



Results of February Interim Analysis of ADAPT Trial and Perspective on Decision to Keep Trial Open

Webcast April 18, 2017

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Webcast Overview

❖ Interim data summary

- Phase 3 ADAPT trial design and IDMC recommendation
- Primary and secondary outcomes in the intent-to-treat (ITT) population

❖ Rationale for continuing ADAPT and longer term survival follow-up

- High degree of censored data and tail-of-curve effect with immunotherapy
- Post-hoc analysis grouping patients by time of enrollment in the trial

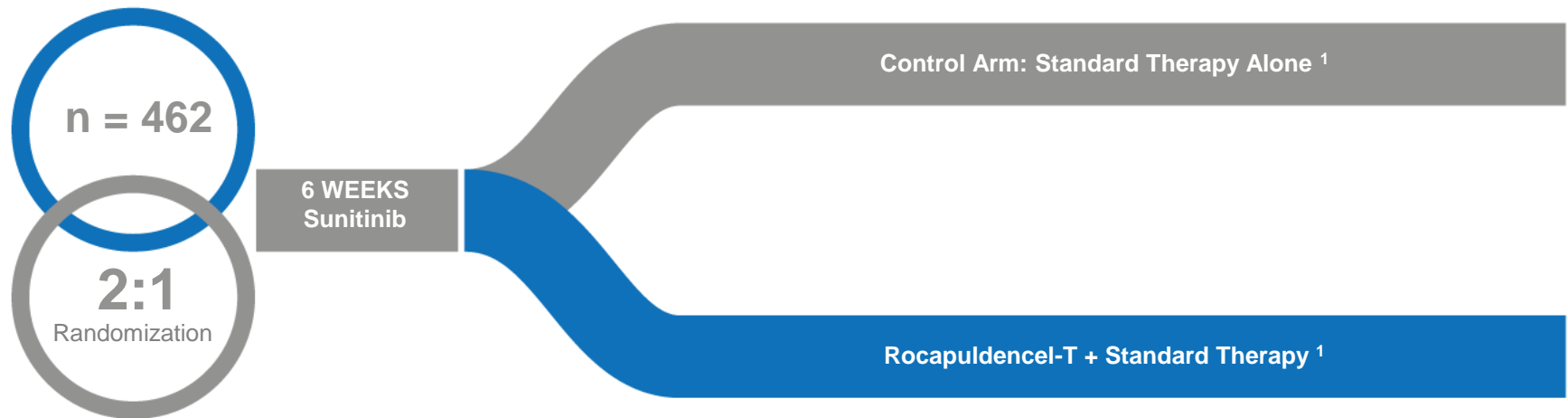
❖ Immune response analysis

- Immune response demonstrated in majority of subjects tested (96 of 109 as of March 31, 2017)
- Patients with induced immune response above median had greater survival than those below median after 7 doses of Rocapuldencel-T
- Correlation of induced immune response with overall survival in patients who received at least 7 doses of Rocapuldencel-T

❖ Next steps

Phase 3 ADAPT Trial Design and Interim Data Summary

Phase 3 ADAPT Trial Design



- Randomized, open label study in patients with newly diagnosed (first line) metastatic renal cell carcinoma (clear cell histology) conducted under a Special Protocol Assessment
- Stratification by measurable disease and by Heng risk factors (77% Intermediate Risk and 23% Poor Risk)
- Dosing with Rocapuldencel-T at weeks 6, 9, 12, 15, 18, 24 and quarterly thereafter
- Primary efficacy endpoint: overall survival (log rank test)
- Secondary efficacy endpoints evaluated to date: progression-free survival, objective response rate and disease control rate
- Exploratory endpoints include immune response data (samples obtained for 190 patients enrolled at US sites who provided consent for immune monitoring)
- Enrollment at 107 sites in North America, Europe and Israel

IDMC Recommendation

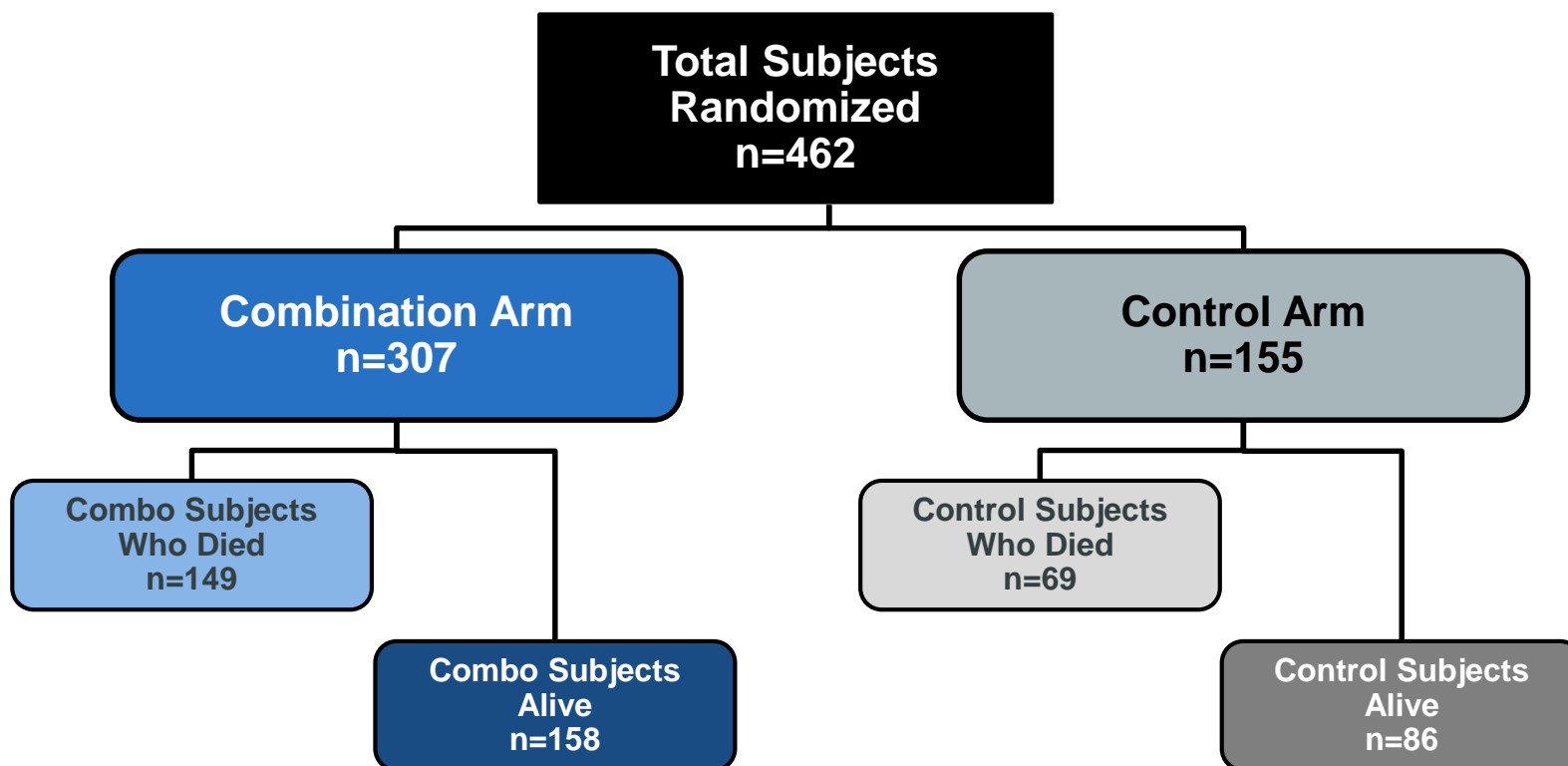
- ❖ IDMC charter established in 2012 based on assumptions regarding survival and standard statistical methodology at that time

| Planned Analyses | % Targeted # of Events (Deaths) | Number of Events |
|--------------------|---------------------------------|------------------|
| Interim Analysis 1 | 25% | 72 |
| Interim Analysis 2 | 50% | 145 |
| Interim Analysis 3 | 75% | 217 |
| Final Analysis | 100% | 290 |

- ❖ **IDMC recommendation at 3rd interim analysis in Feb 2017:** ¹
 - Termination of the study for futility based on analysis of the primary endpoint of overall survival in the ITT population
 - No substantial evidence of harmful effects

(1) The data cut-off date for the February interim analysis was February 3, 2017

Patient Disposition at Interim Analysis ¹



- ❖ ITT population (all randomized patients) includes 39 patients who never received Rocapuldencel-T
- ❖ ~ 67 patients still receiving Rocapuldencel-T in the combination arm

(1) The data cut-off date for the February interim analysis was February 3, 2017

ITT Population Characteristics *

- ❖ No significant differences in baseline characteristics between the combination arm and the control arm
- ❖ Median follow-up is 20 months (range: 0.4 – 47.7 months)
- ❖ Median number of doses of Rocapuldencel-T is 8
- ❖ Generally comparable subsequent standard-of-care treatments in each arm

* See Appendix for supporting slides

Primary Endpoint Interim Analysis - Overall Survival

| Interim Analysis | Combination Arm | Control Arm |
|--|--------------------|--------------|
| ITT Population | n=307 | n=155 |
| Percentage Censored Subjects | 51% | 55% |
| Median Overall Survival (months) ¹ | 27.7 | 32.4 |
| 95% Confidence Interval (CI) | 23.0, 35.9 | 22.5, - |
| Hazard Ratio (95% CI) - Unadjusted | 1.10, (0.83, 1.46) | |
| Hazard Ratio (95% CI) – Adjusted * | 1.06, (0.79, 1.40) | |

* Adjusted for randomization stratification factors - number of Heng risk factors and metastatic disease status (measurable vs. non-measurable)

At Interim Analysis:

- ❖ More than half the subjects in both treatment groups were censored for survival
- ❖ Approximately 98% of the censored subjects remained alive as of February 3, 2017 data cut-off for interim analysis

(1) Median overall survival estimated by Kaplan-Meier methodology

Key Secondary Endpoint Interim Analyses

| Progression Free Survival | Combination Arm | Control Arm |
|--|-----------------|-------------|
| ITT Population | n=307 | n=155 |
| Median Progression Free Survival (months) | 6.0 | 7.8 |
| 95% CI | 5.8, 6.7 | 5.9, 9.3 |
| Hazard Ratio | 1.15 | |
| 95% CI | 0.92, 1.44 | |

| Objective Response Rate | Combination Arm | Control Arm |
|---|------------------------------------|------------------------------------|
| ITT Population | n=307 | n=155 |
| Best Overall Response, n (%) | | |
| Complete Response (CR) | 9 (2.9%) | 3 (1.9) |
| Partial Response (PR) | 122 (39.7%) | 58 (37.4%) |
| Stable Disease (SD) | 121 (39.4%) | 57 (36.8%) |
| Progressive Disease (PD) | 30 (9.8%) | 10 (6.5%) |
| Not Evaluable (NE) | 25 (8.1%) | 27 (17.4%) |
| Objective Response Rate (CR + PR) n (%) (95% Confidence Interval) | 131 (42.7%) (37.1, 48.4) | 61 (39.4%) (31.6, 47.5) |
| Disease Control Rate (CR + PR + SD) , n (%) (95% Confidence Interval) | 253 (82.4%) (77.7, 86.5) | 118 (76.1%) (68.6, 82.6) |

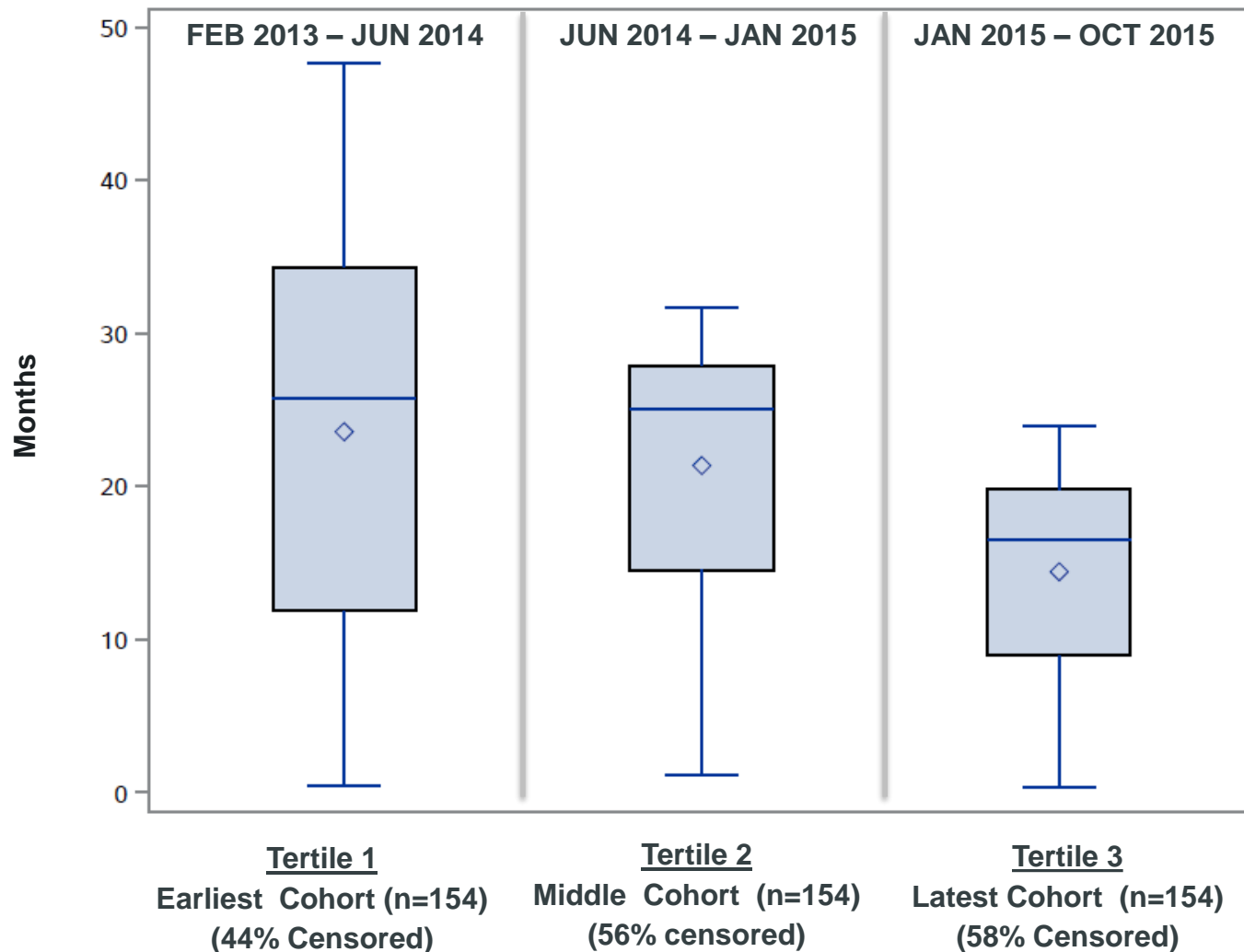
Rationale For Continuing ADAPT and Longer-Term Survival Follow-up

Rationale For Continuing ADAPT And Longer Term Survival Follow-up

- ❖ **Potential for delayed treatment effect (tail-of-curve) with immunotherapy**
 - Interim analyses may not fully capture the potential benefit of an active immunotherapy due to insufficient long-term follow-up¹
 - Rocapuldencel-T induces long-term memory immune responses
 - >50% subjects censored in both treatment groups at interim analysis
 - 98% of censored subjects remained alive
 - Limited survival follow-up at time of interim analysis: median of 20 months
- ❖ **Longer follow-up may provide useful information to identify a potential beneficial effect of Rocapuldencel-T**
 - Censoring may impact assessment of both median survival and potential tail-of-curve effect

(1) TT Chen [Statistical Issues and Challenges in Immuno-oncology](#); Journal for ImmunoTherapy of Cancer, 2013 Oct 21;1:18

Duration of Follow-up at February Interim Analysis by Tertile of Randomization



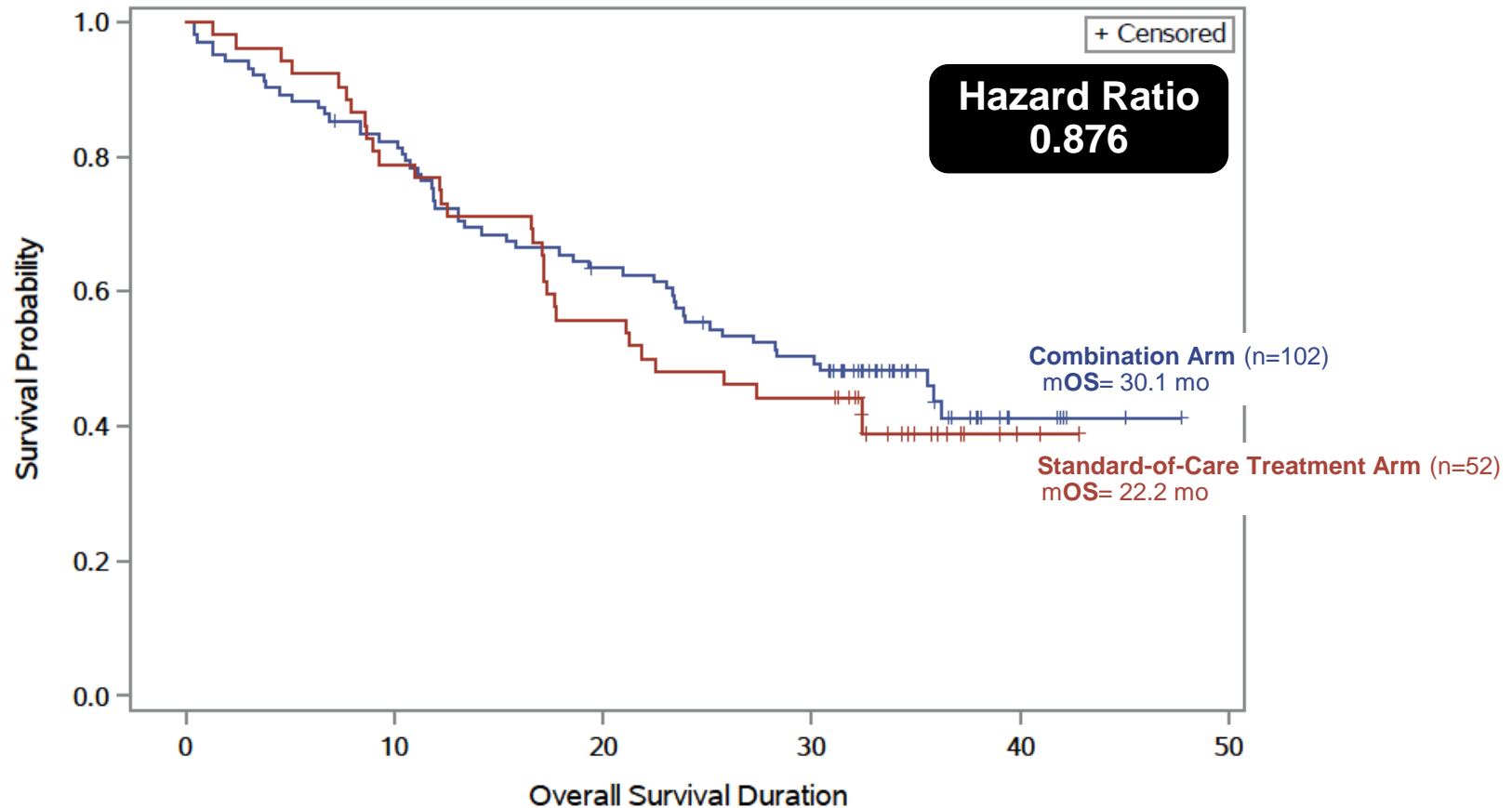
Overall Survival by Time of Randomization¹

| | Combination Arm | | | Control Arm | | | Delta Months | Hazard Ratio |
|--------------------------------------|-----------------|---------------|-----------------------------|-------------|---------------|--------------------------|-----------------|-----------------------------|
| | N | % Censored | Median OS (Months) | N | % Censored | Median OS (Months) | | |
| 1st 33% randomized | 102 | 46 | 30.1 (23.3, -) | 52 | 40 | 22.2 (17.2, -) | +7.9 | 0.88 (0.56, 1.36) |
| 1st 66% randomized | 205 | 51 | 30.4 (24.8,-) | 103 | 50 | 32.4 (21.7, -) | -2.0 | 0.98 (0.70, 1.37) |
| All 100% randomized | 307 | 52 | 27.7 (23.0, 35.9) | 155 | 56 | 32.4 (22.5, -) | -4.7 | 1.10 (0.83, 1.46) |

- ❖ Post hoc subgroup analysis performed subsequent to IDMC meeting
- ❖ Benefit in median overall survival (combination arm vs. control arm) seen in subjects with longest survival follow-up
- ❖ Suggests interim analysis of median overall survival may be premature

(1) Median overall survival estimated by Kaplan-Meier methodology based upon data cut-off as of February 3, 2017

Kaplan-Meier Analysis of Overall Survival in Tertile 1



Immune Response Interim Analysis

High Percentage of Immune Responders with Longer Overall Survival

| Combination Arm n=109 ⁽¹⁾ | | | | | |
|---|----------------------|---|-----|---|-------------------------|
| | | Subjects Meeting Immune Responder Criteria ⁽²⁾ | | | |
| | | | | Median Overall Survival (months) ³ | 95% Confidence Interval |
| | At Anytime | 96/109 | 88% | Not Reached | 30.1, - |
| | After 3 Doses | 76/106 | 72% | 36.3 | 28.3, - |
| | After 5 Doses | 71/99 | 72% | 36.3 | 28.2, - |
| | After 7 Doses | 58/72 | 81% | Not Reached | - , - |

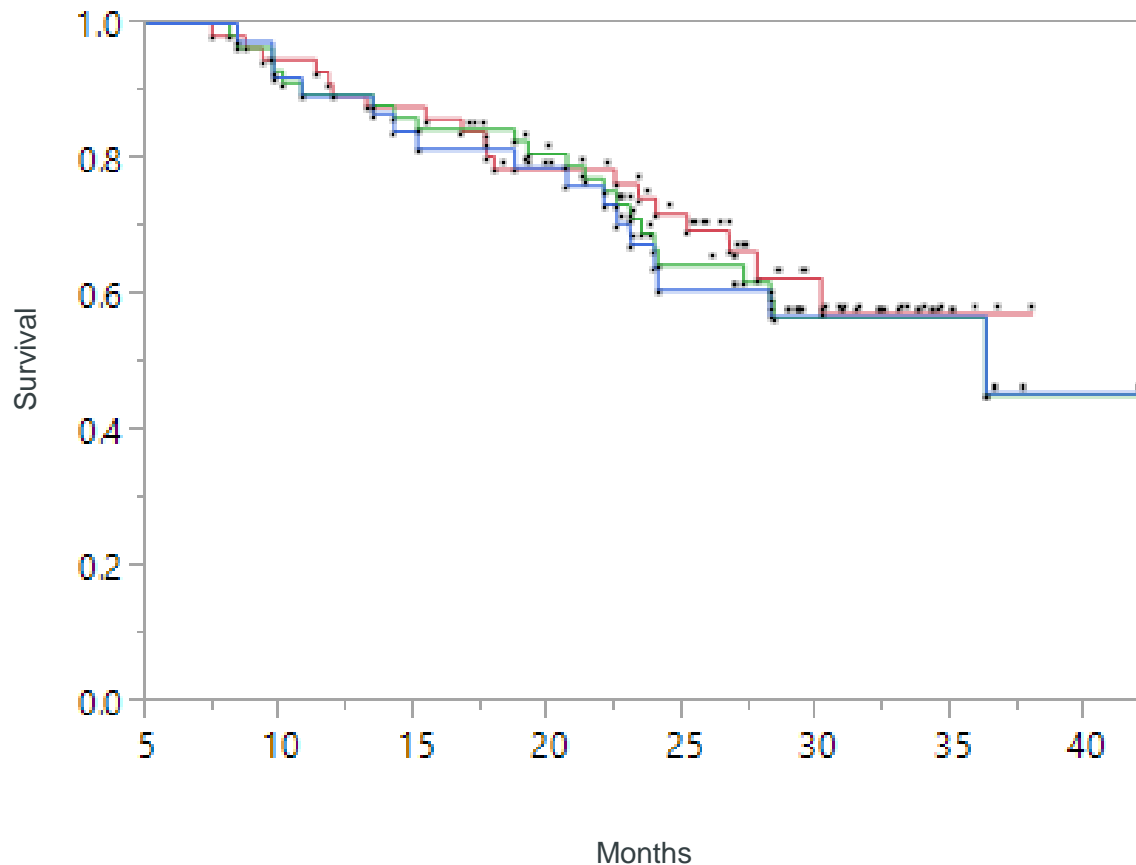
- (1) Of the 190 patient samples in the combination arm available for analysis, 109 (57%) were completed as of March 31, 2017. Note that immune response samples were only obtained for combination arm patients enrolled at US sites who provided consent for immune monitoring and that patients in the control arm were not monitored for immune response
- (2) Pre-specified exploratory endpoint defined as an increase in CD8+/CD28+CD45RA- memory T cells of at least 2 standard deviations from the subject-specific baseline to specific time points after Rocapuldence1-T dosing
- (3) Median overall survival (estimated by Kaplan-Meier methodology) for the immune responder subgroup analysis not representative of the entire combination arm

Correlation Between Increase in Memory T Cells and Overall Survival

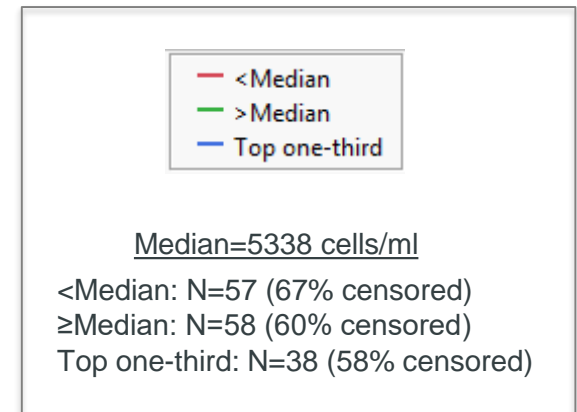
| Patient Group | N | Spearman's Correlation Coefficient * | P-value |
|--|-----|--------------------------------------|---------|
| Patients who received at least 3 Doses | 106 | 0.21 | 0.030 |
| Patients who received at least 5 Doses | 99 | 0.06 | 0.544 |
| Patients who received at least 7 Doses | 72 | 0.38 | 0.001 |

* Pre-specified analysis assessed using post-dose change from baseline after 3, 5, or 7 doses of Rocapuldencel-T; if assessed using only increase above baseline (not pre-specified), there is only statistical significance at 7 doses

Number of Memory T Cells* at Baseline not Associated with Survival



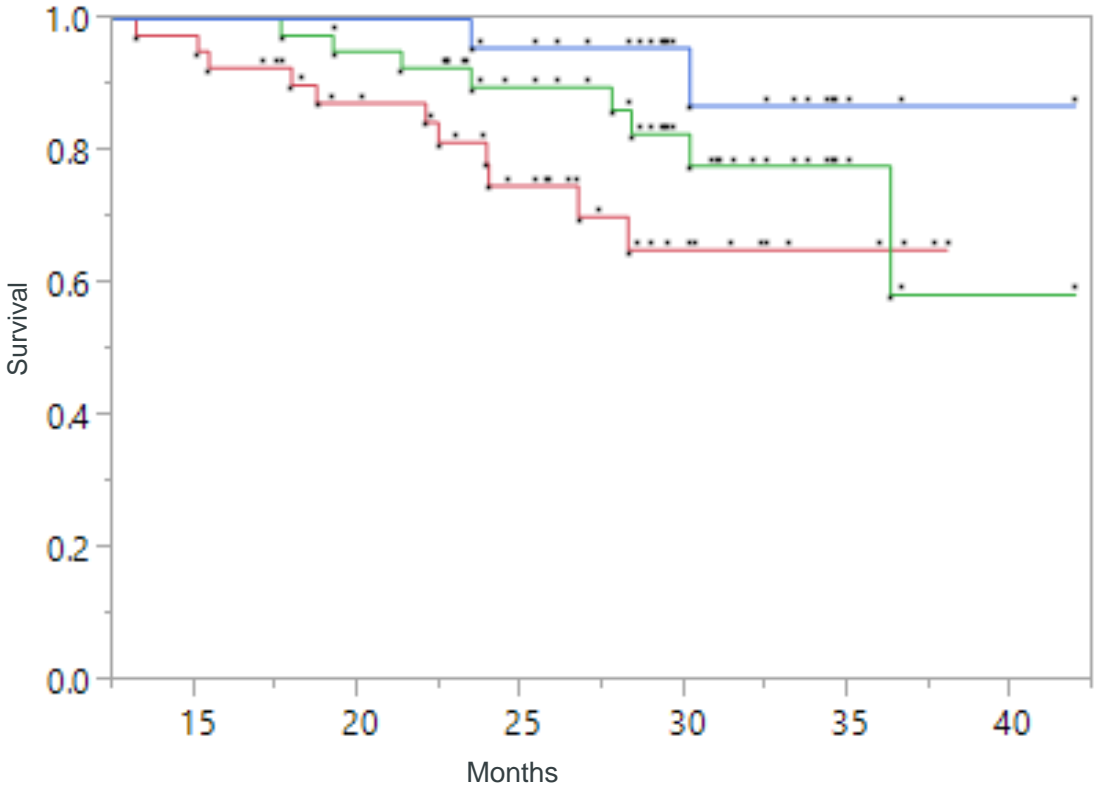
Post hoc analysis includes 115 patients who had baseline memory T cell measurements out of the 117 subjects analyzed for immune response (including patients analyzed subsequent to March 31, 2017)



Baseline immune response vs OS for N=115
 $p=.06, p<0.5247$

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

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



Post hoc analysis includes 83 patients who received at least 7 doses out of the 117 patients analyzed for immune response (including patients analyzed subsequent to March 31, 2017)

— <Median
— >Median
— Top one-third

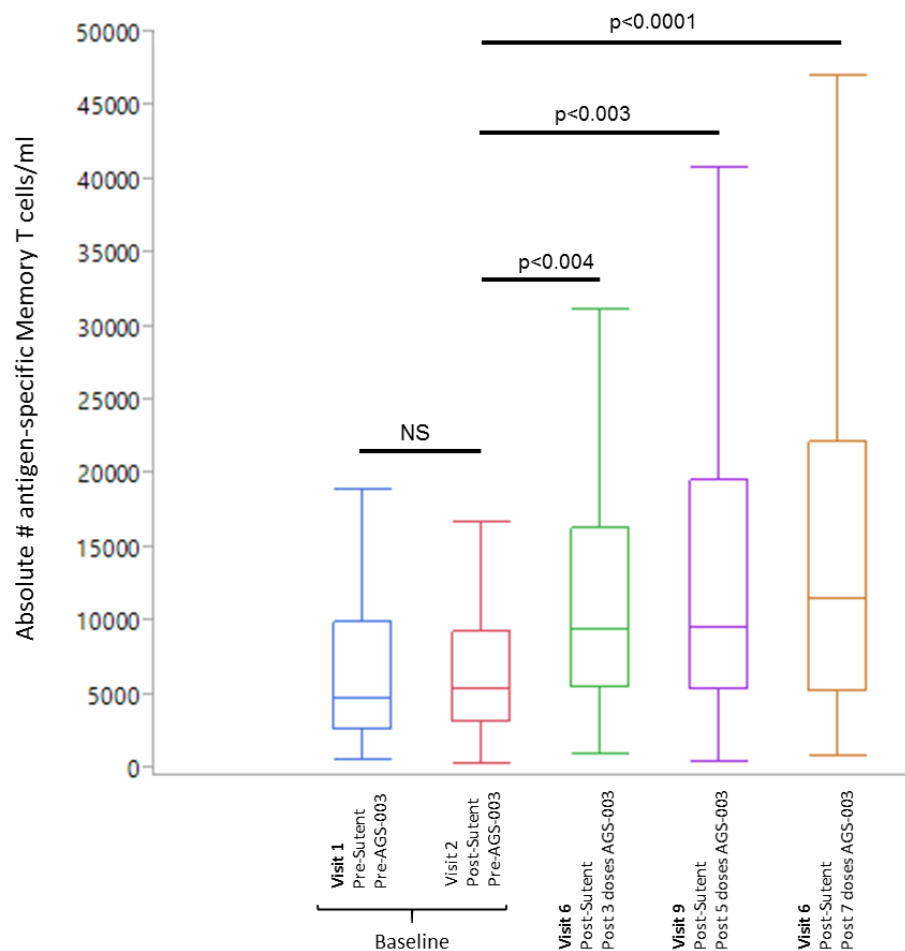
Median increase = 6085 cells/ml

<Median: N=41 (73% censored)
 ≥Median: N=42 (81% censored)
 Top one-third: N=27 (93% censored)

Immune response after 7 doses vs OS for N=83 (Assessed using increase above baseline only)
 $\rho = .33, p < 0.0021$

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

Antigen-Specific Memory T Cells Increase only after AGS-003 Administration



Summary

- ❖ **IDMC recommended discontinuation of ADAPT for futility**
 - Based on 3rd Interim Analysis: 75% of 290 targeted events (death) as of Feb 3, 2017
 - Assessment that study unlikely to demonstrate statistically significant improvement in overall survival in intent-to-treat population based on pre-defined statistical analysis plan
 - No substantial evidence of treatment harm
- ❖ **Argos and principal investigators see merit in continuing ADAPT**
 - Potential for tail-of-curve effect with additional follow-up
 - Over 50% of subjects censored at interim analysis (98% alive)
 - Analysis of subjects with longest follow-up suggests median overall survival at time of the interim analysis may have underestimated potential effect of Rocapuldencel-T
- ❖ **Immune response data suggest activity consistent with mechanism of action**
 - Majority of subjects tested (96/109) demonstrated immune response
 - Patients with induced immune response above median had greater survival than those below median
 - Induced immune response correlates with overall survival
- ❖ **Meeting with FDA scheduled in May to discuss ADAPT data and plan to keep trial open**

Appendix

ITT Population: Baseline Characteristics

| | Combination Arm | | Control Arm | | Treatment Group Comparability p-value* |
|-------------------------------------|-----------------|-------|-------------|--------|--|
| ITT Population | n=307 | | n=155 | | |
| Median Age | 60.0 yr | | 61.0 yr | | 0.615 |
| Gender, Male | 227 | 73.9% | 114 | 73.5% | >0.999 |
| Race | | | | | 0.114 |
| White | 288 | 93.8% | 151 | 97.4% | |
| Non-White | 19 | 6.2% | 4 | 2.6% | |
| Time from Initial Dx | 2.67 mo | | 2.63 mo | | |
| Metastatic Disease | | | | | 0.866 |
| Yes | 305 | 99.3% | 155 | 100.0% | |
| Measurable | 273 | 88.9% | 135 | 87.1% | |
| Non-measurable | 32 | 10.4% | 20 | 12.9% | |
| No | 2 | 0.7% | 0 | 0% | |
| Heng Risk Factors | | | | | |
| Intermediate Risk | 235 | 76.5% | 120 | 77.4% | 0.907 |
| Poor Risk | 72 | 23.5% | 35 | 22.6% | |
| 1 | 84 | 27.4% | 43 | 27.7% | 0.993 |
| 2 | 151 | 49.2% | 77 | 49.7% | |
| 3 | 52 | 16.9% | 26 | 16.8% | |
| 4 | 20 | 6.5% | 9 | 5.8% | |
| Karnofsky Performance Status | | | | | 0.934 |
| 100% | 104 | 33.9% | 55 | 35.5% | |
| 90% | 120 | 39.1% | 61 | 39.4% | |
| 80% | 69 | 22.5% | 32 | 20.6% | |
| 70% | 12 | 3.9% | 7 | 4.5% | |
| 60% | 1 | 0.3% | 1 | 0% | |

*Based on t-test or Fisher's exact tests/Chi-square test

ITT Population: Rocapuldencel-T Dosing

- ❖ Number of subjects by number of Rocapuldencel-T doses received as of February 2017 interim analysis
 - Median number of doses received: 8 (range 0 – 18)

| Combination Arm n=307 | | | | | |
|--------------------------|--------------------|---------------------|------------------------|--------------------|---------------------|
| AGS-003 Doses Received | Number of Subjects | Cumulative Subjects | AGS-003 Doses Received | Number of Subjects | Cumulative Subjects |
| 0 | 39 | 307 | 10 | 33 | 100 |
| 1 | 5 | 268 | 11 | 14 | 67 |
| 2 | 4 | 263 | 12 | 10 | 53 |
| 3 | 9 | 259 | 13 | 15 | 43 |
| 4 | 9 | 250 | 14 | 11 | 28 |
| 5 | 23 | 241 | 15 | 8 | 17 |
| 6 | 30 | 218 | 16 | 5 | 9 |
| 7 | 35 | 188 | 17 | 3 | 4 |
| 8 | 26 | 153 | 18 | 1 | 1 |
| 9 | 27 | 127 | | | |

ITT Population: Subsequent Standard-of-Care Treatment Exposure

- ❖ Number of subsequent standard-of-care treatments generally comparable between the two treatment groups

| | Combination Arm n=307 | | Control Arm n=155 | |
|--|--------------------------|-------|----------------------|-------|
| Number or Subsequent Standard-of-Care Treatments | 194 | 63.2% | 87 | 56.1% |
| 0 | 113 | 36.8% | 68 | 43.9% |
| 1 | 87 | 28.3% | 40 | 25.8% |
| 2 | 47 | 15.3% | 26 | 16.8% |
| 3 | 29 | 9.4% | 11 | 7.1% |
| 4 | 21 | 6.8% | 6 | 3.9% |
| 5 | 7 | 2.3% | 1 | 0.6% |
| 6 | 1 | 0.3% | 2 | 1.3% |
| 7 | 2 | 0.7% | 0 | 0.0% |
| 8 | 0 | 0.0% | 1 | 0.6% |

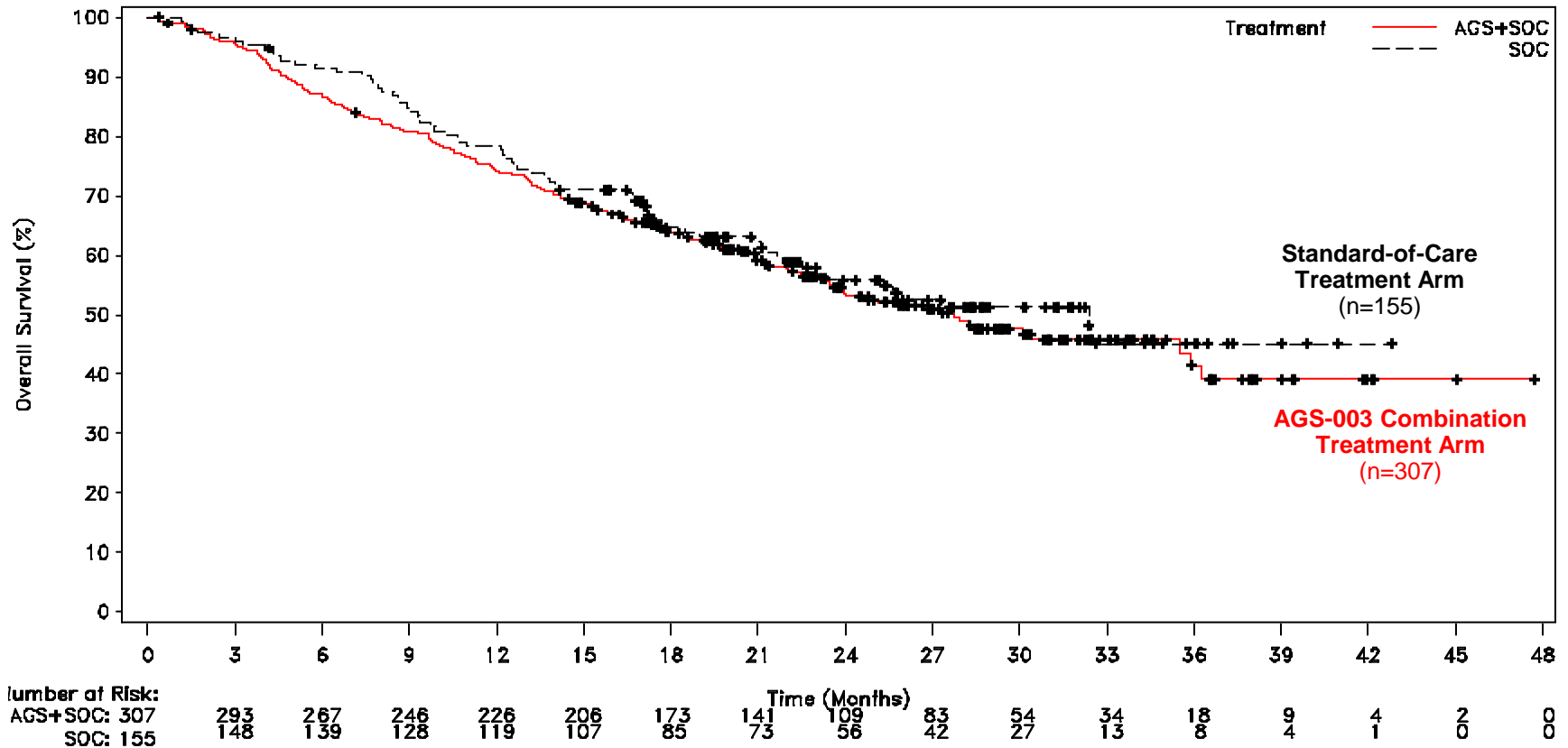
ITT Population: Subsequent Standard-of-Care Treatment Exposure*

- ❖ Generally comparable subsequent standard-of-care treatments in the two treatment arms

| Subsequent Standard-of-Care Treatment | Combination Arm n=307 | | | | Control Arm n=155 | | | |
|---------------------------------------|--------------------------|-----------------|--------------|-------|----------------------|-----------------|--------------|-------|
| | Treatment Phase | Follow-up Phase | Entire Study | | Treatment Phase | Follow-up Phase | Entire Study | |
| Axitinib | 52 | 44 | 91 | 29.6% | 13 | 29 | 38 | 24.5% |
| Nivolumab | 19 | 76 | 89 | 29.0% | 3 | 26 | 27 | 17.4% |
| Everolimus | 38 | 29 | 65 | 21.2% | 12 | 22 | 31 | 20.0% |
| Pazopanib | 28 | 14 | 40 | 13.0% | 9 | 12 | 20 | 12.9% |
| Cabozantinib | 3 | 15 | 18 | 5.9% | 0 | 7 | 7 | 4.5% |
| Bevacizumab | 4 | 13 | 16 | 5.2% | 2 | 4 | 6 | 3.9% |
| Temsirolimus | 1 | 7 | 8 | 2.6% | 0 | 5 | 5 | 3.2% |
| IL-2 | 0 | 6 | 6 | 2.0% | 0 | 3 | 3 | 1.9% |
| Pembrolizumab | 0 | 3 | 3 | 1.0% | 0 | 1 | 1 | 0.6% |
| Ipilimumab | 0 | 1 | 1 | 0.3% | 0 | 0 | 0 | 0.0% |

* Includes treatments administered during active treatment and survival follow-up periods (only active treatment data collected quantitatively)

ITT Population: Kaplan-Meier Analysis of Overall Survival



Number at Risk:
 AGS+SOC: 307
 SOC: 155

+: Censored

Note: AGS = AGS-003; SOC = Standard of Care.

ITT Population: Subgroup Analyses of Overall Survival

| | Combination Arm | Control Arm |
|---|-----------------|-------------|
| Intermediate Risk Population* | N=235 | N=120 |
| Median Overall Survival (months) | 30.1 | 32.5 |
| 95% CI | 24.0, - | 25.2, - |
| Hazard Ratio | 1.11 | |
| 95% CI | 0.80, 1.56 | |
| Poor Risk Population* | N=72 | N=35 |
| Median Overall Survival (months) | 18.7 | 21.1 |
| 95% CI | 12.0, - | 10.2, - |
| Hazard Ratio | 1.03 | |
| 95% CI | 0.60, 1.77 | |

*as defined by Heng risk factors

ITT Population: Subgroup Analyses of Overall Survival by Individual Heng Risk Factors

| Number of Risk Factors | Combination Arm (n=307) | | Control Arm (n=155) | | Hazard Ratio |
|------------------------|----------------------------|-----------------------|------------------------|-----------------------|--------------|
| | | Median OS (months) | | Median OS (months) | |
| 1 | n=84 | 30.4 | n=43 | Not Reached | 1.36 |
| 2 | n=151 | 28.2 | n=77 | 32.4 | 1.01 |
| 3 | n=52 | 21.2 | n=26 | Not Reached | 1.21 |
| 4 | n=20 | 11.9 | n=9 | 16.6 | 0.8 |

ITT Population: Subgroup Analyses of Overall Survival

| | | Combination Arm (n=307) | | Control Arm (n=155) | | Hazard Ratio |
|--------------------|------------|----------------------------|-----------------------|------------------------|-----------------------|--------------|
| Subsequent Therapy | | | Median OS (months) | | Median OS (months) | |
| | Yes | n=194 | 27.2 | n=87 | 23.0 | 0.89 |
| | No | n=113 | Not Reached | n=68 | Not Reached | 1.50 |

| Number of Subsequent Therapies | | | | | | |
|--------------------------------|--------------|-------|--------------------|------|--------------------|-------------|
| | 0 | n=113 | Not Reached | n=68 | Not Reached | 1.50 |
| | 1 | n=87 | 18.7 | n=40 | 17.2 | 0.96 |
| | 2 | n=47 | 35.5 | n=26 | 23.4 | 0.69 |
| | 3 | n=29 | 30.4 | n=11 | 25.2 | 0.70 |
| | >3 | n=31 | 30.1 | n=10 | Not Reached | 1.97 |

Summary of Adverse Events - Safety Population

| | Combination Arm | Control Arm |
|---|--------------------|-------------------|
| Subjects Who Received Any Amount of Study Medication | (n=299) n, % | (n=141) n, % |
| Pre-Treatment Period | | |
| Any Adverse Events | 10 (3.3%) | 2 (1.4%) |
| Any Serious Adverse Events | 1 (0.3%) | 0 (0.0%) |
| Any Grade 3/4/5 AEs | 1 (0.3%) | 0 (0.0%) |
| Randomized Treatment Period | | |
| Any Adverse Events | 296 (99.0%) | 139 (98.6%) |
| AGS-003 Related AEs | 174 (58.2%) | - |
| Standard of Care Related AEs | 285 (95.3%) | 134 (95.0%) |
| Any Grade 3/4/5 AEs | 214 (71.6%) | 98 (69.5%) |
| AGS-003 Related Grade 3/4/5 AEs | 6 (2.0%) | - |
| Standard of Care Related Grade 3/4/5 AEs | 144 (48.2%) | 74 (52.5%) |
| Deaths | 19 (6.4%) | 7 (5.0%) |

Summary of Adverse Events - Safety Population

| | Combination Arm | Control Arm |
|---|--------------------|-------------------|
| Subjects Who Received Any Amount of Study Medication | (n=299) n, % | (n=141) n, % |
| Randomized Treatment Period (Continued) | | |
| Any Serious Adverse Events | 129 (43.1%) | 47 (33.3%) |
| AGS-003 Related SAEs | 0 (0.0%) | - |
| Standard of Care Related SAEs | 48 (16.1%) | 24 (17.0%) |
| Discontinuation of AGS-003 Due to | | |
| Any AEs | 11 (3.7%) | - |
| AGS-003 Related SAEs | 0 (0.0%) | - |
| Standard of Care Related SAEs | 4 (1.3%) | - |
| Discontinuation of Standard of Care Due to | | |
| Any AEs | 60 (20.1%) | 32 (22.7%) |
| AGS-003 Related SAEs | 3 (1.0%) | - |
| Standard of Care Related SAEs | 42 (14.0%) | 21 (14.9%) |

Tertile Subgroup Analysis (*Post Hoc*)

Baseline Characteristics

| | First Tertile <i>Feb 2013 – June 2014</i> | | First 66% <i>Feb 2013 – Jan 2015</i> | | Total Subjects- 100% <i>FEB 2013 – Oct 2015</i> | |
|-------------------------------------|--|-------------|---|-------------|--|-------------|
| | Combination Arm | Control Arm | Combination Arm | Control Arm | Combination Arm | Control Arm |
| Tertile Population | n=102 | n=52 | n=205 | n=103 | n=307 | n=155 |
| Median Age, yr | 59.0 | 59.0 | 59.0 | 61.0 | 60.0 | 61.0 |
| Gender, Male, n (%) | 75 (73.5) | 41 (78.9) | 149 (72.7%) | 78 (75.7%) | 227 (73.9) | 114 (73.6) |
| Race | | | | | | |
| White, n (%) | 99 (97.1) | 51 (98.1) | 192 (93.7) | 99 (96.1) | 288 (93.8) | 151 (97.4) |
| Non-White, n (%) | 3 (2.9) | 1 (1.9) | 13 (6.3) | 4 (3.9) | 19 (6.2) | 4 (2.6) |
| Metastatic Disease | | | | | | |
| Yes, n (%) | 101 (99.0) | 52 (100) | 203 (99.0) | 103 (100) | 305 (99.4) | 155 (100) |
| Measurable, n (%) | 92 (91.1) | 46 (88.5) | 182 (88.8) | 87 (84.5) | 273 (88.9) | 135 (87.1) |
| Non-measurable, n (%) | 9 (8.9) | 6 (11.5) | 21 (10.2) | 16 (15.5) | 32 (10.4) | 20 (12.9) |
| No, n (%) | 1 (0.01) | 0 (0) | 2 (1.0) | 0 (0) | 2 (0.7) | 0 (0) |
| Heng Risk Factors | | | | | | |
| Intermediate Risk, n (%) | 75 (73.5) | 40 (76.9) | 157 (76.6) | 83 (80.6) | 235 (76.5) | 120 (77.4) |
| Poor Risk, n (%) | 27 (26.5) | 12 (23.1) | 48 (23.4) | 20 (19.4) | 72 (23.5) | 35 (22.6) |
| 1, n (%) | 21 (20.6) | 11 (21.1) | 50 (24.4) | 26 (25.2) | 84 (27.4) | 43 (27.7) |
| 2, n (%) | 54 (52.9) | 29 (55.8) | 107 (52.2) | 57 (55.3) | 151 (49.2) | 77 (49.7) |
| 3, n (%) | 18 (17.7) | 7 (13.5) | 38 (18.5) | 13 (12.6) | 52 (16.9) | 26 (16.8) |
| 4, n (%) | 9 (8.8) | 5 (9.6) | 10 (4.9) | 7 (6.8) | 20 (6.5) | 9 (5.8) |
| Karnofsky Performance Status | | | | | | |
| 100%, n (%) | 30 (29.4) | 16 (30.8) | 69 (33.8) | 34 (33.0) | 104 (33.9) | 55 (35.5) |
| 90%, n (%) | 49 (48.0) | 24 (46.2) | 83 (40.7) | 44 (42.7) | 120 (39.1) | 61 (39.4) |
| 80%, n (%) | 20 (19.6) | 11 (21.2) | 44 (21.6) | 23 (22.3) | 69 (22.5) | 32 (20.6) |
| 70%, n (%) | 3 (2.9) | 1 (1.9) | 8 (3.9) | 2 (1.9) | 12 (3.9) | 7 (4.5) |

Pre-planned Immune Responder Analysis

Baseline Characteristics

| | Combination Arm | | Immune Responder Subgroup | |
|-------------------------------------|-----------------|-------|---------------------------|-------|
| | n=289 | | n=96 | |
| Median Age | 60.0 yr | | 58.5 yr | |
| Gender, Male | 212 | 73.4% | 64 | 66.7% |
| Race | | | | |
| White | 271 | 93.8% | 92 | 95.8% |
| Non-White | 18 | 6.2% | 4 | 4.2% |
| Metastatic Disease | | | | |
| Yes | 287 | 99.3% | 95 | 99.0% |
| Measurable | 256 | 88.6% | 79 | 82.3% |
| Non-measurable | 31 | 10.7% | 16 | 16.7% |
| No | 2 | 0.7% | 1 | 1.0% |
| Heng Risk Factors | | | | |
| Intermediate Risk | 223 | 77.2% | 79 | 82.3% |
| Poor Risk | 66 | 22.8% | 17 | 17.7% |
| 1 | 82 | 28.4% | 29 | 30.2% |
| 2 | 141 | 48.8% | 50 | 52.1% |
| 3 | 48 | 16.6% | 12 | 12.5% |
| 4 | 18 | 6.2% | 5 | 5.2% |
| Karnofsky Performance Status | | | | |
| 100% | 103 | 35.8% | 37 | 39.0% |
| 90% | 111 | 38.5% | 36 | 37.9% |
| 80% | 65 | 22.6% | 20 | 21.1% |
| 70% | 9 | 3.1% | 2 | 2.1% |