# P058 Long term durable effect of PectaSol-C Modified Citrus Pectin (P-MCP) treatment (tx) in non- metastatic Biochemically Relapsed Prostate Cancer (BRPC-M0) patients (pts): Results of a prospective Phase II Study

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**Introduction & Objectives:** 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. Pre-clinical and clinical data suggest that P-MCP is active in PC. We recently reported the primary outcome analysis of a prospective phase 2 study of P-MCP tx in BRPC-M0, revealing a 78% response rate, in terms of a decreased/stable PSA, and/or improvement of PSA doubling time (PSADT), and with negative scans, after 6 months (mos) of therapy. We herein report a the long term results after an additional year of therapy.

**Materials & Methods:** Pts with non-castrate BRPC-M0 were enrolled in a prospective phase 2 study of tx with oral P-MCP, at 4.8 grams X 3/ day for 6 mos. Primary endpoint was the rate of patients without PSA progression and/or with improvement of PSADT after 6 months of therapy. Secondary endpoints were the rate of patients without radiologic progression and toxicity. 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. Pts that did not progress clinically, biochemically (PSA dynamics per PSA level and PSADT), and radiologically, at 6 months (mos), were treated for subsequent 12 mos.

**Results:** 60 patients were enrolled. 1 patient withdrew consent after 1 month. Of the remaining 59 patients, after 6 mos, 78% (n=46) responded to therapy, with a decreased/stable PSA (58%, n=34), and/or improvement of PSADT (75%, n=44), and with negative scans, and entered the second 12 mos treatment phase. Among these pts, 6 pts withdrew consent and chose to contimue tx out of pocket. Of the remaining 40 patients, after another year of tx (total of 18 months of tx), 80% (n=32) responded to therapy, with a decreased/stable PSA, and/or improvement of PSADT, and with negative scans. Median PSADT improved significantly ($p = 0.002$).No patient had grade 3/4 toxicity.

**Conclusions:** The present study suggests a potential long term durable benefit of P-MCP tx on progression of BRPC. P-MCP tx is safe.