



February 22, 2017

Independent Data Monitoring Committee Recommends Discontinuation of the ADAPT Phase 3 Clinical Trial of Rocapuldencel-T in Metastatic Renal Cell Carcinoma for Futility Following Its Planned Interim Data Review

-Company to host conference call today, February 22, 2017 at 8:30am EST-

DURHAM, N.C., Feb. 22, 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 announced that the Independent Data Monitoring Committee (IDMC) for the company's pivotal **Phase 3 ADAPT** clinical trial of **rocapuldencel-T** in combination with sunitinib/standard-of-care for the treatment of metastatic renal cell carcinoma (mRCC) has recommended that the study be discontinued for futility based on its planned interim data analysis. The IDMC concluded that the study was unlikely to demonstrate a statistically significant improvement in overall survival in the combination treatment arm, utilizing the intent-to-treat population, the primary endpoint of the study. The IDMC noted that **rocapuldencel-T** was generally well-tolerated in the trial.

In conjunction with its clinical and scientific advisors, the company is analyzing the preliminary **ADAPT** trial data set and plans to discuss the data with the U.S. Food and Drug Administration (FDA). The company plans to leave the **ADAPT** trial open while the company conducts its ongoing data review and discussions with FDA. Based on these analyses and discussions, the company will make a determination as to the next steps for the **rocapuldencel-T** clinical program.

"We are extremely disappointed with these results, which included seventy-five percent of the targeted events needed to permit the primary analysis and assessment of overall survival in the study," said Jeff Abbey, president and chief executive officer of Argos Therapeutics. "We sincerely appreciate the patients and investigators who have participated in the **ADAPT** Phase 3 trial, and remain convinced in the ability of precision immunotherapy to improve the lives of patients."

Rocapuldencel-T is an individualized immunotherapy that is designed to capture mutated and variant antigens that are specific to each patient's tumor and induce an immune response targeting that patient's tumor antigens. The randomized **Phase 3 ADAPT** trial evaluating **rocapuldencel-T** plus sunitinib/standard-of-care therapy versus standard-of-care therapy alone in newly diagnosed mRCC patients was opened in January 2013 and completed enrollment in July 2015. A total of 462 mRCC patients were randomized to the trial. The primary endpoint of the trial is a statistically significant improvement in overall survival.

Conference Call and Webcast Details

Argos executive management will host a conference call today beginning at 8:30am EST.

To participate by telephone, please dial (855) 433-0930 (Domestic) or (484) 756-4271 (International). The conference ID number is 77486645. A live and archived audio webcast can be accessed 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 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 **Phase 2** investigator-initiated clinical trials as neoadjuvant therapy for renal cell carcinoma (RCC) and bladder?. 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 Argos's planned analysis of the data from the ADAPT 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; 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 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, 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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