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# Argos Therapeutics Provides Update on Immunology Data from the Phase 3 ADAPT Trial Presented at the SITC 2017 Annual Meeting

DURHAM, N.C., Nov. 11, 2017 (GLOBE NEWSWIRE) -- Argos Therapeutics, Inc. (NASDAQ:ARGS), an immuno-oncology company focused on the development and commercialization of individualized immunotherapies based on the Arcelis® precision immunotherapy technology platform, today provided an update on the immunology data from the February 2017 interim analysis of data from the ongoing Phase 3 ADAPT clinical trial evaluating Rocapuldencel-T for the treatment of metastatic renal cell carcinoma (mRCC) presented in the poster session at the 32nd Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in National Harbor, Maryland. The presentation is focused primarily upon immunology data from the ADAPT clinical trial and includes both new data and an update to data that was previously presented at the European Society of Medical Oncology Conference in September 2017 that now includes additional patients.

As background, a total of 462 patients were enrolled in the ADAPT study and randomized 2:1 between combination treatment with Rocapuldencel-T and sunitinib (combination arm) vs. sunitinib monotherapy (control arm).

Immunology data from the February 2017 interim analysis of the data from the ADAPT study reported at the SITC Conference were pre-specified and include correlations between survival and (i) the change from baseline in antigen-specific memory T-cells, (ii) the amount of IL-12 secreted by each patient's specific Rocapuldencel-T immunotherapy, and (iii) the percentage of regulatory T-cells at baseline, which was observed in both arms of the study. Of note, data for antigen-specific memory T-cells and regulatory T-cells were available only for patients enrolled at North American sites.

*Increase from Baseline in Antigen-Specific Memory T-Cells*

In subjects for whom immune response data were analyzed (n=146), the number of antigen-specific memory T-cells was found to increase only after administration of Rocapuldencel-T. In those subjects who received at least seven doses of Rocapuldencel-T (n=100), the average number of antigen-specific memory T-cells after the seventh dose was approximately double the number observed before treatment. This increase was found to be statistically significant ($p<0.0001$). Similar data on a smaller number of patients were presented at the European Society for Medical Oncology Conference in September 2017.

Additionally, for those subjects who received at least seven doses of Rocapuldencel-T, there was a statistically significant correlation between survival and the change in the number of antigen-specific memory T-cells from baseline (Spearman's Rho = 0.40; $p<0.0001$). For those 25 patients with the greatest increase in the number of antigen-specific memory T-cells from baseline, no patient deaths had been recorded as of the time of the February 2017 interim analysis.

*IL-12 Secretion by Each Patient's Specific Rocapuldencel-T Immunotherapy*

An analysis was conducted to evaluate the relationship between the amount of IL-12 secreted by each patient's specific immunotherapy and that patient's survival. Samples from patients treated with Rocapuldencel-T as of February 2017 (n=179) were divided into two groups: those with above the median amount of IL-12, and those with below the median amount of IL-12. Comparison of the Kaplan-Meier curves for these two groups revealed that those with higher than median levels of IL-12 demonstrated improved survival. Additionally, there was a statistically significant correlation between the level of IL-12 and survival (Spearman's Rho = 0.27; $p<0.0002$). There was also a statistically significant correlation between the level of IL-12 and the change from baseline in antigen-specific memory T-cells for patients who received at least seven doses of Rocapuldencel-T (n=95; Spearman's Rho = 0.43; $p<0.0001$).

*Regulatory T-Cells*

An analysis was conducted to evaluate the relationship between the percentage of regulatory T-cells at baseline and survival for patients in both arms of the trial. Samples from patients in the combination arm (n=176) were divided into two groups: those with above median percentage of regulatory T-cells at baseline, and those with below median percentage of regulatory T-cells at baseline. Comparison of the Kaplan-Meier curves for these two groups revealed that those with higher than median percentage of regulatory T-cells at baseline demonstrated improved survival. This finding was in contrast to the control arm (n=79), where a greater percentage of regulatory T-cells at baseline was associated with poorer survival. One hypothesis that could potentially explain this result is that Rocapuldencel-T may be acting to convert regulatory T-cells

to effector T-cells.

Commenting on the additional immunology data, Charles Nicolette, Chief Scientific Officer of Argos Therapeutics, noted, "As we have conducted additional analyses of the immunology data from the February 2017 interim analysis, we have been pleased to see that the data are generally supportive of our hypothesis regarding the intended mechanism of action of Rocapuldencel-T to induce an immune response against the tumor in patients with metastatic renal cell carcinoma. While we await further data from the next planned interim data analysis that we expect to be conducted during the first half of 2018, pending agreement with the FDA on a revised protocol that we plan to submit, we are encouraged to see these positive indicators of activity."

As previously reported, the February 2017 interim analysis was conducted by the ADAPT trial's Independent Data Monitoring Committee (IDMC) after 75% of the originally targeted number of 290 events (deaths) for the analysis of the primary endpoint of overall survival had occurred. At the time of the analysis, with more than half of the patients still alive in each arm and a median follow-up time of ~20 months, the IDMC concluded that the trial was unlikely to demonstrate a statistically significant improvement in median overall survival in the combination arm and recommended that the trial be discontinued for futility. However, the ADAPT trial principal investigators and Argos considered the data too immature to observe the delayed effects typically associated with immunotherapy and decided to continue the trial pending further review and analysis of the data and discussions with the U.S. Food and Drug Administration (FDA). In making this determination, Argos considered, among other factors, the degree of maturity of the data set, the mechanism of action of Rocapuldencel-T, which involves the induction of a long-term memory immune response, and the IDMC's assessment of the safety profile of Rocapuldencel-T. This determination was subsequently further supported by the extended durability of tumor responses in the combination arm, as previously reported.

Following the IDMC's interim analysis, the Company met with the FDA to discuss the ADAPT trial and the future direction of the Rocapuldencel-T program in April 2017. The FDA agreed with the Company's decision to continue the ADAPT trial, and further agreed to review a protocol amendment to extend the trial beyond the originally targeted 290 events and a revised statistical analysis plan that the Company plans to submit.

**Conference Call Information**

Argos will hold a conference call to discuss the data presented at the 32nd Annual Meeting of the Society for Immunotherapy of Cancer on Monday, November 13th at 8:30am ET. To participate by telephone, please dial (855) 433-0930 (Domestic) or (484) 756-4271 (International). The conference ID number is 9396519. Slides setting forth the data presented at the SITC 2017 Annual Meeting, and a live and archived audio webcast, will be accessible through the Investors section of the Company's website at www.argostherapeutics.com. The archived webcast will remain available on the Company's website for twelve (12) months following the call.

**About Argos Therapeutics**

Argos Therapeutics is an immuno-oncology company focused on the development and commercialization of individualized immunotherapies for the treatment of cancer and infectious diseases using its Arcelis® technology platform. Argos' most advanced product candidate, Rocapuldencel-T, is being evaluated in the pivotal ADAPT Phase 3 clinical trial for the treatment of metastatic renal cell carcinoma (mRCC). Argos is also developing a separate Arcelis®-based product candidate, AGS-004, for the treatment of human immunodeficiency virus (HIV), which is currently being evaluated in an investigator-initiated Phase 2 clinical trial aimed at HIV eradication in adult patients. Funding for the development of AGS-004 has been provided by the National Institutes of Health, the National Institute of Allergy and Infectious Diseases, and the Collaboratory of Research for AIDS Eradication.

**Forward Looking Statements**

Any statements in this press release about Argos' future expectations, plans and prospects, including statements about Argos' financial prospects, future operations and sufficiency of funds for future operations, clinical development of Argos' product candidates, expectations regarding future clinical trials and FDA activities and future expectations and plans and prospects for Argos and other statements containing the words "believes," "anticipates," "estimates," "expects," "intends," "plans," "predicts," "projects," "targets," "may," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including whether Argos' cash resources will be sufficient to fund its continuing operations for the period anticipated; whether preliminary or interim clinical data, such as the data referenced in this release, will be indicative of the final data from a clinical trial; whether results obtained in clinical trials will be indicative of results obtained in future clinical trials; whether Argos' product candidates will advance through the clinical trial process on a timely basis; whether the results of such trials will warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether Argos' product candidates will receive approval from regulatory agencies on a timely basis or

at all; whether, if product candidates obtain approval, they will be successfully distributed and marketed; whether Argos can successfully establish commercial manufacturing operations on a timely basis or at all; and other factors discussed in the "Risk Factors" section of Argos' Form 10-Q for the quarter ended September 30, 2017, which is on file with the SEC, and in other filings Argos makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent Argos' views as of the date hereof. Argos anticipates that subsequent events and developments will cause Argos' views to change. However, while Argos may elect to update these forward-looking statements at some point in the future, Argos specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Argos' views as of any date subsequent to the date hereof.

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