Evidence of Rocapuldencel-T Activity in Patients from the Phase 3 ADAPT Trial

Immune Correlates to Clinical Outcomes

Overview and Background

- Immunology data presented is from the February 2017 interim analysis of data from the ongoing Phase 3 ADAPT clinical trial evaluating Rocapuldencel-T for the treatment of metastatic renal cell carcinoma (mRCC)
- Immunology data presented in poster session by Mark DeBenedette, PhD, Director of Research, Argos Therapeutics, at the 32nd Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in National Harbor, Maryland
- Immunology data presented includes both new data and an update to data that was previously presented at the European Society for Medical Oncology 2017 Congress in September that now includes additional patients
- A total of 462 patients were enrolled in the ADAPT study and randomized 2:1 between combination treatment with Rocapuldencel-T and sunitinib (combination arm) vs. sunitinib monotherapy (control arm)
- Immunology data presented was pre-specified and includes correlations between survival and:

  (i) the change from baseline in antigen-specific memory T-cells

  (ii) the amount of IL-12 secreted by each patient's specific Rocapuldencel-T immunotherapy

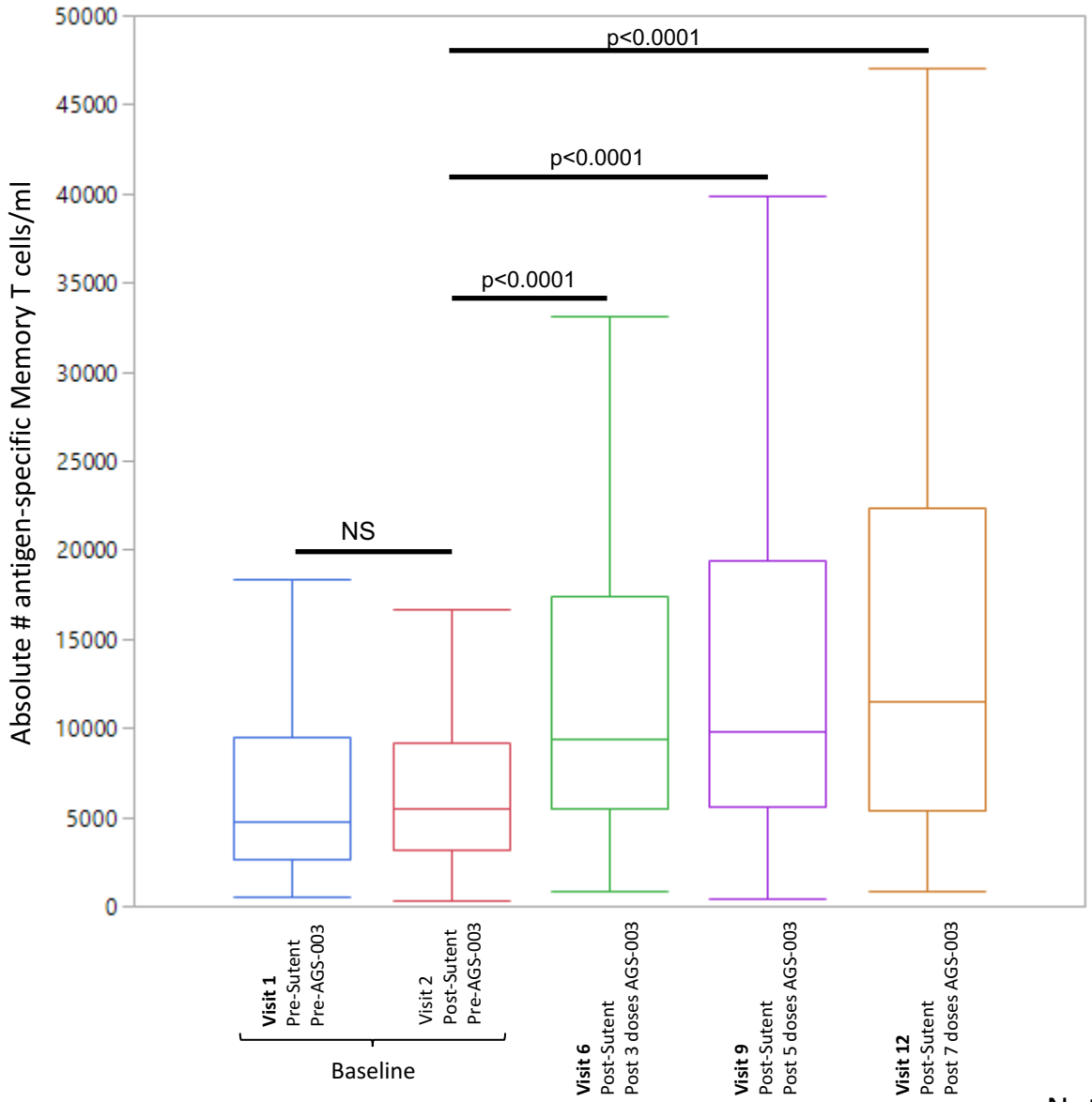
  (iii) the percentage of regulatory T-cells at baseline, which was observed in both arms of the study
- Data for antigen-specific memory T-cells and regulatory T-cells was available only for patients enrolled at North American sites

Overview and Background (continued)

- As previously reported, the February 2017 interim analysis was conducted by the ADAPT trial's Independent Data Monitoring Committee (IDMC) after 75% of the originally targeted number of 290 events (deaths) for the analysis of the primary endpoint of overall survival had occurred
- At the time of the analysis, with more than half of the patients still alive in each arm and a median follow-up time of ~20 months, the IDMC concluded that the trial was unlikely to demonstrate a statistically significant improvement in median overall survival in the combination arm and recommended that the trial be discontinued for futility
- However, the ADAPT trial principal investigators and Argos considered the data too immature to observe the delayed effects typically associated with immunotherapy and decided to continue the trial pending further review and analysis of the data and discussions with the U.S. Food and Drug Administration (FDA)
- In making this determination, Argos considered, among other factors, the degree of maturity of the data set, the mechanism of action of Rocapuldencel-T, which involves the induction of a long-term memory immune response, and the IDMC's assessment of the safety profile of Rocapuldencel-T
- This determination was subsequently further supported by the extended durability of tumor responses in the combination arm, as previously reported
- Following the IDMC’s interim analysis, the Company met with the FDA to discuss the ADAPT trial and the future direction of the Rocapuldencel-T program in April 2017
- The FDA agreed with the Company's decision to continue the ADAPT trial, and further agreed to review a protocol amendment to extend the trial beyond the originally targeted 290 events and a revised statistical analysis plan that the Company plans to submit

Memory T Cell Response

Antigen-Specific Memory T Cells Increased only after Rocapuldencel-T Administration

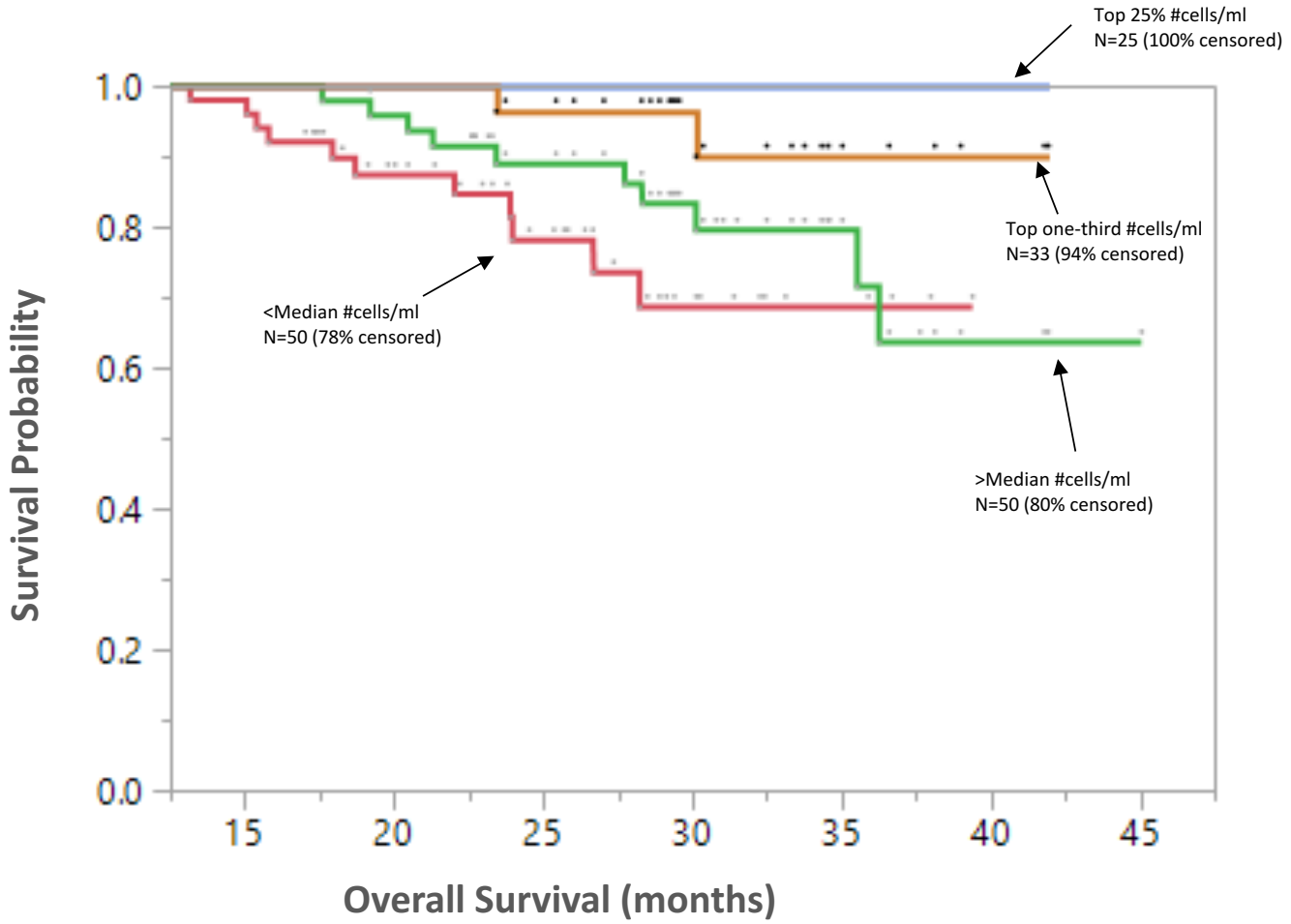


- Updated Memory T cell data on 146 subjects (previously reported on N=117)
- Antigen-specific memory T cells defined as CD8+/CD28+/CD45RA- that are reactive with the tumor RNA encoded antigens
- Memory T cells unaffected by the first cycle of Sutent (V1 vs V2)

Note: Data from patients enrolled at North American sites

Greater Increase in Antigen-Specific Memory T Cells* above Baseline after 7 Doses Associated with Improved Survival

The change in the number of antigen-specific memory T cells/ml correlated with OS after 7 doses (Spearman's Rho=0.40, p<0.0001)



- Analysis included 100 patients who received at least 7 doses out of the 146 patients analyzed for immune response
- Improved correlation and p-value with survival compared to previous analysis of 83 subjects
- Median change = 4796 cells/ml

Baseline (Visit 2) data available for 97 of the 100 subjects who received ≥7 doses as of February 2017

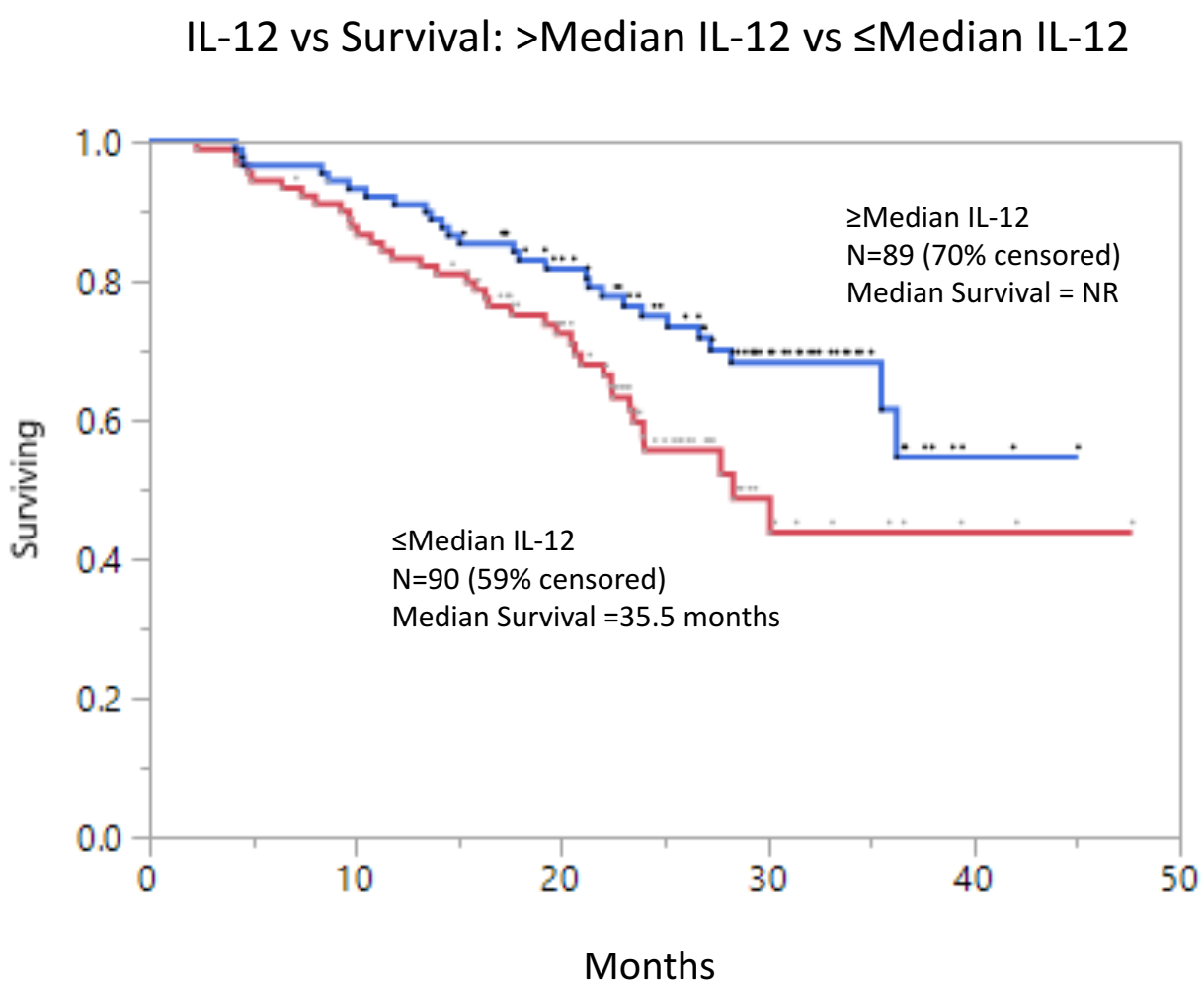
Median #cells/ml present at baseline (4210 cells/ml) do not correlate with survival (Spearman's Rho= 0.13, p<0.1978)

*Memory T cells defined as CD8+CD28+CD45RA- cells reactive with antigens encoded by autologous tumor RNA

Note: Data from patients enrolled at North American sites

Rocapuldencel-T
Potency Marker: IL-12

Rocapuldencel-T Potency Marker (IL-12) Correlate with Survival



- Measurement of IL-12 secreted from subject's immunotherapy performed for 179 subjects
- Median IL-12=394.1 pg/ml

IL-12 Levels Correlate with Survival and Number of Memory T Cells/ml only after Treatment with Rocapuldencel-T

IL-12 correlates with survival in subjects receiving AGS-003

IL-12 levels vs survival			
Group	N	Spearman's Rho	P value
All Subjects	179	0.27	<0.0002
Subjects not dosed	14	0.04	<0.8991

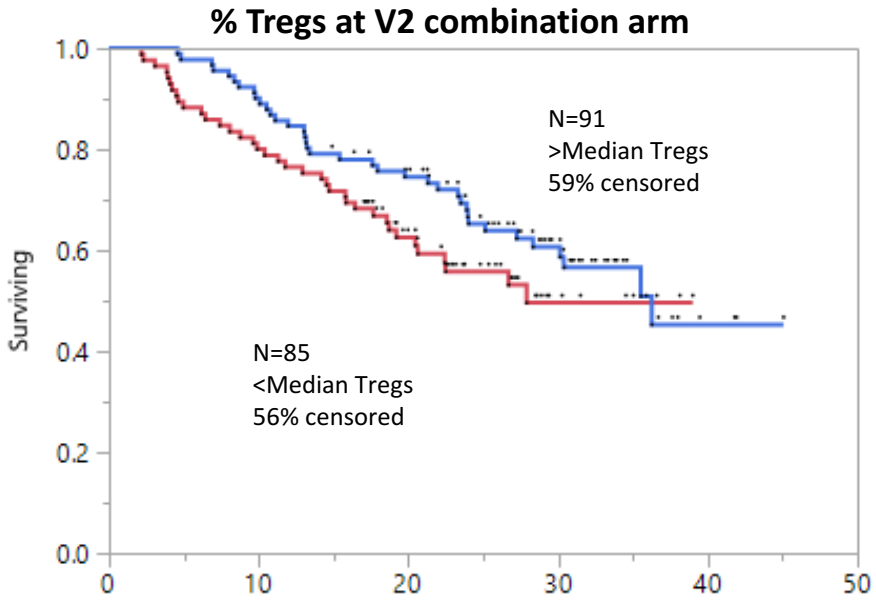
IL-12 correlates with induced immune responses

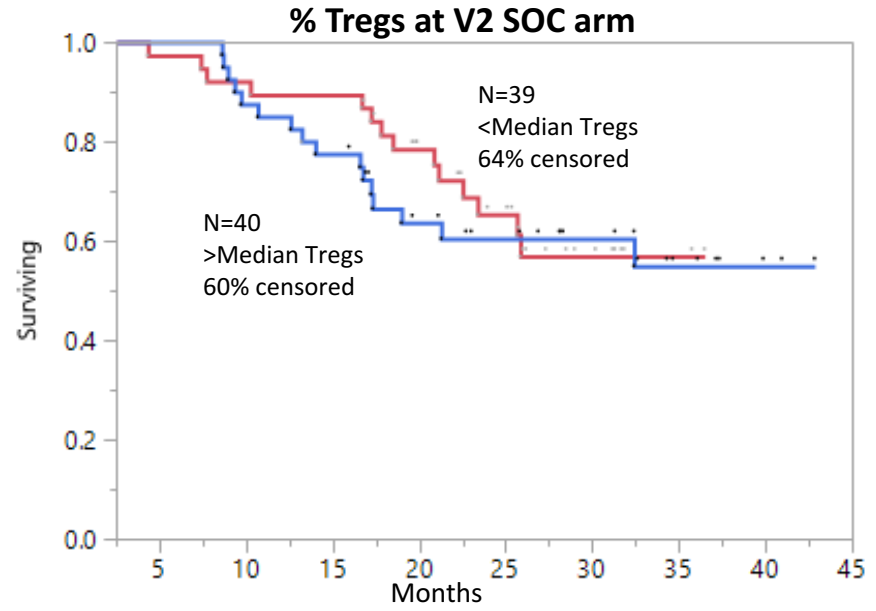
IL-12 values vs increase in memory T cells/ml			
Group	N	Spearman's Rho	P value
Pre-dosing (V2 vs V1)*	139	0.03	<0.6948
After 3 doses (V6 vs V2)	130	0.26	<0.0031
After 5 doses (V9 vs V2)	127	0.39	<0.0001
After 7 doses (V12 vs V2)	95	0.43	<0.0001

**After 1 cycle of Sutent but before AGS-003 administration*

Regulatory T Cells

Unexpectedly, a Higher Percentage of CD4+ T Cells with a Treg Phenotype* Immediately before First Dose (Visit 2) Resulted in Better Survival only in Subjects Treated with Rocapuldencel-T





Treg analysis performed on 294 subjects across both arms

% TReg	vs OS (AGS-003 arm)	vs OS (SOC arm)
V1	N=196 ρ=0.34, p<0.0001	N=86 ρ=0.13, p<0.2358
V2	N=176 ρ =0.27, p<0.0003	N=79 ρ= -0.01, p<0.9235
V6	N=161 ρ=0.20, p<0.0110	N=75 ρ=0.09, p<0.4602
V9	N=157 ρ=0.27, p<0.0007	N=61 ρ=0.12, p<0.3486
V12	N=116 ρ=0.20, p<0.0390	N=51 ρ= -0.06, p<0.6689

**Treg phenotype: $CD4^{+}CD25^{+}FoxP3^{+}CD127^{-}$*

Note: Data from patients enrolled at North American sites