

September 7, 2017



# GSK Exercises Option over SPEAR T-cell Therapy Program Targeting NY-ESO

PHILADELPHIA and OXFORD, United Kingdom, Sept. 07, 2017 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, today announced that GlaxoSmithKline plc (LSE:GSK) (NYSE:GSK) has exercised its option under a collaboration and license agreement signed in 2014 to exclusively license the right to research, develop, and commercialize Adaptimmune's NY-ESO SPEAR T-cell therapy program. Further details will be provided in a conference call scheduled for 8:30 AM EDT this morning; dial-in and webcast details are provided below.

Adaptimmune will receive up to £48 million (~\$61 million) from GSK over the course of the transition period. This includes development milestones of up to £18 million (~\$23 million) and the option payment of £30 million (~\$38 million), which also allows GSK to nominate two additional targets following completion of the transition. Successful continuation of development and subsequent commercialization of NY-ESO would trigger additional payments for development milestones, tiered sales milestones, and mid-single to low double-digit royalties on worldwide net sales.

"This is a very exciting day for Adaptimmune as GSK has exercised its option over our NY-ESO program, earlier than originally planned," commented James Noble, Chief Executive Officer at Adaptimmune. "The commitment by one of the world's leading pharmaceutical companies to the NY-ESO SPEAR T-cell program as a new treatment modality is a testament to the strength of our data in synovial sarcoma recently presented at ASCO. From a financial perspective, this option exercise extends our cash runway into 2020. We anticipate the transition of NY-ESO to GSK to be completed over the coming months, after which we will focus our clinical resources on delivery and execution from our wholly-owned assets MAGE-A4, MAGE-A10, and AFP."

Axel Hoos, SVP Oncology R&D, GSK said "The aim of GSK's R&D is to develop medicines with transformational potential for patients. We have seen compelling data for the NY-ESO investigational cell therapy in synovial sarcoma and, following this option exercise, we will capitalize on our in-house Cell and Gene Therapy capabilities to support the development program for GSK3377794. We will continue to explore the potential for this novel cell therapy in multiple tumor types, and in combination with other cancer therapies."

## Summary of Recent Data in Synovial Sarcoma

In June of this year, data presented in an oral presentation at ASCO from the ongoing study of NY-ESO SPEAR T-cells in synovial sarcoma continued to indicate a favorable risk benefit profile in this aggressive and difficult-to-treat solid tumor. Initial anti-tumor activity was observed in all ongoing cohorts, including low expressors of NY-ESO. NY-ESO SPEAR T-cells continued to be well-tolerated with all reported events of cytokine release syndrome resolved (the majority of events were Grade 1 or 2), and there were no reported events of seizure, cerebral edema, or encephalopathy. Survival data was promising with a median

predicted overall survival of 120 weeks (~28 months) among the 12 treated patients in Cohort 1; or, 159 weeks (~37 months) for the ten patients in this cohort who received the target dose of one billion cells. In addition, 6 responses were observed in Cohort 1 patients.

### **Transition Plan**

Adaptimmune and GSK will work together over the coming months to ensure a smooth transition of the NY-ESO SPEAR T-cell development program to GSK. After the transition, GSK will assume sponsor responsibility for all NY-ESO-related activities including ongoing data publications regarding this program. Current plans for ongoing and planned clinical studies are summarized below by indication:

#### **Sarcoma:**

- Adaptimmune will continue enrollment in the ongoing synovial sarcoma pilot study, which will ultimately transition to GSK.
- GSK will be responsible for continued clinical investigation including initiating the registration study in this indication.
- Adaptimmune will continue to enroll patients in the ongoing myxoid/round cell liposarcoma (MRCLS) study, which will ultimately transition to GSK.

#### **Non-small Cell Lung Cancer (NSCLC):**

- Adaptimmune will cease enrollment in the ongoing NSCLC study, whilst GSK develops plans for its own study of NY-ESO SPEAR T-cells in this indication.

#### **Ovarian:**

- Adaptimmune will cease enrollment in the ongoing ovarian study, and GSK will assume responsibility for any additional work in this indication.

#### **Multiple Myeloma:**

- GSK will take on responsibility for the ongoing multiple myeloma combination study with KEYTRUDA® (pembrolizumab), an anti-PD-1 inhibitor marketed by Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the US and Canada).

### **About the Collaboration and License Agreement between Adaptimmune and GSK**

Adaptimmune and GSK announced their strategic collaboration and license agreement in June 2014 for up to five programs including the first program, NY-ESO. The terms of the agreement were expanded in February 2016 to accelerate development of NY-ESO SPEAR T-cell therapy toward registration trials in synovial sarcoma, to explore development in MRCLS and to enable combination studies.

In January 2017, GSK nominated PRAME as a second target and, as a consequence of this option exercise for NY-ESO, GSK will have the right to nominate its third and fourth targets and Adaptimmune will take these programs through preclinical testing to IND. The agreement excludes targets on which work is already under way, including Adaptimmune's wholly owned MAGE-A10, MAGE-A4, and AFP clinical programs and its active preclinical pipeline.

### **Adaptimmune's Pipeline**

Adaptimmune's proprietary technology enables the Company to consistently generate affinity enhanced T-cell receptors (TCRs) which address intracellular targets on solid tumors that are not accessible to certain other experimental modalities. Adaptimmune has three wholly-owned SPEAR T-cells in active clinical trials, with further first and next generation SPEAR T-cells being developed and evaluated by means of Adaptimmune's proprietary preclinical testing platform.

As stated above, GSK does not have the right to nominate any additional targets on which work is already under way, including Adaptimmune's wholly-owned SPEAR T-cells targeting MAGE-A10, MAGE-A4, and AFP that are being evaluated in four active clinical trials across eight solid tumor indications., These ongoing studies are described in more detail below:

- MAGE-A10: Two active trials, one in NSCLC, and a triple tumor study in urothelial (bladder), melanoma, and head and neck cancer
- MAGE-A4: One active trial across seven solid tumor indications including urothelial, melanoma, head and neck, ovarian, NSCLC, esophageal, and gastric cancers
- AFP: One active study in hepatocellular (liver) cancer

Initial safety and efficacy data across each of these studies is anticipated through 2017 and 2018.

### **Conference Call Information**

The Company will host a live teleconference and webcast to provide additional details at 8:30 a.m. EDT (1:30 p.m. BST) today, September 7, 2017. The live webcast of the conference call will be available via the events page of Adaptimmune's corporate website at [www.adaptimmune.com](http://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 (877) 280-1254 (U.S.) or +44 (0)20 3427 1909 or 0800 279 4992 (U.K.). After placing the call, please ask to be joined into the Adaptimmune conference call and provide the confirmation code (1257702).

### **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 has a number of proprietary clinical programs, and is also developing its NY-ESO SPEAR T-cell program under a strategic collaboration and license agreement with GlaxoSmithKline. The Company is located in Philadelphia, USA and Oxfordshire, U.K. For more information, please visit <http://www.adaptimmune.com>

### **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 August 3, 2017, 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.

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Source: Adaptimmune Therapeutics plc