

LOW-DOSE IL-2 TO EXPAND ENDOGENOUS REGULATORY T CELLS AND ACHIEVE TOLERANCE IN LIVER TRANSPLANTATION

Criteria for Evaluation: Endpoints

Efficacy

Primary efficacy outcome measure was successful IS withdrawal as defined by the absence of rejection and a rejection free biopsy at 1year following IS discontinuation. This outcome was not achieved in any patient Both primary and secondary outcome measures are summarised in Table 1.

The biological activity of LDIL-2 was effective at expanding the target cells, i.e. CD4+CD25+FoxP3+ Tregs. All 6 patients showed a \geq 2-fold increase in absolute number of Tregs from baseline (Table 2 **Table**).

Table 1. Summary of outcome measures

Outcome Measure	Number achieved (n, %)
1°: Successful IS withdrawal at 1 year	0
2°: Allograft dysfunction	5 (83%)
2°: Allograft rejection	6 (100%)
2°: Patient graft survival	5 (83%)
2°: Patients underwent IS withdrawal	5 (83%)
2°: Failure of IS withdrawal	3 (50%)
2°: Operational Tolerance	0

Table 2. Summary of Treg Measurements.

Timepoint	Patient count	# patients with \geq 2-fold increase in Tregs	% of patients with Treg measurements	% of patients eligible
Baseline	6	-	-	-
Visit 1 (1wk)	6 (100%)	6	100%	100%
Visit 2 (4-6wks)	6 (100%)	6	100%	100%

Table 3. Detailed Treg Measurements.

Absolute Treg Quantification			
Patient ID	Baseline	Week 4	Fold-increase
P01	70.6	142.3	2.0
P02	23.5	213.6	9.1
P03	31.2	131.8	4.2
P04	60.9	119.5	2.0
P05	146.5	877.7	6.0
P06	26.8	103.5	3.9