February 5, 2018

Argos Obtains Option to License PD1 Checkpoint Inhibitors

- Data showing synergy between PD1 checkpoint inhibition and analogue of Rocapuldencel-T in a preclinical model of renal carcinoma presented at ASCO-SITC -

- Company to host a conference call on Tuesday, February 6, 2018 at 8:30 a.m. ET -

DURHAM, N.C., Feb. 05, 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 announced that it has entered into an option agreement with Pharmstandard International, S.A. and Actigen Limited under which the Company has an option to license a group of fully human anti-PD1 monoclonal antibodies (PD1 checkpoint inhibitors) and related technology.

Results of a preclinical study of a murine analogue of Rocapuldencel-T (Roca-T), the Company's investigational dendritic cell therapy for the treatment of metastatic renal cell carcinoma (mRCC), in various combinations with a murine PD1 monoclonal antibody (anti-mPD1) and sunitinib in a mouse model of renal cell carcinoma were recently presented at the ASCO-SITC Clinical Immuno-Oncology Symposium. In this model, murine dendritic cell precursors were processed in a similar manner to that by which human monocytes are processed to manufacture Roca-T. Multiple combination dosing strategies were tested, all of which included treatment with sunitinib. Anti-mPD1 was tested both with administration two days following tumor inoculation (therapeutic administration) and with administration six days prior to tumor inoculation (prophylactic administration).

The dosing regimen consisting of dendritic cells followed by anti-mPD1 (therapeutic administration) and sunitinib showed a substantial synergistic effect, with median overall survival (mOS) of 67 days. This compared favorably with the regimen evaluating anti-mPD1 (therapeutic administration) and sunitinib (mOS of 39 days) and with dendritic cells followed by sunitinib (mOS of 46 days). Of note, the timing of anti-mPD1 administration was found to be important, as the regimen consisting of dendritic cells in combination with anti-mPD1 (prophylactic administration) and sunitinib showed a mOS of 48 days. Control mice had a mOS of 29 days.

Of note, histologic evaluation in these studies revealed that murine dendritic cells with similar properties to Roca-T resulted in recruitment and migration of lymphocytes into the tumor microenvironment and an increase in CD8+CD28+CD45RA- memory T cells. An increase in this same type of memory T cell after seven doses of Roca-T, as measured in blood samples, correlated with longer survival in the Company's phase 3 ADAPT clinical trial of Roca-T in mRCC patients. These findings suggest that the mechanism of action of the murine analogue of Roca-T in this model is similar to that of Roca-T in man.

"Data from this study support the rationale for combining dendritic cell therapy with a PD1 checkpoint inhibitor in the treatment of renal cell carcinoma," noted Charles Nicolette, chief scientific officer, Argos Therapeutics. "These data also demonstrate the importance of the administration sequence for active immunotherapy with a murine analogue of Roca-T and a PD1 checkpoint inhibitor, along with sunitinib, and suggest that the cellular immune response must be initiated and established prior to administration of anti-mPD1 and sunitinib in order to achieve synergy in this murine model of mRCC."

Jeff Abbey, president and chief executive officer, Argos Therapeutics, added "We are pleased to have secured an option to license a group of fully human PD1 antibodies from Pharmstandard and Actigen. Provided sufficient funding is available, we expect to exercise this option and undertake the necessary preclinical studies in order to initiate clinical development of Roca-T in combination with a PD1 antibody."

Conference Call Logistics

The Company will host a conference call beginning at 8:30 a.m. Eastern Time on Tuesday, February 6, 2018. To participate by telephone, please dial (855) 433-0930 (Domestic) or (484) 756-4271 (International). The conference ID number is 8327219. 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 twelve (12) months following the call.

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). 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 clinical development of Argos' product candidates 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 will exercise its option under the Option Agreement or, if it does, whether it will reach agreement with Pharmstandard and Actigen upon the terms of a license; whether Argos' cash resources will be sufficient to fund its continuing operations for the period anticipated; whether preliminary or interim clinical data will be indicative of the final data from a clinical trial; whether results obtained in preclinical studies or early 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, 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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