

SITE-SPECIFIC IMMUNOMODULATORS (SSIs): A NOVEL IMMUNOTHERAPY FOR CANCER

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Chronic inflammation that suppresses adaptive anti-tumour immunity and promotes neoplastic cell growth is a hallmark of cancer. Induction of acute-type inflammation can reverse tumour-induced immune suppression, leading to immune-mediated tumour regression. To mimic acute infection-type immune responses, Qu Biologics developed Site-Specific Immunomodulators (SSIs), a platform of immunotherapies derived from specific species of killed bacteria known to commonly cause infection in a particular organ or tissue. Repeated subcutaneous injection of SSI may provide an effective method for the induction of site-specific acute-type inflammation. In preclinical cancer models, SSIs stimulate the immune system and reverse dysfunction in the tumor microenvironment, enabling effective anti-cancer immune responses (see Kalyan *et al.*). In compassionate use protocols, 254 patients with advanced cancer were treated with one or more SSIs for up to 3.5 years. In retrospective analysis, patients with metastatic breast cancer receiving SSIs as part of their treatment (the largest patient group) had a 20 month longer median survival than those not treated with SSIs. In a case-matched study in all late-stage cancer patients, those receiving SSI as part of their treatment had a median survival advantage of 12 months compared to those not receiving SSI (n = 43 per group). While this experience comprises uncontrolled, unblinded observations, the data suggest that SSI may induce productive anti-tumour immunity. Qu's QBKPN SSI product, designed to induce a lung site-specific response, is currently being studied in a Phase 2a clinical trial in patients with non-small cell lung cancer, in collaboration with the BC Cancer Agency (Trial NCT02256852).