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Argos Therapeutics Reports Results of Interim Analysis of the ADAPT Trial and Announces Review of Strategic Alternatives

- Company to terminate the ADAPT study —
- Company has retained Stifel to provide advice on possible strategic alternatives —
- Trading in the common stock to be transferred from Nasdaq to the OTCQB Venture Market -

DURHAM, N.C., April 19, 2018 (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. Based on these results, the Company has decided to discontinue the trial.

As previously reported, 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. The Company recently submitted a protocol amendment to the U.S. Food and Drug Administration providing for four co-primary endpoints focused on various measures of survival. Based upon review of the interim data, the Company does not believe that it would achieve these endpoints if the trial were to be continued. After consulting with the principal investigators of the trial, the Company has therefore decided to discontinue the trial and has informed the FDA of its decision.

The most recent interim analysis was conducted after 51 new events (deaths) had occurred since the time of the February 2017 interim analysis. Median overall survival for the intent-to-treat patient population, one of the four co-primary endpoints, was estimated using the Kaplan-Meier method. The estimated median overall survival for the combination arm was 28.2 months (95% Confidence Interval (CI): 23.4, 35.2) compared to 31.2 months (95% CI: 23.0, 44.5) for the control arm. The hazard ratio was 1.10 (95% CI: 0.85, 1.42). The two other co-primary endpoints that were evaluated at this time, including overall survival for the patients who remained alive at the time of the February 2017 interim analysis and overall survival for all patients for whom at least 12 months of follow-up was available, also did not demonstrate a favorable result. A fourth endpoint, five-year survival, was not evaluated because there was insufficient data at this time to perform this analysis.

Based on a review of the status of its internal programs, resources and capabilities, Argos plans to explore a wide range of strategic alternatives that may include a potential merger or sale of the Company, among other potential alternatives that could maximize both near and long-term value for our shareholders. The Company has retained Stifel, Nicolaus & Company, Incorporated to serve as its financial advisor in the process.

Argos does not have a defined timeline for the exploration of strategic alternatives and is not confirming that the process will result in any strategic alternative being announced or consummated. Argos does not intend to discuss or disclose further developments during this process unless and until its Board of Directors has approved a specific action or otherwise determined that further disclosure is appropriate.

Argos also today reported that it does not expect to regain compliance with The Nasdaq Capital Market continued listing requirements by the April 24, 2018 deadline. As a result, Argos expects that its common stock will be delisted from The Nasdaq Capital Market and that trading in the Company's common stock on The Nasdaq Capital Market will be suspended effective at the open of business on April 23, 2018. The Company has filed an application to transfer trading and quotation of its common stock to the OTCQB® Venture Market, operated by OTC Markets Group Inc., under its current trading symbol "ARGS," effective as of April 23, 2018. Quotation and trading information for the common stock will be available on www.otcm Markets.com.

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 is

developing an 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; what the impact of the transfer of Argos' common stock to the OTCQB® will have on the trading of Argos' common stock and ability to raise funds; whether preliminary or interim clinical data 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 FDA 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, 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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