Inclusion Criteria:

- Patients with rising PSA (≥0.2ng/mL at any time point after initiation of menopausal suppression therapy) and PSA >2 ng/mL at baseline
- Patients with prior treatment failure with ADT and/or other therapies that may be associated with the ADT standard, delaying further treatment with ADT
- Patients with a prostate bed or lymph nodes identified on imaging
- Patients with prior radiotherapy or surgery

Exclusion Criteria:

- Patients with known or suspected metastatic disease
- Patients with a Gleason score of 7 or higher
- Patients with documented or untreated prostate cancer recurrence
- Patients with uncontrolled comorbidities

OBJECTIVES

- To evaluate SM-88 in patients with rising PSA and menopausal suppression treatment failure
- To assess the safety and side effect profile of SM-88
- To evaluate the impact of SM-88 on PSA kinetics
- To evaluate the impact of SM-88 on radiographic progression

RESULTS

- Median baseline PSA for all subjects was 16.2ng/mL
- Median baseline CTCs was 1 (range 0-112)
- Median baseline Gleason score was 8 (range 7-9)
- Median duration of ADT was 14 months (range 6-37.6 months)

CONCLUSIONS

- Favorable changes in PSA kinetics including rising PSA were observed in cases with high testosterone levels at baseline and with no radiographic progression
- The adverse profile included only 1 Grade 2 (fatigue) and 1 Grade 3 (fatigue) adverse events
- SM-88 was generally well tolerated with no radiographic progression
- SM-88 may provide disease control without the side effects associated with the ADT standard, delaying the need for ADT or other systemic therapy

DISCUSSION

- These results suggest a clinically meaningful prolongation of time to PSA progression in metastatic prostate cancer patients with rising PSA
- SM-88 can be considered in cases where testosterone lowering treatments may compromise quality of life
- Radiations in CTC number may be more informative indicator of benefit than changes in PSA for further study with SM-88 and other non-steroidal modifiers
- Prospective trials to confirm these results are planned

REFERENCES

- Priore F, et al. J Clin Oncol 37, 2019 (suppl 7S; abstr 917)
- Scher HI. J Clin Oncol 36, 2018 (suppl 6S; abstr 424.6)
- Reference to any commercial product, service or company is not to be construed as an endorsement or as prescribing its use.