Ord Table 8.12.6h Eligibility criteria for patients not randomized but met eligibility criteria for 68-PSMA-11 scan (PSMA-11 safety analysis set)

Inclusion/exclusion category Inclusion/exclusion criteria	Overall (N=1003) n (%)
Patients not randomized, n	39
Any eligibility criteria not met	37 (94.9)
Any exclusion criteria met	13 (33.3)
A superscan as seen in the baseline bone scan	4 (10.3)
Any investigational agents within 28 days prior to day of randomization	1 (2.6)
Concurrent serious medical conditions that in the opinion of the investigator would impair study participation or cooperation	3 (7.7)
Diagnosed with other malignancies that are expected to alter life expectancy. however, patients with a prior history of malignancy that has been adequately treated are eligible	2 (5.1)
Symptomatic cord compression, or clinical or radiologic findings indicative of impending cord compression	1 (2.6)
Transfusion for the sole purpose of making a subject eligible for study inclusion	2 (5.1)
Any inclusion criteria not met	26 (66.7)
Albumin >3.0 g/dL (3.0 g/dL is equivalent to 30 g/L)	5 (12.8)
Patients must have a life expectancy >6 months	2 (5.1)
Patients must have adequate organ function: bone marrow reserve: white blood cell count >=2.5 x 10/L or absolute neutrophil count >=1.5 x 10/L; platelets >=100 x 10/L; hemoglobin >=9 g/dL	11 (28.2)
Patients must have an ECOG performance status of 0 to 2	3 (7.7)
Patients must have been previously treated with at least 1, but no more than 2 taxane regimens. the patient is eligible if the patient's physician deems him unsuitable to receive second taxane regimen	5 (12.8)
Patients must have progressive mCRPC. documented progressive mCRPC will be based on: serum PSA progression measured at least 1 week prior; soft-tissue progression; progression of bone disease	2 (5.1)
Patients must have the ability to understand and comply with all protocol requirements	1 (2.6)

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