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Argos Provides Update on its ADAPT Trial Following Meeting with FDA

DURHAM, N.C., May 10, 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 ADAPT trial, a randomized, active controlled, open-label, multi-center Phase 3 trial of Rocapuldencel-T in combination with sunitinib/standard-of-care for the treatment of newly diagnosed metastatic renal cell carcinoma (mRCC), following a meeting with the FDA.

As previously reported, the Company has continued to conduct the ADAPT trial notwithstanding the recommendation by the Independent Data Monitoring Committee in February 2017 to terminate the trial for futility. 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. 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.

The Company submitted information related to its analysis of the interim data to the FDA and met with the FDA to discuss the future direction of the ADAPT trial and the Rocapuldencel-T development program. Participating in the meeting along with representatives from the Company were Robert Figlin, MD, Chairman of Hematology Oncology and Professor of Medicine, Cedars Sinai Medical Center; Nizar Tannir, MD, Professor and Deputy Chairman, Department of Genitourinary Medical Oncology, MD Anderson Cancer Center; and Gary Koch, PhD, Professor of Biostatistics, University of North Carolina.

The FDA agreed with the Company's plan to continue the trial in accordance with the current protocol to 290 events, the pre-specified number of events at which the analysis of overall survival, the primary endpoint, is to be conducted. The Company believes that 290 events will have occurred by late 2017 or early 2018. The Company also proposed to submit, and the FDA agreed to review, a protocol amendment to increase the pre-specified number of events for the primary analysis of overall survival beyond 290 events, which the Company believes could enhance its ability to detect whether Rocapuldencel-T has a delayed treatment effect. The Company can extend the study past 290 events without needing to enroll additional patients.

As previously reported, the Company has analyzed interim data from a predefined subset of patients who demonstrated an immune response to Rocapuldencel-T at 48 weeks, whose immune response is consistent with the mechanism of action of the therapy and correlates with survival, suggesting that the treatment is biologically active. Analysis of the data from the ADAPT trial, including immune response data, remains ongoing. The Company expects to provide further updates on the future direction of the ADAPT trial and the Rocapuldencel-T program following further analysis of the data from the trial and further discussions with the FDA.

"We are pleased to be able to continue the ADAPT trial," noted Robert Figlin, MD, principal investigator for the trial. "We believe that Rocapuldencel-T may offer patients and their physicians an important new option for the treatment of mRCC, a disease that remains an area of high unmet medical need. By amending the protocol to extend the ADAPT trial, we believe we can potentially increase the likelihood of detecting a treatment effect, if one exists, given that immunotherapy is expected to result in a delayed treatment effect. We appreciate the collaborative efforts of the FDA as we seek to determine the potential utility of Rocapuldencel-T in the treatment of this difficult disease."

"We remain committed to the clinical development of Rocapuldencel-T, and look forward to providing additional updates on the ADAPT trial and the Rocapuldencel-T development program moving forward," noted Jeff Abbey, CEO of Argos. "We appreciate the continued commitment of the investigators and patients in the ADAPT trial as we continue to explore the potential benefit of this unique therapy."

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 discussions 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 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-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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