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# Argos Therapeutics Reports on Interim Analysis of Phase 3 ADAPT Trial Presented at ESMO 2017 Congress

DURHAM, N.C., Sept. 12, 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 reported on an update on the interim analysis of data from the ongoing Phase 3 ADAPT clinical trial evaluating Rocapuldencel-T for the treatment of metastatic renal cell carcinoma (mRCC) that was presented on September 11, 2017 by Robert Figlin, MD, Professor and Chairman, Division of Hematology and Oncology at Cedars Sinai Medical Center, and co-principal investigator of the ADAPT trial at the European Society for Medical Oncology (ESMO) 2017 Congress in Madrid, Spain.

A total of 462 patients with previously untreated advanced or metastatic renal cell carcinoma were enrolled in the ADAPT trial and randomized 2:1 between combination treatment with Rocapuldencel-T and sunitinib (combination arm) vs. sunitinib monotherapy (control arm) after undergoing cytoreductive nephrectomy.

As previously reported, as of February 3, 2017, the cut-off date for the most recent interim analysis which was conducted in February 2017, 42.7% of the 307 patients in the combination arm demonstrated an objective response by RECIST criteria, a secondary endpoint in the trial, as compared with 39.4% of the 155 patients in the control arm. Additional data from the trial reported for the first time at the ESMO Conference included data related to the duration of tumor response. Patients in the combination treatment arm who demonstrated an objective response had a median duration of response of 8.4 months compared to 6.3 months for patients in the control arm. Additionally, 16% of those patients with an objective response in the combination treatment arm had durable responses lasting at least 30 months compared to 7% of those who had an objective response in the control arm. Also of note, as of the date of the interim analysis, all of the patients in the combination arm who had achieved a duration of response of at least 30 months had maintained those responses through 36 months.

In addition, Dr. Figlin updated immune response data that had been previously reported by the Company, presenting data on 117 patients analyzed for immune response. Samples were collected from patients in the combination arm enrolled at US sites who provided consent for immune monitoring. Of the 117 patients for whom this analysis was completed, 96 (82%) met the criterion for inclusion in the pre-defined subgroup of immune responders, suggesting that Rocapuldencel-T is having its intended effect of stimulating an immune response in the majority of patients. Immune responders are defined as patients who have an increase of more than two standard deviations from the patient-specific baseline in the number of memory T cells (CD8+/CD28+/CD45RA-) at one or more time points. Of note, median overall survival at the time of the February interim analysis had not yet been reached in the subgroup of immune responders (95% CI: 30.1, -). Additionally, consistent with the mechanism of action of Rocapuldencel-T, a statistically significant correlation was observed between the increase from baseline in the number of Rocapuldencel-T-induced memory T cells (CD8+/CD28+/CD45RA-) and overall survival in patients for whom immune response data has been analyzed and who received at least seven doses of Rocapuldencel-T (including both immune responders and non-responders, n=83).

Commenting on the data, Dr. Figlin noted, "Although we did not see a benefit in median overall survival at the February 2017 interim analysis, the data set was relatively immature, with over half of the subjects in both treatment arms still alive. Additionally, for an immunotherapy agent such as Rocapuldencel-T, one might reasonably expect to see a delayed treatment effect, as evidenced by the fact that a statistically significant correlation of the immune response with survival did not emerge until patients had received at least seven doses of Rocapuldencel-T. Thus, median overall survival and other traditional measures of efficacy such as progression-free survival and objective response rate may not be the best endpoints for evaluating the potential benefit of this therapy for patients with limited treatment options, especially in light of the favorable safety and tolerability profile demonstrated to date. Instead, it may be more appropriate to evaluate this agent in light of the potential for a significant "tail-of-the-curve" effect. Thus, my co-principal investigator and I support Argos' decision to continue the ADAPT trial, and we look forward to reviewing a more mature data set at the next interim analysis, currently planned for the first half of 2018."

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 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 reported today.

Following the IDMC 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.

Dr. Figlin's complete presentation at the ESMO 2017 Congress is available for review on Argos' website at www.argostherapeutics.com. Argos plans to hold a conference call to discuss Dr. Figlin's presentation on Wednesday, September 20th at 4:30pm ET and will provide logistical information in a subsequent announcement.

**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). In addition, Rocapuldencel-T is being studied in a Phase 2 investigator-initiated clinical trial as neoadjuvant therapy for renal cell carcinoma (RCC). 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 combination with vorinostat, a latency-reversing drug, 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 the ADAPT trial and the interim data from the trial, the clinical development of Argos' product candidates 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 presented 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 June 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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