



Argos Therapeutics Reports Fourth Quarter and Full-Year 2015 Financial Results and Operational Highlights

- *Completed Patient Enrollment in Pivotal Phase 3 ADAPT Clinical Trial of AGS-003 in July 2015 –*
- *Independent Data Monitoring Committee (IDMC) Recommended Continuation of Pivotal Phase 3 ADAPT Clinical Trial of AGS-003 Following Data Reviews in June and December 2015 -*
- *Established Scientific Advisory Board in July 2015 –*
- *Early stage RCC trial of AGS-003 Commenced at Roswell Park Cancer Institute in July 2015 -*
- *Conference Call and Webcast Today, March 29th, at 4:30 p.m. ET -*

DURHAM, N.C., March 29, 2015 (GLOBE NEWSWIRE) -- Argos Therapeutics, Inc. (Nasdaq:ARGS), an immuno-oncology company focused on the development and commercialization of truly individualized immunotherapies for the treatment of cancer based on the **Arcelis®** technology platform, today reported financial results for the fourth quarter and full-year ended December 31, 2015 and provided an update on the Company's clinical programs.

"In the past year we have achieved a number of important milestones, both from a clinical and a corporate perspective," said Jeff Abbey, president and chief executive officer. "In July, we successfully completed enrollment of our Phase 3 ADAPT trial of AGS-003 in metastatic renal cell carcinoma. The ADAPT trial also successfully navigated two data analyses, in June and December, by the Independent Data Monitoring Committee (IDMC). The next review of data by the IDMC is scheduled to take place in June of 2016. We expect a subsequent IDMC meeting and review of data to occur in late 2016 and anticipate having a sufficient number of events from the ADAPT trial to permit the primary analysis and assessment of overall survival to occur in the first half of 2017."

"We also successfully formed our Scientific Advisory Board in 2015. These highly-regarded individuals are a significant resource as we continue to advance our clinical development programs," said Mr. Abbey. "Additionally, we also saw the initiation of an early stage investigator-sponsored RCC trial of AGS-003 at Roswell Park Cancer Institute in Buffalo, NY. With this study, for the first time we will assess the effects of AGS-003 in patients with kidney cancer that has not spread to nearby lymph nodes or other parts of the body. As we have emphasized, this is an important opportunity to manufacture AGS-003 using a needle biopsy procedure for tumor collection prior to surgery, while directly studying immune changes within the primary tumor before and after administration of AGS-003."

Mr. Abbey continued, "With the accomplishments of 2015 and those we have already announced in 2016, including the hiring of Dr. Lee Allen as our chief medical officer, the initiation of an investigator-sponsored trial of AGS-003 in non-small cell lung cancer, and our recently announced financing of up to \$60 million, which, if it is funded in full, should fund our operations into the second quarter of 2017 when we anticipate final data of the ADAPT trial, we believe we have taken many of the necessary steps to be successful."



2015 Operational Highlights:

- In June and December 2015, following data reviews, the IDMC recommended continuation of the pivotal Phase 3 ADAPT clinical trial of AGS-003 in combination with standard targeted therapy for the treatment of mRCC
- In July 2015, the ADAPT clinical trial reached its enrollment goal of at least 450 randomized patients
 - 462 patients enrolled
 - The breakdown of patients enrolled in the ADAPT study is approximately 73% intermediate risk patients, meaning they present with 1 or 2 risk factors at diagnosis, and approximately 27% poor risk patients, meaning they present with either 3 or 4 risk factors at diagnosis
- In July 2015, the Company established a Scientific Advisory Board (SAB)
 - Inaugural members include distinguished oncologists and immunologists to provide perspectives in further research and development of AGS-003
- In July 2015, an investigator-initiated early stage RCC trial of AGS-003 commenced at Roswell Park Cancer Institute in Buffalo, NY
 - Preliminary data expected in the fourth quarter of 2015

Selected Fourth Quarter and Full-Year 2015 Financial Results

Net loss attributable to common stockholders for the three months ended December 31, 2015 was \$17.6 million, or \$0.84 per share, compared to a net loss attributable to common stockholders of \$16.2 million, or \$0.83 per share, for the same period in 2014. Net loss attributable to common stockholders for the full-year ended December 31, 2015 was \$74.8 million, or \$3.66 per share, compared to a net loss attributable to common stockholders of \$54.2 million, or \$3.12 per share, for the same period in 2014.

Revenue for the three months ended December 31, 2015 totaled \$0.1 million compared to \$0.3 million for the same period in 2014. Revenue for the full-year ended December 31, 2015 totaled \$0.5 million compared to \$2.0 million for the same period in 2014.

Research and development expense for the three months ended December 31, 2015 totaled \$14.0 million compared to \$13.5 million for the same period in 2014. Research and development expense for the full-year ended December 31, 2015 totaled \$62.1 million compared to \$45.5 million for the same period in 2014.

General and administrative expense for the three months ended December 31, 2015 totaled \$3.0 million compared to \$2.5 million for the same period in 2014. General and administrative expense for the full-year ended December 31, 2015 totaled \$11.0 million compared to \$8.6 million for the same period in 2014.

As of December 31, 2015, Argos' cash, cash equivalents and short-term investments totaled \$7.2 million compared to \$56.2 million as of December 31, 2014.



Conference Call and Webcast Details

Argos executive management will host a conference call beginning at 4:30p.m. Eastern Time today to discuss these results and to answer questions.

To participate by telephone, please dial (855) 433-0930 (Domestic) or (484) 756-4271 (International). The conference ID number is 77643066. 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 the Arcelis® Technology Platform

Arcelis® is a truly personalized immunotherapy technology that captures mutated and variant antigens that are specific to each patient's disease. It is designed to overcome immunosuppression by producing a durable memory T-cell response without adjuvants that may be associated with toxicity. The technology is potentially applicable to a wide range of different cancers, and is designed to overcome many of the manufacturing and commercialization challenges that have impeded other personalized cancer immunotherapies. The **Arcelis®** process uses only a small tumor or blood sample 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. The activated, antigen-loaded dendritic cells are then formulated with the patient's plasma and administered via intradermal injection.

About Argos Therapeutics

Argos Therapeutics is an immuno-oncology company focused on the development and commercialization of truly individualized immunotherapies for the treatment of cancer using its Arcelis® technology platform. Argos' most advanced product candidate, **AGS-003**, 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 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 Argos and other statements containing the words "believes," "anticipates," "plans," "expects," 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 these forward-looking statements as a result of various important factors, including whether Argos' cash resources will be sufficient to fund our continuing operations for the period anticipated; 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; and other factors discussed in the “Risk Factors” section of Argos’ Annual Report on Form 10-Q for the quarter ended September 30, 2015 and other filings we may with the SEC from time to time. In addition, the forward-looking statements included in this press release represent Argos’ views as of March 29, 2016. 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 March 29, 2016.

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ARGOS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Revenue	\$ 73,818	\$ 303,453	\$ 518,329	\$ 1,974,019
Operating expenses				
Research and development.....	13,975,602	13,459,178	62,054,823	45,498,916
General and administrative	3,041,054	2,480,025	11,011,011	8,599,359
Total operating expenses	17,016,656	15,939,203	73,065,834	54,098,275
Operating loss	(16,942,838)	(15,635,750)	(72,547,505)	(52,124,256)
Interest expense	(618,292)	(597,335)	(2,263,599)	(1,123,579)
Other income (expense), net	2,210	12,675	22,583	(58,103)
Net loss	(17,558,920)	(16,220,410)	(74,788,521)	(53,305,938)
Accretion of redeemable convertible preferred stock	—	—	—	(863,226)
Net loss attributable to common stockholders	\$ (17,558,920)	\$ (16,220,410)	\$ (74,788,521)	\$ (54,169,164)
Net loss attributable to common stockholders per share, basic and diluted	\$ (0.84)	\$ (0.83)	\$ (3.66)	\$ (3.12)
Weighted average shares outstanding, basic and diluted	20,823,456	19,656,209	20,457,245	17,367,665



ARGOS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2015	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	\$ 6,163,144	\$ 37,223,590
Short-term investments	1,003,160	19,016,347
Restricted cash and other current assets	1,647,494	1,277,366
Total current assets	8,813,798	57,517,303
Property and equipment, net.....	22,306,384	5,513,555
Other assets	11,020	1,336,020
Total assets	<u>\$ 31,131,202</u>	<u>\$ 64,366,878</u>
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities		
Accounts payable	\$ 2,907,683	\$ 1,860,491
Accrued expenses.....	3,676,846	1,405,378
Current portion of notes payable	1,578,284	30,885
Total current liabilities.....	8,162,813	3,296,754
Long-term portion of notes payable	30,821,761	19,796,545
Long-term portion of manufacturing research and development obligation.....	7,777,436	3,475,552
Long-term portion of facility lease obligation	7,249,627	3,380,223
Deferred liabilities.....	5,321,000	3,066,000
Total stockholders' (deficit) equity	(28,201,435)	31,351,804
Total liabilities and stockholders' (deficit) equity.....	<u>\$ 31,131,202</u>	<u>\$ 64,366,878</u>