

June 5, 2017



# **Adaptimmune Announces an Oral Presentation on Data from NY-ESO Study in Synovial Sarcoma and Four Trials in Progress Posters at the American Society of Clinical Oncology (ASCO) Annual Meeting**

PHILADELPHIA and OXFORD, United Kingdom, June 05, 2017 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, today announced an oral presentation on updated data from its NY-ESO study in synovial sarcoma, as well as four trials in progress posters. The data were presented at the 2017 ASCO annual meeting in Chicago, Illinois.

The Company will host a live teleconference and webcast slide presentation on June 6<sup>th</sup> from 8:00–9:00 AM EDT (1:00–2:00 PM BST) to discuss the updated synovial sarcoma clinical data. Call in details and the webcast link are provided below.

“We have seen responses across all of our ongoing cohorts in our NY-ESO study in synovial sarcoma, including in patients who express lower levels of NY-ESO, and in those receiving conditioning with modified doses of fludarabine / cyclophosphamide,” said Rafael Amado, Adaptimmune’s Chief Medical Officer. “A lower response rate was observed in the absence of fludarabine conditioning and that cohort is now closed. For patients from Cohort 1, an updated survival analysis shows a promising median predicted overall survival of 120 weeks or approximately 28 months. The data continue to suggest that NY-ESO is well-tolerated. We have seen no events of seizure, cerebral edema, or encephalopathy; most events of cytokine release syndrome are grades 1-2 and all resolved with supportive care.”

He continued: “We are in a period of significant operational momentum with ongoing trials in our three wholly-owned assets, MAGE-A4, MAGE-A10 and AFP, as well as additional studies through our collaboration with GSK with NY-ESO in myxoid / round cell liposarcoma, ovarian, and non-small cell lung cancer – study designs and screening progress for some of these trials were also presented at ASCO.”

## **Data Update from the Ongoing NY-ESO Synovial Sarcoma Study**

During an oral presentation on June 5<sup>th</sup> entitled, “Open label, non-randomized, multi-cohort pilot study of genetically engineered NY-ESO-1 specific NY-ESO-1<sup>c259t</sup> in HLA-A2<sup>+</sup> patients with synovial sarcoma (NCT01343043),” Dr. Sandra P. D’Angelo of the Memorial Sloan Kettering Cancer Center presented an update on all cohorts from Adaptimmune’s ongoing study.

- NY-ESO continues to be generally well-tolerated and initial anti-tumor activity has been observed in all ongoing cohorts including low expressors of NY-ESO (Cohort 2)
- Of the twelve patients treated in Cohort 1 (non-modified fludarabine / cyclophosphamide [“Flu/Cy”] lymphodepletion regimen), five remain alive with a median predicted overall survival of 120 weeks (~28 months) (data cutoff March 30, 2017)
- Confirmed responses have been observed in all cohorts as follows:
  - Cohort 1 (High Flu/Cy, High NY-ESO): 6/12 (50%) patients with a median progression free survival (PFS) of 15 weeks (range:8, 38); 6/10 (60%) response rate in patients who received a target dose of at least one billion cells
  - Cohort 2 (High Flu/Cy, Low NY-ESO): 2/5 (40%); ongoing
  - Cohort 3: (High cyclophosphamide, no fludarabine, High NY-ESO): 1/5 (20%); cohort closed
  - Cohort 4 (Modified Flu/Cy, High NY-ESO): 3/6 (50%); (ongoing)
- Peak and long-term expansion of NY-ESO SPEAR T-cells appears to correlate with clinical efficacy
- Fludarabine appears to be an important component of the lymphodepletion regimen
- All reported events of cytokine release syndrome resolved with supportive care, and the majority of events were Grade 1 or 2
- There were no reported events of seizure, cerebral edema, or encephalopathy

### **Overview of Study Designs from the Trials in Progress Posters**

The four trials in progress posters summarized the study designs for Adaptimmune’s ongoing NY-ESO trials in myxoid/round cell liposarcoma (MRCLS), ovarian cancer, and non-small cell lung cancer (NSCLC); the Company’s ongoing MAGE-A10 trial in NSCLC, and its MAGE-A10 triple tumor study in patients with head and neck, melanoma, or urothelial “bladder” tumors.

- ***NY-ESO in MRCLS (NCT02992743):***
  - Open-label, non-randomized pilot study evaluating the safety, tolerability, and antitumor activity of NY-ESO SPEAR T-cells in patients with MRCLS
  - Initially, 10 subjects are planned to be enrolled, with potential to enroll an additional 5 subjects. Subjects who do not receive the minimum cell dose or who do not receive the T-cell infusion may be replaced.
  - Subjects must be: ≥ 18 yrs old; HLA-A\*02:01, \*02:05, or \*02:06 positive; have advanced (metastatic or inoperable) MRCLS expressing NY-ESO-1 at 2+/3+ intensity in ≥30% of tumor cells by IHC; measurable disease; prior systemic anthracycline therapy; have ECOG status 0 or 1; and adequate organ function.
  - Lymphodepletion regimen: fludarabine (30mg/m<sup>2</sup>/day) and cyclophosphamide (600 mg/m<sup>2</sup>/day) for 3 days; same as Cohort 4 in Synovial Sarcoma study
  - Target dose of 1 – 8 × 10<sup>9</sup> transduced SPEAR T-cells
  - Efficacy assessed by overall response rate, time to response, duration of response, progression-free survival, and overall survival at weeks 4, 8, and 12, month 6, and then every 3 months until confirmation of disease progression
  - This study is open and actively enrolling; as of May 18, 2017, 3 subjects have been enrolled
- ***NY-ESO in Ovarian Cancer (NCT01567891):***
  - Single-arm, open-label clinical trial evaluating the safety, tolerability, and antitumor

activity of NY-ESO SPEAR T-cells in patients with ovarian cancer

- Subjects must be  $\geq 18$  years old; HLA-A\*02:01, \*02:05, or \*02:06 positive; have recurrent epithelial ovarian, primary peritoneal or fallopian tube carcinoma with refractory or platinum-resistant disease expressing NY-ESO-1 at  $\geq 1+$  intensity in  $\geq 10\%$  of tumor cells by IHC; have measurable disease; have ECOG status 0 or 1; and have adequate organ function.

- The study evaluates two lymphodepleting regimens: cyclophosphamide alone (enrollment completed; n=7) and cyclophosphamide plus fludarabine (up to 10 subjects to be treated)

- The first 6 subjects were lymphodepleted prior to T-cell infusion with various regimens of cyclophosphamide alone. None of these subjects achieved a response per RECIST v1.1 (ASCO 2016).

- The lymphodepletion regimen has been amended to include both fludarabine and cyclophosphamide (fludarabine [30mg/m<sup>2</sup>/day] and cyclophosphamide [600 mg/m<sup>2</sup>/day] for 3 days; same as Cohort 4 in Synovial Sarcoma study)

- Target dose of  $1 - 6 \times 10^9$  transduced SPEAR T-cells

- Efficacy assessed by response rate, duration of response, progression-free survival, and overall survival at weeks 4, 8, and 12, month 6, and then every 3 months until confirmation of disease progression

- Enrollment is ongoing

- **NY-ESO (NCT02588612) and MAGE-A10 (NCT02592577) in NSCLC:**

- Open-label studies of NY-ESO or MAGE A-10 SPEAR T-cells in patients with NSCLC

- Subjects are screened under a separate protocol (Screening Protocol: NCT02636855) to identify those who have the relevant HLA-A\*02 alleles and NY-ESO-1 or MAGE-A10 tumor expression.

- Subjects must have Stage IIIb or IV NSCLC, have failed at least one platinum-containing regimen (may have received CPIs), have measurable disease, ECOG 0-1, adequate organ function, and be without brain metastases, history of severe autoimmune disease or current uncontrolled illness

- The NY-ESO trial is a 10 subject study with a target dose of  $1-6 \times 10^9$  transduced cells

- The MAGE-A10 trial is a first-in-human study utilizing a modified 3+3 design in up to 28 patients with escalating doses of 0.1, 1.0 and  $1-6 \times 10^9$  transduced T-cells to evaluate safety, including dose limiting toxicities (DLTs). The DLT observation period will be during the first 30 days following SPEAR T-cell infusion for each patient in all groups.

- For the NY-ESO study, the lymphodepletion regimen is: fludarabine (30mg/m<sup>2</sup>/day) and cyclophosphamide (600 mg/m<sup>2</sup>/day) for 3 days; same as Cohort 4 in Synovial Sarcoma study

- For the MAGE-A10 study, the lymphodepletion regimen for the first group is cyclophosphamide alone : cyclophosphamide (1800 mg/m<sup>2</sup>/day) for 2 days; subsequent groups will receive fludarabine (30mg/m<sup>2</sup>/day) and cyclophosphamide (600 mg/m<sup>2</sup>/day) for 3 days; same as Cohort 4 in Synovial Sarcoma study

- For both studies, efficacy assessed by response rate, duration of response, progression-free survival, and overall survival at weeks 4, 8, and 12, month 6, and

then every 3 months (for 2 years) and then every 6 months until confirmation of disease progression

— These studies are currently active and enrolling; as of May 18, 2017, 3 subjects have been enrolled in the NY-ESO-1 study and 2 subjects have been enrolled in the MAGE-A10 study

- ***MAGE-A10 Triple Tumor (NCT02989064):***

— Open-label first-in-human study utilizing a modified 3+3 design in up to 10 patients receiving the target dose with escalating doses of 0.1, 1.0 and 1-6 x 10<sup>9</sup> transduced T-cells to evaluate safety, including DLTs. The DLT observation period will be during the first 30 days following SPEAR T-cell infusion for each patient in all groups.

— Subjects are screened under a separate protocol (Screening Protocol: NCT02636855).

— Subjects must be HLA\*02:01 and/or \*02:06 positive and have inoperable or metastatic (advanced) urothelial “bladder” cancer, melanoma, or squamous cell head and neck tumors with MAGE-A10 expression at ≥1+ intensity in ≥10% of tumor cells by IHC; and, have received standard of care therapies and have progressive disease.

— Lymphodepletion regimen: fludarabine (30mg/m<sup>2</sup>/day) and cyclophosphamide (600 mg/m<sup>2</sup>/day) for 3 days; same as Cohort 4 in Synovial Sarcoma study

— Efficacy assessed by overall response rate, best overall response, time to response, duration of response, duration of stable disease, progression-free survival, and overall survival at weeks 6, 12, 18, and 24 weeks, and then every 3 months until confirmation of disease progression

— This study is currently active and enrolling; as of May 18, 2017, 4 subjects have been enrolled

### **Conference Call and Webcast Link for Slide Presentation**

The Company will host a live teleconference and slide presentation to discuss the updated synovial sarcoma data at 8:00 a.m. EDT (1:00 p.m. BST) tomorrow, June 6, 2017. The live webcast of the conference call will be available via the Investors section of Adaptimmune’s website at <http://adaptimmune.equisolvewebcast.com/data-update>. An archive will be available after the call at the same address. To participate in the live webinar, if preferred, please dial (866)-405-1247 (U.S. and Canada) or + 201-689-8045 (International).

### **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 licensing 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 May 10, 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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