IMAAGEN Trial Update: Effect of Abiraterone Acetate and Low Dose Prednisone on PSA in Patients With Non-mCRPC

Figure 1: IMAAGEN Study Design

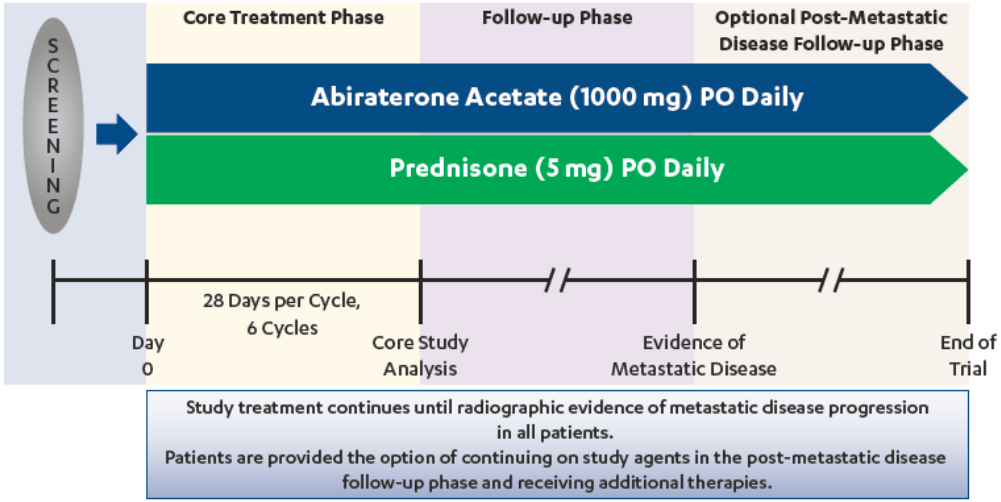

Table 2: PSA and PSADT at Screening

	Abiraterone Acetate Plus Prednisone
PSA, ng/ml	
N	131
Median, range	11.9 (1.3-167.8)
PSADT for subjects with PSA <10 ng/mL, months	
N	52
Median, range	3.4 (1.1-9.4)

Table 1: Baseline Characteristics

	Abiraterone Acetate Plus Prednisone (n=131)
Age, years	
Mean, range	71.2 (48.0-90.0)
Race, n (%)	
White	108 (82.4)
Black or African American	19 (14.5)
Asian	2 (1.5)
Other	1 (0.8)
Not Reported	1 (0.8)
Calculated Gleason Score, n (%)	
n*	125
< 7	17 (13.6)
7	59 (47.2)
≥ 8	49 (39.2)
Mean, SD	7.5 (1.14)
Median	7.0
Range	4.0-10.0
Testosterone, ng/dL	
n	116
Mean	10.31
SD	11.49
Range	1.55-117.38

*n = Data for 6 subjects were not available at the time of the data base lock, 31Dec2013

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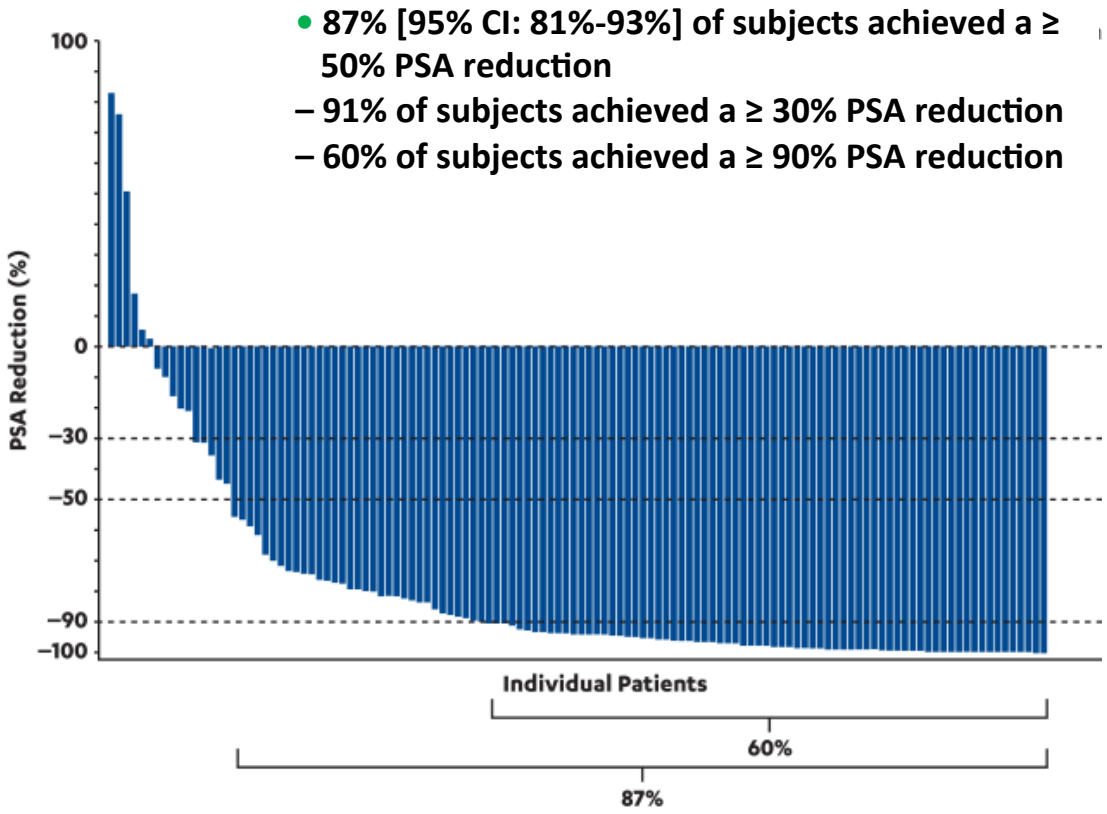
Primary Endpoint

Figure 3: Maximum PSA Reduction During Cycles 1-6



Secondary Endpoints

- The median time to PSA progression was 28.7 months (95% CI: 21.2, NE)
- Event-free rates for PSA progression at 12, 18 and 24 months were 79.7%, 68.4% and 56.6%, respectively
- As of this update:
  - 45 (34.4%) subjects showed evidence of PSA progression
- In this update, 21 (16.0%) subjects had radiographic evidence of disease progression as reported by investigators
- The median time to disease progression was not reached

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Figure 5: PSA Progression

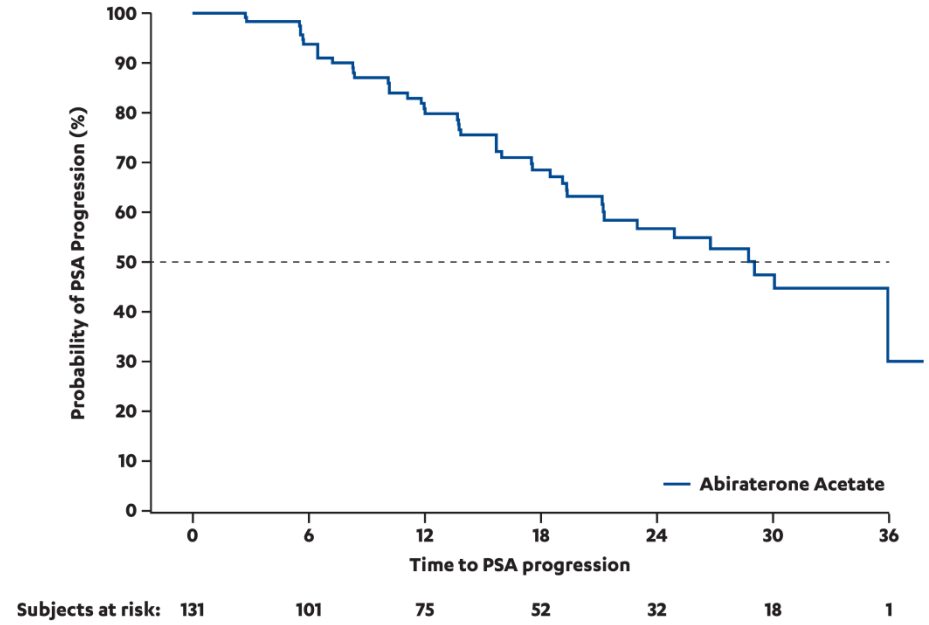

Figure 4: Radiographic Evidence of Disease Progression

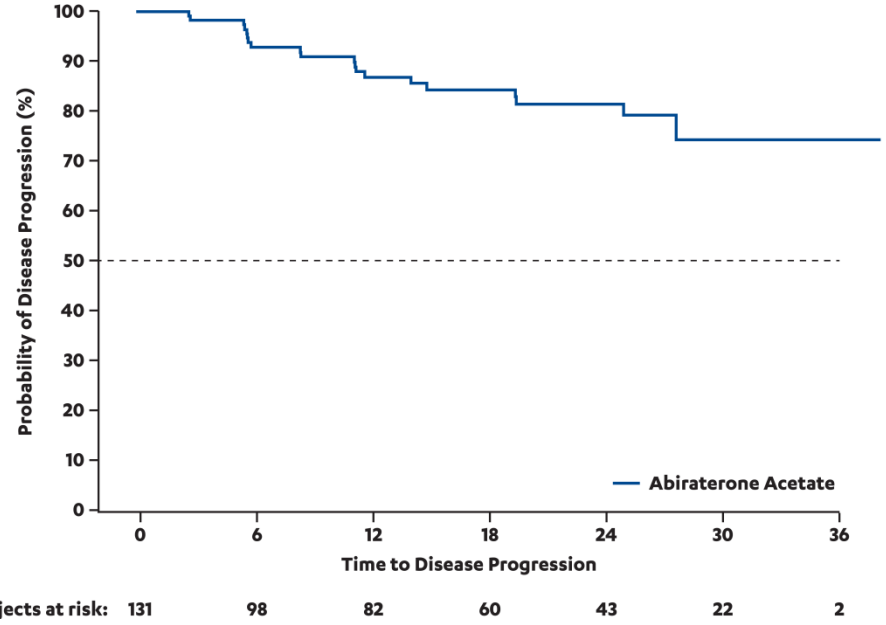

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Table 3: Incidence of Adverse Events Reported in at Least 1% of Subjects

AA (N = 131)	Grade 3	Grade 4	Grade 5
Hypertension	29 (22.1%)	0	0
Hypokalemia	8 (6.1%)	0	0
Dehydration	4 (3.1%)	0	0
Hyperglycemia	4 (3.1%)	0	0
Hematuria	5 (3.8%)	0	0
Urinary Retention	4 (3.1%)	0	0
Nephrolithiasis	2 (1.5%)	0	0
Renal failure acute	2 (1.5%)	0	0
Pneumonia	5 (3.8%)	0	1 (0.8%)
Urinary tract infection	2 (1.5%)	0	0
Sepsis	0	3 (2.3%)	1 (0.8%)
Diarrhea	2 (1.5%)	0	0
Syncope	3 (2.3%)	0	0
Atrial fibrillation	2 (1.5%)	0	0
Bradycardia	2 (1.5%)	0	0
Coronary artery disease	2 (1.5%)	0	1 (0.8%)
Myocardial infarction	1 (0.8%)	0	1 (0.8%)
Asthenia	2 (1.5%)	0	0
Chest pain	2 (1.5%)	0	0
Edema peripheral	2 (1.5%)	0	0
Fall	2 (1.5%)	0	0
Muscular weakness	2 (1.5%)	0	0
Anemia	3 (2.3%)	0	0

The percentage of subjects with a Grade 3 or higher treatment emergent adverse event and system organ class rows are based on all subjects. Worst toxicity is reported for recurring events of different non-missing toxicity grades for each subject. Preferred terms reported are events occurring in at least 1% of subjects in any group.

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- Treatment of high-risk nmCRPC patients with AA (1000mg) + P (5mg) resulted in a median time to PSA progression of 28.7 months
- The median time to radiographic disease progression was not reached at the data cut-off through 03Dec2014
- The safety profile in this trial using prednisone 5 mg is consistent with previously reported data