options	3,037	401
Net cash provided by financing activities	102,690	103,568
Effect of currency exchange rate changes on cash, cash		
equivalents and restricted cash	3,335	2,328
Net decrease in cash and cash equivalents	(15,820)	(74,500)
Cash, cash equivalents and restricted cash at start of period	88,296	162,796
Cash, cash equivalents and restricted cash at end of period	\$ 72,476	\$ 88,296

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Source: Adaptimmune Therapeutics plc