

## 4th International Conference and Exhibition on Immunology

September 28-30, 2015 Crowne Plaza Houston River Oaks, Houston, TX, USA

Immunomodulatory anti-CD6 monoclonal antibody, itolizumab produces long term remission and sustains improved quality of life in chronic moderate to severe plaque psoriasis: Results from a 52 week, double blind, randomized withdrawal, placebo controlled trial

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**Background:** Itolizumab, an anti-CD 6 monoclonal antibody downregulates Th1 and Th17 pathway. Twenty eight week results from a double-blind, placebo controlled, phase-3 trial of itolizumab was reported previously in 225 moderate-to-severe plaque psoriasis patients demonstrating safety and efficacy.

Objective: To determine the long term efficacy of itolizumab and effect on quality of life during the randomized withdrawal phase.

**Methods:** At week 28, patients with PASI≥75 were re-randomized to placebo (group 1P; n=39) or itolizumab (group 1M; n=40). Partial responders (PASI≥50 but <75) were switched to open-label itolizumab (group 2; n=59). Group 3 (n=39) remained on itolizumab irrespective of PASI at week 28.

Results: In group 1P 52.5% maintained PASI≥75 and 70% maintained PASI≥50 at week 52. Groups 1M and 3 had higher responses (66.7% and 84.6%). Over 50% of the partial responders at week 28 achieved a late PASI≥75 response at week 52. At week 28, mean DLQI (Dermatology Life Quality Index) scores were >4 across all groups and this improvement was maintained across all groups at week 52 with group 2 showing maximum improvement (10.2% at week 28 reported "no impact of disease" on QoL compared to 27.6% at week 52). In group 2, the physical component scale and mental component scale of SF-36 improved by 1.3 and 1.6 points at week 52. There was no significant difference in the scores for the other groups from week 28 to 52.

Conclusions: Itolizumab produces long term remission and sustains improved quality of life for both physical and mental components.

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## Study the role of Urotensin II as a predictor for hepatorenal syndrome

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epatorenal syndrome (HRS type 1, 2) is one of the serious complications of chronic liver disease with high mortality.

The Aim: Of this study was to evaluate the diagnostic role of urotensin II in patients with chronic liver diseases (both ascitic and non ascitic patients). Forty patients were selected, Group (1) 20 patients with ascites (9 males and 11 females). Group (2) 20 patients without ascites (8 males and 12 females) their age and sex matched.

**Results:** For ALT, T.B, DB serum urea and platelet count, there was a statistically significant decrease between the 2 groups (p<0.05). The Ultrasound findings of the kidney's were of statistically significant difference between the two groups as regard nephropathy (8 patients in ascitic group [1] while one patient in non ascitic group [2]) (p value <0.05). There was a statistically significant correlation between Urotensin II and blood urea level in group 2,. The cut-off value of Urotensin II was of sensitivity 66.7%, specificity 64.5%, PPV 35.3% and NPP 86.96% with Accuracy 59% and p value <0.42 of no statistically significant difference.

**Conclusion:** Urotensin II was of statistically significant positive correlation with blood urea level in patients without ascites, that means the relevant clinical importance to use urotensin II in the early stages of liver disease, that is of crucial prognostic important for follow up.

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