



AMG 160 DATA AT ESMO VIRTUAL CONGRESS 2020

SEPTEMBER 21, 2020

AMGEN[®]

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AGENDA

Introduction

David Reese, M.D.—Executive Vice President, Research and Development

AMG 160 Data Overview

Gregory Friberg, M.D.—Vice President, Global Development and Oncology Therapeutic Area Head

Q&A

**David Reese, M.D.
Gregory Friberg, M.D.**



INTRODUCTION

DAVID REESE, M.D.

EXECUTIVE VICE PRESIDENT, RESEARCH AND DEVELOPMENT



AMGEN IS THE LEADER IN BiTE[®] IMMUNO-ONCOLOGY



**BLINCYTO[®] is the only
FDA Approved BiTE[®]
Therapy**



**Most robust pipeline
with 10 investigational
molecules across
solid tumors and
blood cancers**



Most Patients Studied
To date, Amgen's BiTE[®]
immuno-oncology
platform has been
investigated in more
than 3,000 patients

BiTE[®] = bispecific T-cell engager

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AMGEN'S BITE[®] PLATFORM: A CLINICALLY VALIDATED IMMUNO-ONCOLOGY THERAPY

- Clinically validated off-the-shelf immuno-oncology therapy
- Seamlessly integrated, scalable, industrialized platform
- Clinical activity demonstrated in both liquid and solid tumors
- Advancing half-life extended BiTE[®] constructs against high-quality targets in prostate cancer, SCLC, MM and gastric cancer
- Applying learnings across programs to optimize dose / schedule and mitigate adverse events
- Exploring strategies to prevent resistance
 - Combinations with PD-1 antibodies are ongoing
 - Additional combinations and rational sequences are planned

SCLC = small cell lung cancer; MM = multiple myeloma; PD-1 = programmed cell death protein 1

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AMG 160 UPDATE

GREGORY FRIBERG, M.D.

VICE PRESIDENT, GLOBAL DEVELOPMENT AND ONCOLOGY
THERAPEUTIC AREA HEAD

AMGEN[®]

PROSTATE CANCER IS A LEADING CAUSE OF MORTALITY IN MEN

- **#1 diagnosed non-cutaneous cancer in men in the U.S. and EU, #2 worldwide¹⁻⁴**
- **~ 1.3 million new diagnoses and ~ 360,000 estimated deaths due to prostate cancer worldwide in 2018⁵**
- **Androgen-deprivation therapy (ADT) is the standard of care for regional or advanced prostate cancer, however most men progress to castrate resistant prostate cancer (CRPC)^{6,7}**
- **~ 1/3 of patients with CRPC develop metastases within two years of diagnosis⁸**
- **Metastatic CRPC (mCRPC) remains incurable despite current treatments, including ADT, chemotherapy, immunotherapy, radium isotope and palliative therapies⁹**
- **The five-year survival rate for mCRPC is 30%, representing a high unmet medical need²**

1. Ferlay J, et al. *Eur J Cancer*. 2018;103:356-387. 2. SEER Cancer Stat Facts: Prostate Cancer. seer.cancer.gov/statfacts/html/prost.html. Accessed March 14, 2019. 3. Bray F, et al. *CA Cancer J Clin*. 2018;68:394-424. 4. Gandaglia G, et al. *Prostate*. 2014;74:210-216. 5. The Global Cancer Observatory. <https://gco.iarc.fr/today/data/factsheets/cancers/27-Prostate-fact-sheet.pdf>. 6. Crawford ED, et al. *Urol Oncol*. 2017;355:S1-S13. 7. Nouri M, et al. *Front Oncol*. 2014;4:370. 8. Kirby M, et al. *Int J Clin Pract*. 2011;65:1180-1192. 9. Sumanasuriya S, et al. *Cold Spring Harb Perspect Med*. 2018;8:a030635.

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PROSTATE-SPECIFIC MEMBRANE ANTIGEN (PSMA): A COMPELLING TARGET FOR PROSTATE CANCER

- **PSMA is a type II transmembrane glycoprotein highly expressed on the surface of prostate cancer cells**
- **Considered an independent indicator of poor prognosis¹⁻⁵**
 - High expression on biopsy is associated with increased chance of disease recurrence
 - Expression increases with tumor aggressiveness, androgen independence, metastatic disease, and disease recurrence
- **Low, predominantly cytoplasmic expression in some normal tissues, including prostate, brain, kidney, liver and small intestine**
- **Low membrane expression on select tumors: NSCLC, neuroendocrine, breast**

1. Chang SS. Rev Urol. 2004;6(suppl 10):S13-S18. 2. Bouchelouche K, et al. Discov Med. 2010;9:55-61. 3. Bravaccini S, et al. Sci Rep. 2018;8:4254. 4. Chang SS, et al. Cancer Res. 1999;59:3192-3198. 5. Hupe MC, et al. Front Oncol. 2018;8:623..

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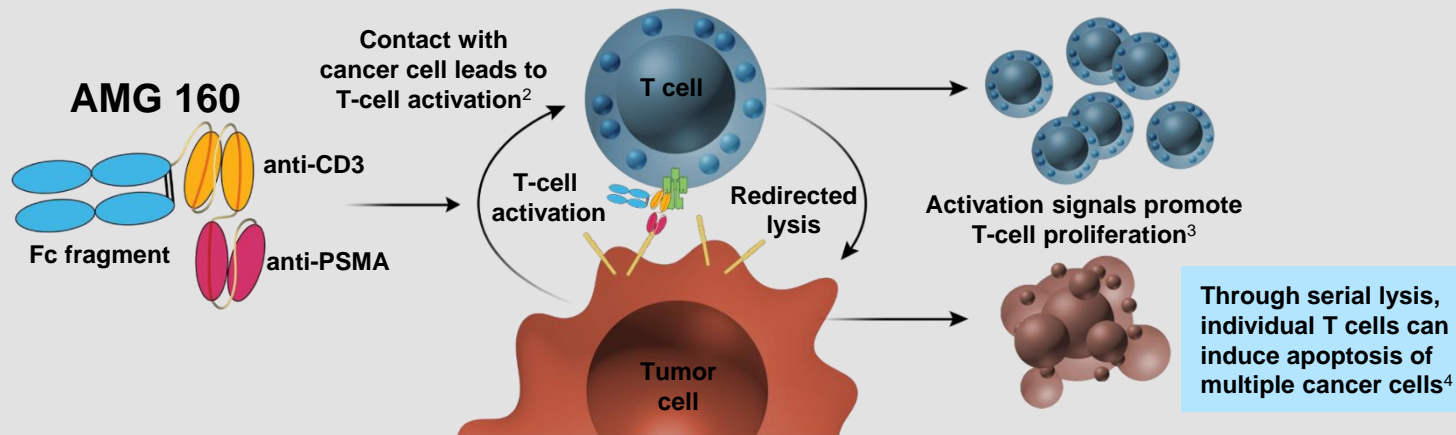
Interim results from a phase 1 study of AMG 160, a half-life extended (HLE), PSMA-targeted, bispecific T-cell engager (BiTE[®]) immune therapy for metastatic castration-resistant prostate cancer (mCRPC)

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Presented at European Society of Medical Oncology 2020 Virtual Congress, September 19-21, 2020

AMGEN BITE[®] (BISPECIFIC T-CELL ENGAGER) IMMUNOTHERAPY



- BiTE[®] molecules engage a patient's own T cells to attack and eradicate cancer cells¹
 - T-cell activation induces transient cytokine release and tumor killing¹
- Blinatumomab (BLINCYTO[®], Amgen Inc.) is the first and only bispecific immunotherapy approved in oncology worldwide¹
- **AMG 160** is a **half-life extended** PSMA x CD3 BiTE[®] immunotherapy for mCRPC

1. Baeuerle PA, et al. Cancer Res. 2009;69:4941-4. 2. Klinger M, et al. Immun Rev. 2016;270(1):193-208. 3. Bargou R, et al. Science. 2008;321:974-7. 4. Stieglmaier J, et al. Expert Opin Biol Ther. 2015;15(8):1093-9.

FIRST-IN-HUMAN DOSE EXPLORATION STUDY OF AMG 160

Part 1: FIH Monotherapy

Dose Exploration
(n = 1–4 per dose cohort)

MTD/RP2D

Dose Expansion
MTD/RP2D
(n ~ 30)

Safety follow-up: 30 days after last dose of AMG 160
Long-term follow-up: every 6 months up to 3 years
after first dose of AMG 160

Part 2: Combination With Pembrolizumab

Dose Exploration
(n = 3–4 per dose cohort)

Primary Objectives

- Evaluate safety and tolerability in mCRPC
- Determine MTD or RP2D

Secondary Objectives

- Characterise PK
- Evaluate preliminary antitumor activity

Exploratory Objectives

- Evaluate biomarkers of PD activity
- Identify potential patient selection biomarkers

- **Study design** – Phase 1, global, open-label study evaluating safety and tolerability of AMG 160 monotherapy (Part 1) or in combination with pembrolizumab (Part 2)
- **Dosing schedule** – IV infusion every 2 weeks (after target dose reached)

FIH = first-in-human; IV = intravenous; mCRPC = metastatic castration-resistant prostate cancer; MTD = maximum tolerated dose; PD = pharmacodynamics; PK = pharmacokinetics; RP2D = recommended phase 2 dose

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KEY ELIGIBILITY CRITERIA AND DEMOGRAPHICS

- **Inclusion Criteria**

- **Histologically or cytologically confirmed mCRPC refractory to novel hormonal therapy and**
 - **Have failed 1–2 taxane regimens; or**
 - **Patient deemed unsuitable for or has refused taxanes**
- **Evidence of progressive disease per PCWG3**

- **Exclusion Criteria**

- **Active autoimmune disease or requiring immunosuppressive therapy**
- **Prior PSMA-targeted therapy (patients treated with PSMA radionuclide therapy may be eligible)**
- **CNS metastases, leptomeningeal disease, or spinal cord compression**

Baseline Demographics	All (N = 43)
Median (range) age, y	66.0 (49–78)
Race, n (%)	
Asian	2 (4.7)
Black	2 (4.7)
White	34 (79.1)
Other	5 (11.6)
Prior lines of therapy, n (%)	
1	2 (4.7)
2	4 (9.3)
3	9 (20.9)
≥ 4	26 (60.5)
Median (range)	4 (1–9)
Median (range) PSA at baseline, µg/L	79.2 (0.1–4035.0)
RECIST-measurable disease, n (%)	15 (34.9%)

ADVERSE EVENTS (AES) AND ANTIDRUG ANTIBODIES (ADAS)

- 43 patients received ≥ 1 dose of AMG 160 monotherapy
 - 41 (95.3%) patients experienced TEAEs
 - 19 (44.2%) patients remained on AMG 160 at the time of data analysis
 - 6 (14.0%) received treatment ≥ 6 months

TRAEs

- 41 (95.3%) patients experienced TRAEs
 - No grade 5 events, and none resulted in treatment discontinuation
- 3 reversible dose-limiting toxicities occurred
 - Grade 3 rash (n = 2)
 - Grade 3 GI hemorrhage (n = 1)

ADAs

- 6 of 30 (20.0%) patients assessed developed ADAs affecting drug exposure between cycles 1 and 10
 - No AEs associated with ADAs were observed

TRAEs in $\geq 20\%$ of patients (N = 43)*

TRAE, n (%)	All Grade, n (%)	Grade 3, n (%)
CRS (Lee criteria) [†]	39 (90.7)	11 (25.6)
Fatigue	19 (44.2)	1 (2.3)
Vomiting [†]	19 (44.2)	0 (0)
Nausea [†]	17 (39.5)	0 (0)
Pyrexia [†]	16 (37.2)	0 (0)
Headache [†]	15 (34.9)	0 (0)
Diarrhoea [†]	14 (32.6)	2 (4.7)
Dry mouth	13 (30.2)	0 (0)
Rash [†]	12 (27.9)	4 (9.3)
Hypophosphataemia	11 (25.6)	4 (9.3)
Hypotension [†]	10 (23.3)	5 (11.6)
Chills [†]	10 (23.3)	0 (0)
Dysgeusia	10 (23.3)	0 (0)
Decreased appetite	9 (20.9)	0 (0)

* 8 patients experienced grade 4 laboratory abnormalities that were clinically non-significant;

[†] CRS-related

20 July 2020 cutoff; ADA = antidrug antibody; AE = adverse event; CRS = cytokine release syndrome; GI = gastrointestinal; TEAE = treatment-emergent adverse event;

TRAE = treatment-related adverse event

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CHARACTERISTICS OF CYTOKINE RELEASE SYNDROME

- CRS was reversible, manageable, most severe in cycle 1 and associated with fever, hypotension, transient transaminitis, nausea/vomiting and/or diarrhea (Lee 2014 grading)
 - No grade 4/5 CRS events or treatment discontinuations
 - 26 (60.5%) patients had grade 2 CRS as worst grade (hypotension: 15 [34.9%]; transaminitis: 13 [30.2%])*
 - 11 (25.6%) patients had grade 3 CRS as worst grade (hypotension: 6 [14.0%]; transaminitis: 10 [23.3%])*
 - Transaminitis events were short-term AST/ALT elevations not associated with long-term hepatic dysfunction
 - 4 (9.3%) patients experienced reversible atrial fibrillation in setting of CRS/tachycardia

CRS Grading (Lee 2014)			
Grade 1	Grade 2	Grade 3	Grade 4 [†]
Fever, nausea, fatigue, etc, requiring symptomatic treatment only	Grade 1 CRS symptoms and <ul style="list-style-type: none"> • O₂ requirement < 40% • Intravenous fluids or low-dose vasopressor for hypotension • Grade 3 transaminitis 	Grade 1 CRS symptoms and <ul style="list-style-type: none"> • O₂ requirement ≥ 40% • High-dose or multiple vasopressors for hypotension • Grade 4 transaminitis 	Grade 1 CRS symptoms and <ul style="list-style-type: none"> • Requirement for ventilator • Grade 4 organ toxicity (excluding transaminitis)

* Data from investigators, database-reported AEs, and laboratories (20 July 2020); † No grade 4 CRS events were observed at the time of data cutoff (20 July 2020)

AE = adverse event; ALT = alanine aminotransferase; AST = aspartate aminotransferase; CRS = cytokine release syndrome

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PROPHYLACTIC MITIGATIONS TO IMPROVE CRS PROFILE

Prophylactic Mitigations in Cycle 1 Priming Cohort		
Dose priming	Dexamethasone premedication	Prophylactic IV hydration
Lower run-in dose before maintenance target dose	8 mg PO and 8 mg IV before AMG 160 dose*	1L normal saline after AMG 160 dose

Safety Outcomes With Prophylactic Mitigation Strategy	
Cohort 5 (unoptimised), 0.3 mg (n = 4)	Cohort 5 (optimised), 0.3 mg (n = 5)
<ul style="list-style-type: none"> • No DLTs • SAEs, (n = 4; including 3 CRS events) • Grade 2 CRS (n = 3) • Grade 3 CRS (n = 2) 	<ul style="list-style-type: none"> • No DLTs • No SAEs • Grade 2 CRS (n = 3) • No Grade 3 CRS

20 July 2020 data cutoff; CRS = cytokine release syndrome; DLT = dose limiting toxicity; IV = intravenous; PO = oral administration; SAE = serious adverse event
 *Dexamethasone premedication: 8 mg PO (6–16 hours before) and 8 mg IV (1 hours before) before AMG 160 doses in cycle 1
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AMG 160 DEMONSTRATES EFFICACY WITH LONG-TERM RESPONSES

PSA/CTC Responses (n = 13–35)

Response	All, n (%)
PSA response, confirmed*	8 (27.6)
PSA response, unconfirmed†	4 (11.4)
CTC0 response‡	3 (23.1)

RECIST Responses (n = 15)

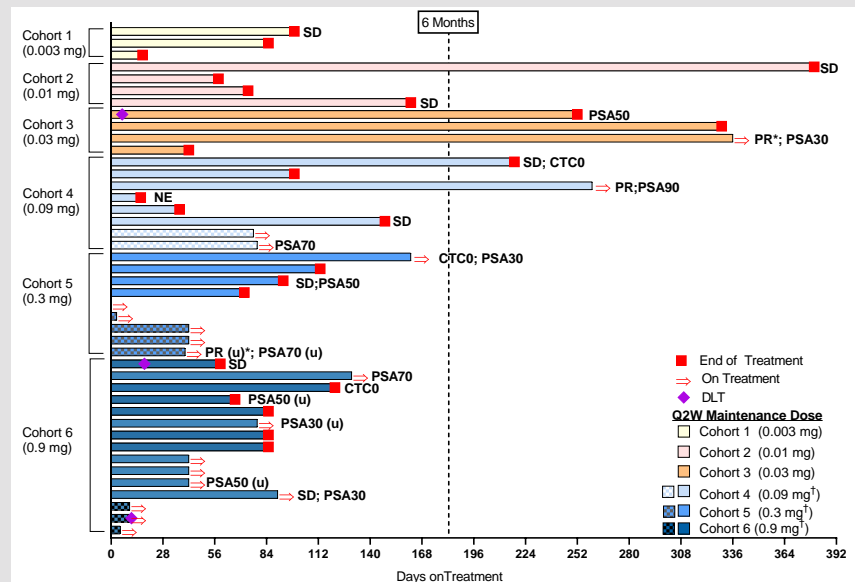
Response	All, n (%)
Partial response, confirmed	2§ (13.3)
Partial response, unconfirmed	1§ (6.7)
Stable disease	8 (53.3)

* ≥ 30% reduction based on 29 patients with 2 postbaseline PSA results

† ≥ 30% reduction based on 35 patients with measurable PSA at baseline

‡ Based on 13 patients with baseline CTC > 0 and postbaseline CTC assessment

§1 PR(u) and 1 PR confirmation occurred after 20 July 2020



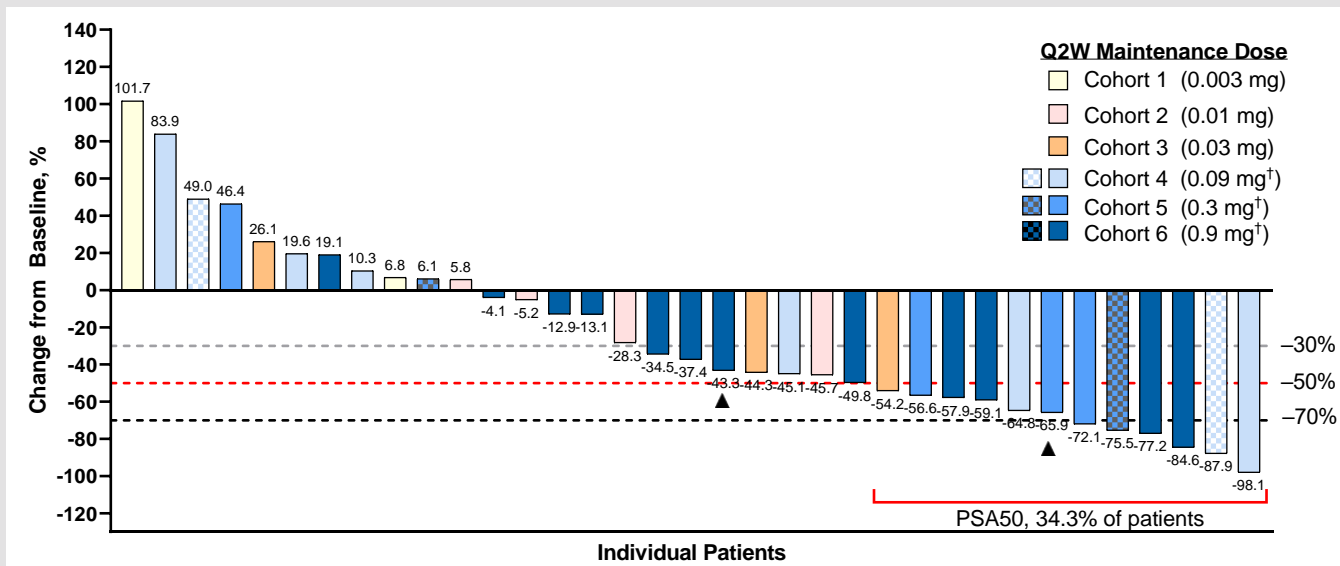
CTC = circulating tumor cell; DLT = dose-limiting toxicities; NE = not evaluable; PSA = prostate-specific antigen; PR = partial response; Q2W = every 2 weeks; RECIST = Response Evaluation Criteria in Solid Tumors; SD = stable disease; (u) = unconfirmed

* PR occurred before but reported after 20 July 2020 data cutoff; PR (u) reported after 20 July 2020 data cutoff

† Checkered bars indicate cohorts with optimised cycle 1 priming strategies

PSA REDUCTIONS IN THE MAJORITY OF EVALUABLE PATIENTS*

- PSA reductions (best response) were dose dependent and occurred in 24/35 (68.6%) evaluable patients (20 July 2020)
- PSA reductions > 50% occurred in 12/35 (34.3%) evaluable patients

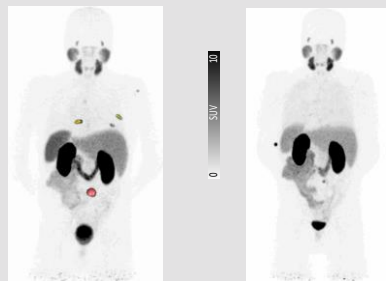


PSA50 = PSA decrease of $\geq 50\%$; Q2W = every 2 weeks; * Best PSA reductions at any time point in evaluable patients included those who had received ≥ 1 dose of AMG 160 and had measurable baseline PSA; [†] Checkered bars indicate cohorts with optimised cycle 1 priming strategies; \blacktriangle Indicates patient who had failed prior LuPSMA treatment
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EXAMPLES OF DEEP RESPONSES TO AMG 160

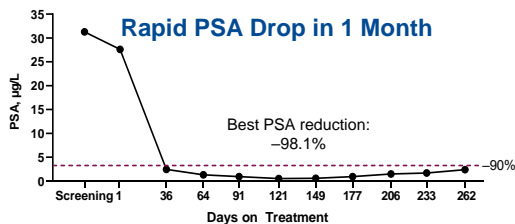
Patient	10112001002
Prior Rx	Surgery, radiotherapy, docetaxel, enzalutamide, bicalutamide, and talazoparib
Cohort	4 (0.09 mg with cycle 1 priming)

PR by 3 Months
PSMA PET/CT



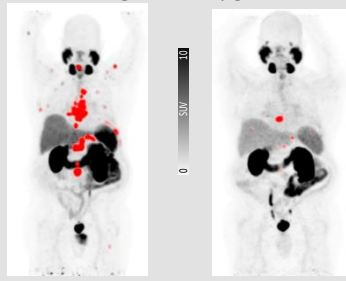
Baseline

Week 12



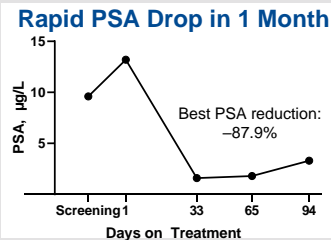
Patient	10166004005
Prior Rx	Surgery, docetaxel, enzalutamide, sipuleucel
Cohort	4 (0.09 mg with optimised cycle 1 priming)

Not RECIST evaluable
PSMA PET/CT



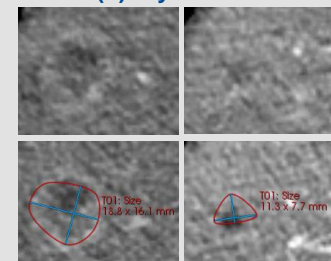
Baseline

Week 12



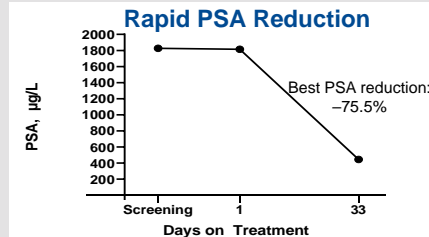
Patient	10166004006
Prior Rx	Radiotherapy, apalutamide, docetaxel, sipuleucel-T, radium-223
Cohort	5 (0.3 mg with optimised cycle 1 priming)

PR (u)* by 2.5 Months



Baseline
T01 Liver
Segment VIII

Week 10
40% reduction
vs baseline



PET/CT = positron emission tomography-computed tomography; PR = partial response; PSA = prostate-specific antigen; PSMA = prostate-specific membrane antigen; RECIST = Response Evaluation Criteria in Solid Tumors; u = unconfirmed; * PR (u) response reported after 20 July, 2020 data cutoff
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CONCLUSIONS

- **AMG 160 had a manageable safety profile as monotherapy**
 - CRS was reversible and manageable with priming doses and standard mitigations
 - No grade 5 TRAEs or treatment-related discontinuations
- **In heavily pretreated patients, AMG 160 showed preliminary evidence of efficacy**
 - Overall, 68.6% of patients showed any PSA decline across all monotherapy dose cohorts
 - 34.3% of patients showed \geq PSA50 reduction
 - Among the 15 patients with measurable disease, 3 PR (2 confirmed) and 8 SD were observed
- **44.2% of patients remained on AMG 160 at the time of data analysis, with 6 (14.0%) patients continuing treatment for \geq 6 months**
- **MTD has not been reached and dosing optimisation of AMG 160 continues as study nears RP2D; investigation of AMG 160 in combination with pembrolizumab is in progress**

For more information, please contact Amgen Medical Information: medinfo@amgen.com



Q&A

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