April 18, 2017

Argos Reports Interim Results of the ADAPT Trial and Provides Perspective on Decision to Continue the Trial

DURHAM, N.C., April 18, 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 interim results from its randomized, active controlled, open-label, multi-center Phase 3 ADAPT trial of Rocapuldencel-T in combination with sunitinib/standard-of-care for the treatment of newly diagnosed metastatic renal cell carcinoma (mRCC). The Company also provided perspective on its decision to continue the trial.

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). For both arms, the protocol permits switching to other standard-of-care treatments for mRCC for reasons such as intolerance to therapy or disease progression. The primary efficacy endpoint for the study is a statistically significant improvement in overall survival, with secondary efficacy endpoints evaluated to date of progression-free survival, objective response rate and disease control rate, and an exploratory efficacy endpoint of immune response. The trial was opened in January 2013 and completed enrollment in July 2015 at 107 sites across North America, Europe and Israel.

The most recent interim analysis was conducted by the Independent Data Monitoring Committee (IDMC) in February 2017 (data cut-off as of February 3, 2017) after 75% of the targeted number of 290 events (deaths) for the analysis of the primary endpoint of overall survival had occurred. In accordance with the statistical analysis plan, median overall survival was estimated using the Kaplan-Meier method. At the time of the interim analysis, the estimated median overall survival for the combination arm was 27.7 months (95% Confidence Interval (CI): 23.0, 35.9) compared to 32.4 months (95% CI: 22.5, -) for the control arm. The hazard ratio was 1.10 (95% CI: 0.83, 1.46), which was greater than the pre-defined futility boundary for the final interim analysis of 0.98. As a result, the IDMC recommended that the study be discontinued for futility. The IDMC concluded that the study was unlikely to demonstrate a statistically significant improvement in overall survival in the combination arm, utilizing the intent-to-treat population, the primary endpoint of the study. The IDMC also noted that Rocapuldencel-T was generally well-tolerated in the trial.

As previously reported, notwithstanding the IDMC recommendation, the Company determined to continue to conduct the trial pending further review and analysis of the data and discussions with the FDA. This determination was made after discussion of the results of the interim analysis with the ADAPT trial principal investigators, Robert Figlin, MD (Cedars Sinai) and Christopher Wood, MD (MD Anderson Cancer Center). 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 long-term memory immune responses, and the IDMC's assessment of the safety profile of Rocapuldencel-T. Of note, at the time of the IDMC's February interim analysis, the median duration of follow-up was 20.0 months and more than half the patients in both treatment groups were still alive.

Subsequent to the IDMC meeting, to explore the hypothesis that longer follow-up time may provide useful information to identify a potential beneficial effect of Rocapuldencel-T, the Company conducted a *post-hoc* subgroup analysis of overall survival in the first third of patients enrolled in the study (n=154). In these patients, for whom generally the longest follow-up data was available, the estimated median overall survival for the combination arm was 30.1 months (95% CI: 23.3, -) compared to 22.2 months (95% CI: 17.2, -) for the control arm. The hazard ratio in this *post-hoc* subgroup analysis was 0.88 (95% CI: 0.56, 1.36).

In addition, also subsequent to the IDMC meeting, the Company began conducting a pre-defined analysis of immune responses, an exploratory efficacy endpoint, using multi-parametric flow cytometry. Data available as of March 31, 2017 included 109 of the 190 samples from patients in the combination arm, with analysis of the remaining samples ongoing. Samples were collected from patients in the combination arm enrolled at US sites who provided consent for immune monitoring. Of the 109 subjects for whom this analysis was completed, 96 (88%) 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=72).

The Company continues to analyze the data from the trial and plans to meet with the FDA in May 2017, but currently believes based on the data it has reviewed that the trial should be continued until completion. Based on these analyses and discussions, the Company will make a determination as to the next steps for the Rocapuldencel-T clinical program.

Conference Call and Webcast Details

Argos executive management will host a conference call beginning at 4:30 p.m. Eastern Time today to discuss these results and to answer questions. Argos management will be presenting slides during the conference call and the slides will be viewable under the Investors section of the Company's website at www.argostherapeutics.com. To participate by telephone, please dial (855) 433-0930 (Domestic) or (484) 756-4271 (International). The conference ID number is 8568073. A live and archived audio webcast with the accompanying slide presentation can be accessed through the Investors section of the Company's website at www.argostherapeutics.com. The archived webcast and accompanying slide presentation will remain available on the Company's website for twelve (12) months following the call.

About the Arcelis® Technology Platform

Arcelis® is a precision immunotherapy technology that captures both mutated and variant antigens that are specific to each patient's individual disease. It is designed to overcome immunosuppression by producing a specifically targeted, durable memory T cell response without adjuvants that may be associated with toxicity. The technology is potentially applicable to the treatment of a wide range of different cancers and infectious diseases, and is designed to overcome many of the manufacturing and commercialization challenges that have impeded other personalized immunotherapies. The Arcelis® process uses only a small disease sample or biopsy as the source of disease-specific antigens, and the patient's own dendritic cells, which are optimized from cells collected by a single leukapheresis procedure. The proprietary process uses RNA isolated from the patient's disease sample to program dendritic cells to target disease-specific antigens. These activated, antigen-loaded dendritic cells are then formulated with the patient's plasma, and administered via intradermal injection as an individualized immunotherapy.

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 an investigator-initiated Phase 2 clinical trial aimed at HIV eradication in adult patients.

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, Argos' anticipated meeting with the FDA, 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 periods anticipated and through completion of the trial; the impact of the planned analysis of the data and discussions with the FDA on the development of rocapuldencel-T; the impact of the recommendation of the IDMC on the continuation of the ADAPT trial; whether preliminary or interim clinical data such as the interim data reported 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-K for the year ended December 31, 2016, 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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