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PAIN

SHIP-1 ACTIVATION FOR IC/BPS?

Moderate-to-severe abacterial interstitial cystitis/bladder pain syndrome (IC/BPS) remains largely untreatable, resulting in substantially reduced quality of life for patients with this chronic disease. Now, findings of a phase II clinical trial investigating AQX-1125, a novel, orally administered, SH2-containing inositol-5'-phosphatase 1 (SHIP1) activator that modulates inflammatory processes and immune cell activation, reveal that this treatment is more effective than placebo in patients with IC/BPS.

In a randomized, double-blind, multicentre trial, women with IC/BPS for >6 months but <15 years were randomly assigned to receive daily oral AQX-1125 or placebo for a study duration of 6 weeks, with follow-up monitoring for an additional 4 weeks after treatment cessation. After 6 weeks of treatment, patients receiving AQX-1125 had no significant reduction in self-reported daily pain as a substantial reduction in daily pain was also observed in the placebo group; however, statistically significant reductions in all other pain parameters were observed relative to placebo. Surprisingly, only 51.4% of patients receiving AQX-1125 reported any treatment-induced adverse events, compared with 78.1% of patients in the placebo group; although, patients receiving AQX-1125 had higher incidences of dyspepsia, gastroesophageal reflux disease, and sinusitis than those in the placebo group.

These data indicate that, in the short-term, AQX-1125 is an effective and well-tolerated oral therapy for patients with IC/BPS and represents an unmet clinical need. Data on the outcomes of patients with IC/BPS who receive AQX-1125 for longer treatment durations are eagerly awaited.

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ORIGINAL ARTICLE Nickel, J. C.*et al.* Phase II study of efficacy and safety of a novel, oral SHIP1 activator, AQX-1125, in subjects with moderate to severe interstitial cystitis/bladder pain syndrome (IC/BPS). *J. Urol.* http://dx.doi.org/10.1016/j.juro.2016.03.003 (2016).