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PRESENTER: Arnaud Foussat
PRESENTER (E-MAIL ONLY): foussat@txcell.com

Abstract

TITLE: CATS-1 Study: Immunomonitoring and clinical results of Treg Cell therapy for Crohn's disease.

AUTHORS (LAST NAME, FIRST NAME): Foussat, Arnaud[7]; Desreumaux, Pierre[2]; Allez, Matthieu[4]; Beaugerie, Laurent[3]; Hebuterne, Xavier[5]; Bouhnik, Yoram[6]; Nachury, Maria[9]; Brun, Valérie[1]; Duchange, Agnès[8]; Clerget-Chossat, Nathalie[1]; Forte, MIguel[1]; Colombel, Jean-Frederic[2]

INSTITUTIONS (ALL): 1. Clinical, TxCell, Valbonne Sophia-Antipolis, France.
2. Gastroenterology, Claude Huriez Hospital, Lille, France.
3. Gastroenterology, St-Antoine Hospital, Paris, France.
4. Gastroenterology, St-Louis Hospital, Paris, France.
5. Gastroenterology, L'Archet 2, Nice, France.
6. Gastroenterology, Beaujon Hospital, Clichy, France.
7. R&D, TxCell, Valbonne Sophia-Antipolis, France.
8. Effi-Stat, Paris, France.
9. Gastroenterology, Jean Minjoz Hospital, Besançon, France.

ABSTRACT BODY: INTRODUCTION: CATS1 study assessed the tolerability and efficacy of Ovasave, an antigen-specific T regulatory (Treg) therapy for patients with Crohn's Disease (CD). Treg cells induce immunomodulating effects through cytokines secretion and cell-cell contact.

AIMS & METHODS: CATS1 was an open label, 12-week multicenter, single injection, ascending dose, phase I/II study in 20 patients (4 dose groups of 10e6 cells: 8 pts; 10e7: 3 pts; 10e8: 3 pts; 10e9: 6pts) with CD and

active inflammation. Ovasave was produced ex vivo from patients' PBMC (peripheral blood mononuclear cells) exposed to ovalbumin followed by cell cloning, cell expansion and formulation for infusion. Patients were assessed for tolerability and efficacy (CDAI: responder: decrease >=100; in remission: <150; IBDQ and CRP). Patient's peripheral blood was collected before and 1, 3, 8 and 12 weeks after Ovasave administration. Change in peripheral blood immune cell populations was evaluated by flow cytometry. The impact of Ovasave on the proliferative response of patients' PBMC to ovalbumin in vitro was also evaluated.

RESULTS: Mean age was 34.5 and disease duration 12.9 years. CD was predominantly ileo-colic (65%) with a baseline CDAI of 364±81 (n=20) and IBDQ of 114±21 (n=19); 19/20 had previous failure to immuno supressors and anti-TNF and 16 had previous CD related surgery.
Ovasave injections were well tolerated with 54 adverse events (15 possibly and 2 definitely related) and 11 serious adverse events (3 possibly related), all recovered.
Response was observed in 40% (8/20) patients at weeks 5 and 8. In the best dose group (10e6 cells), response was 75% (6/8) at both time points; remission was 38% (3/8) and 25% (2/8) and the mean CDAI reduction 143.4±105 (p=0.0062) and 131.6.3±65.4 (p=0.002) at weeks 5 and 8 respectively. CRP (mg/l) dropped significantly (p=0.04) in responder (-11.4±6.3) patients versus non-responders (5.2±4.2).
Immunomonitoring studies revealed that blood CD16+ pro-inflammatory monocytes, one of the contributors of mucosal inflammation, were selectively decreased 3 weeks after Ovasave administration in the group of responder patients. In this group, the proliferative response of PBMC to ovalbumin in vitro was abolished 3 weeks after treatment, suggesting a direct suppression of ovalbumin-specific immune response.

CONCLUSION: Treg cell therapy is well tolerated and shows a positive dose related efficacy in severe CD patients consistent across multiple assessment methods including mechanistic immunological measurements in patient's blood.

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Disclosure Status

The following authors have completed their 2012 DDW disclosure:

Arnaud Foussat: No Answer.

Pierre Desreumaux: No Answer.

Matthieu Allez: No Answer.

Laurent Beaugerie: Disclosure completed

Xavier Hebuterne: No Answer.

Yoram Bouhnik: No Answer.

Maria Nachury: No Answer.

Valérie Brun: No Answer.

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Nathalie Clerget-Chossat: Disclosure completed

MIguel Forte: No Answer.

Jean-Frederic Colombel: Disclosure completed

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