BACKGROUND
Despite toxicity and no clinical benefit, non-metastatic recurrent prostate cancer (nmPC) is typically treated with medical intervention in North America. MM-88 is a non-toxic investigational therapy that is designed to directly target circulating tumor cells (CTCs) [1,2]. The CTC burden in patients with nmPC has been shown to be a major determinant of overall survival [3]. Randomized phase I/II trials demonstrated stable or rising tumor levels at baseline while achieving CTC regression and survival benefit in androgen deprivation therapy for prostate cancer (ADT) resistant disease [1,2,3]. The phase I/II human trial demonstrated that no radiation-identifiers were identified.

OBJECTIVES
• To assess the therapeutic benefit and QoL impact of SM-88, a relatively non-toxic investigational therapy for nmPC
• To quantify any induction in circulating tumor cells (CTCs)
• To generate radiographic progression-free survival data
• To report effect on testosterone, PSA and other markers of disease progression

RESULTS
Seven patients completed at least 1 cycle (median 6, range 3-11). Median age was 69 (IQR 67-74); all had prior ADT after curative intent RT (7/9) or biopsy grade >7 (4/9) with or without metastases (3/9). One subject died within 3 months of the trial (PFS 0%). Median tumor volume was 0.5 cm³ (IQR 0.03-1.1 cm³). No subject developed or remained in stable disease (9/9).

UPATED ONGOING, OPEN-LABEL, MULTI-CENTER, SINGLE-ARM PHASE II STUDY
INDICENTS—Recurrent nmPC ECOG 1, PSA >1 ng/mL, no radiographically detectable lesions, and rising PSA following Prostate Cancer Working Group 3 (PCWG) criteria.

TREATMENT—SM-88 (Hoffman Pharmaceuticals, Inc.), a proprietary combination of biologically active molecules, was designed to target androgen-independent prostate cancer and inhibit androgen-receptor signaling. 45 mg oral daily for 28 days followed by 14 days off treatment (28/14 cycle). Both positive and negative controls were included. SM-88 exhibits an extensive safety profile, which is not known for previous therapies, such as docetaxel or enzalutamide. It is currently in phase III clinical trials for nmPC.

TESTOSTERONE AND OTHER RESPONSES—Testosterone increased over baseline in 7/9 subjects (78%) at 8 weeks. Other markers of nmPC control were improved in 7/9 subjects (78%) as shown by absolute PSA, VISP (visfatin), DHEA, and testosterone. In 6/9 subjects, no chemotherapy or androgen deprivation therapy (ADT) was given at the same time. A major tumor volume reduction was observed in all subjects.

CONCLUSIONS
SM-88 may be a viable alternative therapy in biochemical recurrent prostate cancer.

REFERENCES

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Figure 1. Percent of Patients with PFS

Figure 2. Circulating Tumor Cells (CTC) levels

Figure 3. Average Response to EORTC QLQ-P30-G35 vs 35

Table 1. Demographics (updated August 1, 2017)

Table 2. PSA Doubling Time (months) (p cycle)

Table 3. Reported Adverse Event by Grade

ADVERSE EVENTS (AE) Adverse events were evaluated in all patients Therapy was well tolerated with no treatment-related serious adverse events. No adverse events result in death, discontinuation, or reduction of dose (Table 3).