GENITOURINARY (PROSTATE) CANCER
DOI: 10.1200/JCO.2017.35.15_suppl.e16588 *Journal of Clinical Oncology* - published online before print May 30, 2017

Effect of PectaSol-C modified citrus pectin (P-MCP) treatment (tx) on PSA dynamics in patients (pts) with nonmetastatic, biochemically relapsed prostate cancer (BRPC): Results of the interim analysis of a prospective phase II study.

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Abstract e16588

Background: 30% of pts with localized PC will have a biochemical relapse post local tx. The optimal tx of these pts remains elusive. While androgen deprivation therapy is effective in reducing PSA level, its long term benefit on survival remain undefined, and it is associated with significant cumulative toxicities.Thus evaluation of new non-toxic compounds in this pt population is warranted. P-MCP is a competitive inhibitor of galectin-3, a carbohydrate-binding protein, which is known to be involved in cancer pathogenesis. Preliminary pre-clinical and clinical data suggest that P-MCP is active in PC. We aimed to evaluate the safety and PSA dynamics of tx with P-MCP in pts with BRPC. **Methods:** Pts with non-castrate non metastatic BRPC were enrolled in a prospective phase 2 study of tx with oral P-MCP, at 4.8 grams X 3/day. Pts that did not progress clinically, biochemically (PSA), and radiologically, at 6 months (mos), were treated for subsequent 12 mos. Sample size provided 85% power to assess a decrease in PSA progression rate from 80% (natural history) to 40% (P-MCP tx) at 6 mos. We report here first results of a pre-planned interim analysis after ≤ 50% of planned enrolled pt completed 6 mos of tx. **Results:** The study was

initiated in June 2013. We report here the 6 mos data of the first 35 pts enrolled. Median age was 74 years. Treatment of the primary tumor consisted of surgery in 11% (n = 4), radiation in 69% (n = 24), and both in 20% (n = 7). No pt had tx related grade 3/4 toxicity. One patient withdrew his consent after 1 mos. Of the 34 pts analysed, 18% (n = 6) had grade 1 toxicity. 62% (n = 21) had a stabilization/decrease of PSA, and negative scans, at 6 mo, and entered into the second 12 mos tx phase. A stabilization or improvement (increase) of PSA doubling time was noted in 79% (n = 27) of pts. Disease progression at 6 mos was noted in 38% (n = 13: PSA only 29%, n = 10; PSA and scans 9%, n = 3). A future final report will include full tx data (18 mos) and correlative analysis. **Conclusions:** The interim analysis of the present study suggests a potential benefit of P-MCP tx on progression of BRPC. P-MCP tx is safe. Final analysis is pending. Clinical trial information: NCT01681823.