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### **ONE YEAR MULTIPLE INJECTIONS OF ANTIGEN SPECIFIC T REGULATORY LYMPHOCYTES IN REFRACTORY CROHN'S DISEASE PATIENTS, EXTENSION OF CATS1 STUDY**

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#### *Abstract:*

**INTRODUCTION:** CATS1 was an open label phase I/II study with Ovasave, an antigen-specific Treg therapy of Crohn's Disease (CD). This study was extended to assess the tolerability of several injections for patients who benefited from the initial injection.

**METHODS:** CATS1 extension included patients with refractory CD, active inflammation. Ovasave was produced ex vivo from patients' PBMC exposed to ovalbumin, followed by cell cloning and expansion using feeder cells prior to formulation for infusion. Safety was assessed by clinical and laboratory parameters and efficacy by CDAI. Ovasave's impact on the proliferative response of patients' PBMC to ovalbumin was assessed in vitro.

**RESULTS:** Seven patients received a 2nd injection and 2 were treated for up to 1 year. Mean age was 34.5; disease was extensive (duration 12.9 years) with high baseline CDAI; Patients were refractory to standard therapies and 6/7 to immunosuppressors and anti-TNF $\alpha$ . Ovasave was well tolerated with 17 adverse events (AE) post-second injection: 16 not related; 1 related (recovered) and 3 serious AE not related. Upon re-injection of 2 patients who showed immunogenicity to feeder cells after the 1st highest dose injection 1 presented a mild acute reaction and the other was successfully treated with the induction of tolerance protocol. Two patients showed a perceived sustained benefit and were treated for up to 1 year, receiving a total of 4 and 5 injections of 10e6 cells (best dose), respectively with good tolerability. Reduction of in vitro PBMC proliferation to ovalbumin was only observed at the 10e6 cell dose.

**CONCLUSION:** CATS1 extension indicated good tolerability and patient benefit of multiple injections for up to one year. These data together with the existing ability to produce several years of treatment from a single patient batch are supportive of planned studies to assess chronic treatment of refractory CD with antigen specific Treg cells.

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