P046 Long term effect of PectaSol-C modified citrus pectin treatment in non-metastatic biochemically relapsed prostate cancer patients: Results of a prospective phase II study

EUR Urol Suppl 2019;18(11):e3467

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Introduction & Objectives: Thirty percent of patients (pt) with localized prostate cancer (PC) will have a biochemical relapse post local treatment (tx). The optimal tx of these pts remains elusive. While androgen deprivation therapy is effective in reducing prostate-specific antigen (PSA) level, its long-term benefit on survival remains undefined, and it is associated with significant cumulative toxicities. Thus, evaluation of non-toxic compounds in this pt population is warranted. PectaSol-C modified citrus pectin (P-MCP) is a competitive inhibitor of galectin-3, a carbohydrate-binding protein, which is known to be involved in cancer pathogenesis. Pre-clinical and clinical data suggest that P-MCP is active in PC. We previously presented the interim 6 months safety and benefit of P-MCP in non-metastatic biochemically relapsed prostate cancer (BRPC) in 46 patients, where we saw PSA dropping or PSADT lengthening in 76% (n=35). Herein, we aimed to evaluate its long-term effect of patients who continued to the second 18 months follow up phase.

Materials & 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 for 6 months (mos). Thirty one pts that did not progress clinically, biochemically (PSA), and radiologically, at 6 mos, were treated for subsequent 12 mos. Sample size provided 85% power to assess a decrease in PSA progression rate from the expected 80% (natural history) to 40%.

Results: The 31 patients that completed 6 mos of tx and did not progress, entered the long-term treatment phase and were analyzed. The median age was 75 years. Treatment of the primary tumor consisted of surgery in 16% (n = 5), radiation in 65% (n = 20), and both in 19% (n = 6). No pt had tx related grade 3/4 toxicity. Twenty three percent (n = 7) had grade 1 adverse effects (all gas and bloating). Sixty five percent (n = 20) had long term (18 mos) stable PSA and PSADT with negative scans at 18 mos. Disease progression during the long-term phase was noted in only 35% (n = 11: PSA only 10%, n = 3; PSA and scans 26%, n = 8). One of the 11 patients who did not respond in the first 6 months but continued taking P-MCP on their own showed a response on PSA escalation persisting for over 3 years now.

Conclusions: The present study suggests a potential long-term benefit and safety, in addition to the short term benefit previously documented, of P-MCP tx on the progression of BRPC.