

Argos Therapeutics (ARGS)

Overweight

Renal Cell at ASCO – Post Data KOL Review Call

CONCLUSION

In this note we preview some of what we believe are the most interesting presentations at ASCO'14 for emerging treatment of mRCC (metastatic renal cell carcinoma). Considering our current coverage, we are focused on mRCC given the presentations we anticipate by Argos and potential relevance for its ongoing Phase III for its cancer vaccine AGS-003 in mRCC, the ADAPT study. Argos will have two presentations, one on Monday, June 2nd (abstract TPS4599) will update progress with ADAPT and another on Friday, May 30th (4524) examines efficacy and immunological correlates from the Phase II study of '003, particularly in poor-risk patients, outlined below. In addition, we plan to host a physician-expert call on RCC following the meeting to discuss the key takeaways on mRCC from ASCO'14; invite to follow.

- **Argos presentations should provide some color on '003 in mRCC.** The exceptional survival results (mOS of 57 months in intermediate risk patients) have been previously discussed. Thus we expect the presentation on updated Phase II data to pretty much tell us what we already know, that '003 plus Sutent has produced compelling survival advantage. Most meaningful, however, might be additional data on the long-term survivors. We hope to see additional data on the correlation between memory T-cells (CD8+, CD28+) and survival and progression. Most important for the ADAPT Phase III, we expect, may be the enrollment of intermediate risk patients, as this is where Argos expects to see the greatest benefit over Sutent alone. Recall that Argos plans to complete enrollment by year-end with interim futility and efficacy analyses conducted in 2015. We anticipate there should be low levels of tumor heterogeneity as the ASCO abstract indicates ~25% of screened patients have been excluded for lacking clear-cell histology.

- **Other vaccine studies in mRCC**, as well as Argos' presentations, are outlined in Exhibit 1. Most notable and relevant to Argos, in our view, may be a Phase I/II study from Immunicum AG (abstract 3085). That group is taking non-patient-derived dendritic cells (DCs) and activating them, then injecting them into the tumor. In this study, the DCs were injected into mRCC approximately 2 weeks prior to nephrectomy. The abstract discloses 9 of 11 evaluated patients (12 enrolled) had anti-tumor T-cell responses and 2 of 5 poor-prognosis (Heng criteria) patients had survived over 17 months without targeted therapy. More treatment options and data on effectiveness is a positive for the field, however we continue to favor Argos's patient- and tumor-specific vaccine approach over less specific designs.

RISKS TO ACHIEVEMENT OF PRICE TARGET

Failure of AGS-003 in mRCC Phase III or other studies.

COMPANY DESCRIPTION

Argos Therapeutics develops dendritic cell vaccines for oncology and infectious diseases.

PRICE: US\$8.27

TARGET: US\$18.00

DCF of AGS-003 in metastatic renal cell carcinoma in the U.S. + a technology/pipeline value of ~\$5/share

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Changes	Previous	Current
Rating	—	Overweight
Price Tgt	—	US\$18.00
FY14E Rev (mil)	—	US\$6.8
FY15E Rev (mil)	—	US\$0.0
FY14E EPS	—	US\$(3.36)
FY15E EPS	—	US\$(4.00)
52-Week High / Low	US\$13.74 / US\$7.97	
Shares Out (mil)	19.9	
Market Cap. (mil)	US\$164.6	
Avg Daily Vol (ooo)	72	
Book Value/Share	US\$6.93	
Net Cash Per Share	US\$8.04	
Debt to Total Capital	0%	
Div (ann)	NA	
Fiscal Year End	Dec	

Price Performance - 1 Year



Source: Bloomberg

YEAR	REVENUE (US\$ m)						EARNINGS PER SHARE (US\$)					
	Mar	Jun	Sep	Dec	FY	FY RM	Mar	Jun	Sep	Dec	FY	FY P/E
2013A	—	—	—	0.7	4.4	37.4x	—	—	—	(36.19)	(147.37)	NM
2014E	0.8A	2.0	2.0	2.0	6.8	24.2x	(1.05)A	(0.77)	(0.77)	(0.77)	(3.36)	NM
2015E	—	—	—	—	0.0	NA	—	—	—	—	(4.00)	NM

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Other interesting mRCC presentations. The diversity of presentations include characterization of less common RCC types like non-clear cell and sarcomatoid, which we do not cover here. Also, there are a number of investigations into biomarkers to better define patient populations and possibly responders and more finely defined subgroups such as, for example, MSKCC poor-responders (Exhibit 2). We don't discern anything directly relevant to Argos, however abstract 4531 looking at biomarkers from a failed study of everolimus, abstract 4533 looking at responses to 1st-line Sutent based on VEGFR polymorphisms, and abstract 4503 looking at genetic impact on responses to Sutent or Votrient may be relevant in the future. Investors may also want to check out a review of ongoing clinical trials in RCC (abstract #e15542, publication only) which should provide a useful overview.

Increased evidence for role of immune function in mRCC. Immunomodulation continues to be an active space (Exhibit 3). A number of presentations examining targeting of the PD-1/PD-L1 pathway in mRCC are to be presented at the meeting. Most notable, we think, could be a Phase II of nivolumab (abstract 5009) which will update survival numbers at higher doses (3 and 10 mg/kg) at the meeting. A Phase I of nivolumab plus Sutent or Votrient is also worth noting (abstract 5010), particularly with regard to safety we believe, and updated follow up is to be presented at the meeting. Lastly, and again with a view to potential future combinations with vaccines such as Argos's '003, we note a immune biomarker study looking at cytokine responses and tumor-infiltrating T-cells in mRCC patients treated with nivolumab (abstract 5012). Notably, CD8+ infiltrates increased by 88% (61-257% range) at cycle 2 of nivolumab. This could prove to be a powerful approach to boosting the effectiveness of T-cell priming vaccines such as '003, we believe.

Exhibit 1

VACCINE-RELATED PRESENTATIONS FOR MRCC AT ASCO14

Authors/sponsors	Title	Sub-category:	Category:	Abstract No:	Type:	Time:	Location:
Argos	Long-term survival in unfavorable-risk mRCC patients treated with a combination of autologous immunotherapy (AGS-003) plus sunitinib.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	4524	Poster Highlights Session	Friday May 30, 1:00 PM to 4:00 PM & Friday May 30, 4:30 PM to 5:45 PM	S102 & S100bc
Immunicum AB	Intratumoral vaccination with activated allogeneic dendritic cells in patients with newly diagnosed metastatic renal cell carcinoma (mRCC).	Vaccines	Developmental Therapeutics - Immunotherapy	3085	General Poster Session	Sunday June 1, 8:00 AM to 11:45 AM	S Hall A2
Inovio	Synthetic IL-33 DNA as anti-tumor adjuvant in vivo.	Vaccines	Developmental Therapeutics - Immunotherapy	3098	General Poster Session	Sunday June 1, 8:00 AM to 11:45 AM	S Hall A2
Argos	Enrollment insights in the synchronous mRCC population: An update from the ongoing ADAPT* phase 3 study experience.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	TPS4599	General Poster Session	Monday June 2, 1:15 PM to 5:00 PM	S Hall A2
Charité University Medicine	Gene expression profiling in renal cell cancer (RCC) during tumor vaccination with a gene-modified allogeneic cancer vaccine: Tumor-induced immunosuppression and a key role for NF-κB.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	e15555	Publication only abstract	NA	NA
Mologen AG	Final results of patients with metastatic renal cell carcinoma treated with MGN1601 in the ASET study.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	e15590	Publication only abstract	NA	NA

Source: ASCO.org and Piper Jaffray

Exhibit 2

OTHER INTERESTING MRCC ABSTRACTS (MAINLY BIOMARKERS) AT ASCO14

Authors/sponsors	Title	Sub-category:	Category:	Abstract No:	Type:	Time:	Location:
Novartis, MSKCC	Identification and validation of predictive biomarkers (BM) for everolimus (EVE) in metastatic renal cell carcinoma: Analysis of 442 patients on RECORD-3.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	4531	Poster Highlights Session	Friday May 30, 1:00 PM to 4:00 PM & Friday May 30, 4:30 PM to 5:45 PM	S102 & S100bc
Multiple academic	Prognostic and predictive tumor-based biomarkers in patients (pts) with advanced renal cell carcinoma (RCC) treated with interferon alpha (IFN) with or without bevacizumab (Bev): Results from CALGB (Alliance) 90206.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	4532	Poster Highlights Session	Friday May 30, 1:00 PM to 4:00 PM & Friday May 30, 4:30 PM to 5:45 PM	S102 & S100bc
Università Politecnica delle Marche	VEGF and VEGFRs polymorphisms analysis in advanced renal cell carcinoma tissues: Is heterogeneity ever the answer?	Kidney Cancer	Genitourinary (Nonprostate) Cancer	4533	Poster Highlights Session	Friday May 30, 1:00 PM to 4:00 PM & Friday May 30, 4:30 PM to 5:45 PM	S102 & S100bc
GSK, multiple academic	Genome-wide association study (GWAS) of efficacy and safety endpoints in pazopanib- or sunitinib-treated patients with renal cell carcinoma (RCC).	Kidney Cancer	Genitourinary (Nonprostate) Cancer	4503	Oral Abstract Session	Monday June 2, 9:45 AM to 12:45 PM	E Hall D1
UAB	Comprehensive functional kinase profiling to classify clear cell (cc)-renal cell carcinoma (RCC).	Kidney Cancer	Genitourinary (Nonprostate) Cancer	4572	General Poster Session	Monday June 2, 1:15 PM to 5:00 PM	S Hall A2
International mRCC Database Consortium	The impact of body mass index (BMI) on treatment outcome of targeted therapy in metastatic renal cell carcinoma (mRCC): Results from the International Metastatic Renal Cell Cancer Database Consortium.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	4576	General Poster Session	Monday June 2, 1:15 PM to 5:00 PM	S Hall A2
H. Lee Moffitt Cancer Center	Molecular subtypes of clear cell renal cell carcinoma: Impact of diabetes mellitus, metformin, and immunotherapy on patient outcomes.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	4579	General Poster Session	Monday June 2, 1:15 PM to 5:00 PM	S Hall A2
Dana-Farber and other academic	A phase II biomarker trial of everolimus in patients with advanced renal cell carcinoma (08-313).	Kidney Cancer	Genitourinary (Nonprostate) Cancer	e15565	Publication only abstract	NA	NA
OncoMax	FGFR1 overexpression and anti-FGFR compound sensitivity in renal cell carcinoma.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	e15544	Publication only abstract	NA	NA
University of Wisconsin	Predictive and pharmacodynamic biomarkers of kinase inhibitors in renal cell carcinoma circulating tumor cells using the versa platform.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	e15600	Publication only abstract	NA	NA
Stanford	Timing of angiotensin system inhibitor use and overall survival in patients on tyrosine kinase inhibitors for renal cell carcinoma.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	e15587	Publication only abstract	NA	NA
Spanish Oncology Genitourinary Group	Prospective assessment of circulating endothelial cells (CECs) as markers of activity of first-line treatment in advanced clear cell renal cell carcinoma (CCRCC): The CIRCLIS study (SOGUG 2011-01).	Kidney Cancer	Genitourinary (Nonprostate) Cancer	e22019	Publication only abstract	NA	NA

Source: ASCO.org and Piper Jaffray

Exhibit 3

IMMUNOMODULATION & MRCC ABSTRACTS AT ASCO14

Authors/sponsors	Title	Sub-category:	Category:	Abstract No:	Type:	Time:	Location:
BMS, MSKCC, other academic	Nivolumab for metastatic renal cell carcinoma (mRCC): Results of a randomized, dose-ranging phase II trial.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	5009	Clinical Science Symposium	Saturday May 31, 3:00 PM to 4:30 PM	E Arie Crown Theater
BMS, Fox Chase, other academic	Nivolumab (anti-PD-1; BMS-936558, ONO-4538) in combination with sunitinib or pazopanib in patients (pts) with metastatic renal cell carcinoma (mRCC).	Kidney Cancer	Genitourinary (Nonprostate) Cancer	5010	Clinical Science Symposium	Saturday May 31, 3:00 PM to 4:30 PM	E Arie Crown Theater
BMS, Dana Farber, other academic	Immunomodulatory activity of nivolumab in previously treated and untreated metastatic renal cell carcinoma (mRCC): Biomarker-based results from a randomized clinical trial.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	5012	Clinical Science Symposium	Saturday May 31, 3:00 PM to 4:30 PM	E Arie Crown Theater
Johns Hopkins	Phase I study of nivolumab in combination with ipilimumab in metastatic renal cell carcinoma (mRCC).	Kidney Cancer	Genitourinary (Nonprostate) Cancer	4504	Oral Abstract Session	Monday June 2, 9:45 AM to 12:45 PM	E Hall D1
Brigham and Women's Hospital	PD-L1 expression in primary clear cell renal cell carcinomas (ccRCCs) and their metastases.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	4585	General Poster Session	Monday June 2, 1:15 PM to 5:00 PM	S Hall A2
Merck, GSK	A phase III study to assess the safety and efficacy of pazopanib and MK-3475 in subjects with advanced renal cell carcinoma.	Kidney Cancer	Genitourinary (Nonprostate) Cancer	TPS4604	General Poster Session	Monday June 2, 1:15 PM to 5:00 PM	S Hall A2
University of Utah	Correlation of tumor programmed death ligand-1 (PD-L1) expression and response to treatment with high-dose interleukin-2 (HD IL-2) in clear cell metastatic renal cell carcinoma (ccmRCC).	Kidney Cancer	Genitourinary (Nonprostate) Cancer	e15584	Publication only abstract		

Source: ASCO.org and Piper Jaffray

Argos (\$ in thousands, except per share amounts)	2011	2012	2013	1Q14	2Q14E	3Q14E	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E
Income Statement																
Revenue																
License and milestone fees, grants	7,643	7,039	4,422	799	2,000	2,000	2,000	6,799	-	-	-	-	-	-	-	-
% total revenue	100%	100%	100%	100%	100%	100%	100%	100%	na	na	na	na	na	na	0%	0%
Revenues under collaborative agreements	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
% total revenue	0%	0%	0%	0%	0%	0%	0%	0%	na	na	na	na	na	na	0%	0%
Product sales and royalties	-	-	-	-	-	-	-	-	-	-	-	-	-	-	33,503	109,677
% total revenue	0%	0%	0%	0%	0%	0%	0%	0%	na	na	na	na	na	na	100%	100%
Total Revenues	7,643	7,039	4,422	799	2,000	2,000	2,000	6,799	-	-	-	-	-	-	33,503	109,677
Costs & Expenses:																
Cost of product revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3,350	10,968
R&D	12,668	17,617	23,991	8,472	6,000	6,000	6,000	26,472	6,090	6,181	6,274	6,368	24,914	27,405	28,775	30,214
SG&A	3,704	6,136	4,662	1,933	4,000	4,000	4,000	13,933	4,060	4,121	4,183	4,245	16,609	17,440	21,799	25,069
Total Operating Expenses	16,372	23,752	28,653	10,406	10,000	10,000	10,000	40,406	10,150	10,302	10,457	10,614	41,523	44,844	53,925	66,251
Operating Income (loss)	(8,729)	(16,713)	(24,232)	(9,607)	(8,000)	(8,000)	(8,000)	(33,607)	(10,150)	(10,302)	(10,457)	(10,614)	(41,523)	(44,844)	(20,422)	43,426
Investment income	1	5	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Interest expense	(6,656)	(292)	(1)	-	-	-	-	-	-	-	-	-	-	-	-	-
Other expense	(4,756)	6,530	308	(394)	-	-	-	(394)	-	-	-	-	-	-	-	-
Income (loss) before income taxes	(20,141)	(10,471)	(23,922)	(10,001)	(8,000)	(8,000)	(8,000)	(34,001)	(10,150)	(10,302)	(10,457)	(10,614)	(41,523)	(44,844)	(20,422)	43,426
Income tax (benefit) provision	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tax rate	-	-	-	-	35.0%	35.0%	35.0%	26.3%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%
Net operating loss	-	0	31,054	34,387	37,054	39,721	42,387	42,387	45,771	49,205	52,690	56,228	56,228	71,176	77,984	63,508
Net operating loss offset	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss)	(20,141)	(10,471)	(23,922)	(10,001)	(8,000)	(8,000)	(8,000)	(34,001)	(10,150)	(10,302)	(10,457)	(10,614)	(41,523)	(44,844)	(20,422)	43,426
Net loss from non-controlling interest	(63)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss) available to common stockholders	(20,078)	(10,471)	(23,922)	(10,001)	(8,000)	(8,000)	(8,000)	(34,001)	(10,150)	(10,302)	(10,457)	(10,614)	(41,523)	(44,844)	(20,422)	43,426
Add back: accretion of redeemable convertible preferred stock	(927)	(352)	4,773	-	-	-	-	-	-	-	-	-	-	-	-	-
Less: net income attributable to participating securities	-	-	(14,726)	(863)	-	-	-	(863)	-	-	-	-	-	-	-	-
Net income (loss) to common shareholders	(21,004)	(10,824)	(33,875)	(10,864)	(8,000)	(8,000)	(8,000)	(34,864)	(10,150)	(10,302)	(10,457)	(10,614)	(41,523)	(44,844)	(20,422)	43,426
Basic Earnings Per Share	(32.88)	(9.10)	(\$147.37)	(\$1.05)	(\$0.77)	(\$0.77)	(\$0.77)	(\$3.36)	(\$0.98)	(\$0.99)	(\$1.01)	(\$1.02)	(\$4.00)	(\$2.74)	(\$1.25)	\$2.65
Diluted Earnings Per Share	(32.88)	(9.10)	(\$147.37)	(\$1.05)	(\$0.77)	(\$0.77)	(\$0.77)	(\$3.36)	(\$0.98)	(\$0.99)	(\$1.01)	(\$1.02)	(\$4.00)	(\$2.74)	(\$1.25)	\$2.65
Basic Shares Outstanding	639	1,190	230	10,377	10,377	10,377	10,377	10,377	10,377	10,377	10,377	10,377	10,377	16,377	16,377	16,377
Diluted Shares Outstanding	639	1,190	230	10,377	10,377	10,377	10,377	10,377	10,377	10,377	10,377	10,377	10,377	16,377	16,377	16,377

Proprietary to Piper Jaffray & Co. May 15, 2014
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