SYNOPSYS OF ABBREVIATED CLINICAL STUDY REPORT

A phase IIb, multicentre, randomised, double-blinded, placebo-controlled, multi-dose and multi-injection, parallel groups study to evaluate the efficacy and the safety of ovasave® (ovalbumin-specific autologous treg cells [ova-treg]) in patients with active refractory crohn's disease (crohn's and treg study: cats29)

Study/Protocol No.:	TXC-CD-002-2011
EudraCT number	2014-001295-65
Investigational Medicinal Product:	Ova-Treg
Indication:	Active refractory Crohn's Disease
Study Phase:	Phase IIb
Sponsor:	TxCell Allée de la Nertière Les Cardoulines, 06560 Valbonne Sophia-Antipolis FRANCE
Coordinating Investigator:	Pr. Séverine VERMEIRE Department of Gastroenterology University Hospital Gasthuisberg Herestraat 49 3000 Leuven BELGIUM
Study Manager/Sponsor:	Mrs Valérie BRUN
Study Manager/Contract Research Organisation:	Cindy VAN SANDE SGS Life Science Noorderlaan 87 2030 Antwerpen, BELGIUM
First Patient First Visit:	03 December 2014
Last Patient Last Visit:	07 November 2016
Early Study Termination:	11 October 2016
Date of Abbreviated Clinical Study Report:	06 October 2017
Abbreviated Clinical Study Report Version:	Final Draft
Date of Previous Report:	Non applicable

The study was conducted according to the protocol and in compliance with Good Clinical Practice (GCP), with the Declaration of Helsinki and with other applicable regulatory requirements, including archiving.

CONFIDENTIAL

SIGNATURE PAGE

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

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SYNOPSIS

Name of Sponsor: TxCell	**Individual Study Table Referring to Part of the Dossier**	**(For National Authority Use Only)**
Name of Finished Product: Ovasave	Volume:	
Name of Active Ingredient: Ovalbumin-specific autologous Treg cells (Ova-Treg)	Pages:	

Study title: A phase IIb, multicentre, randomised, double-blinded (DB), placebo-controlled, multi-dose and multi-injection, parallel groups study to evaluate the efficacy and the safety of Ovasave® (ovalbumin-specific autologous regulator T lymphocyte [Treg] cells [Ova-Treg]) in patients with active refractory Crohn's Disease (Crohn's And Treg Study: CATS29).

Protocol Number: TXC-CD-002-2011

Investigator(s): Eleven investigators were involved, one at each of the 11 active sites.

Study Centre(s): Twenty-six study centres were initiated, of which 11 were active sites. Patients were recruited from the active sites as follows: 4 centres in France, 3 centres in Belgium, 3 centres in Germany and 1 centre in Austria.

Publications based on Study: None

Studied Period:		**Phase of Development:** IIb
First Patient First Visit:	03 Dec 2014	
Last Patient Last Visit:	07 Nov 2016	

Objectives:

Primary Objective

The primary objective of this study was to confirm the ability of a single intravenous (i.v.) injection of 1.10^6 cells dose of Ovasave (Ova-Treg cells) to induce a significant Crohn's Disease activity index (CDAI) response (CDAI decrease from baseline ≥100 points) 6 weeks post-administration compared to placebo, in patients with moderately to severely active refractory Crohn's Disease (CD).

Secondary Objectives

The main secondary efficacy objectives of this study were:

- CDAI remission of 1.10^6 cells dose at Week 6.

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- CDAI response and remission of 1.10^6 cells dose at Week 14.
- CDAI response and remission of different doses (placebo, 1.10^4 and 1.10^7 cells) at Week 6 and at Week 14.
- Reduction of steroids treatment of different doses (placebo, 1.10^4, 1.10^6 and 1.10^7 cells) at Week 14.
- Other assessments (immuno-monitoring, inflammatory bowel disease questionnaire [IBDQ]) of different doses (placebo, 1.10^4, 1.10^6 and 1.10^7 cells).

The main secondary safety objectives of this study were:

- Safety assessment of a 1st and 2nd i.v. injection of Ovasave (Crohn's and Treg Study 29 [CATS29] – DB).
- Safety assessment of a 3rd and 4th i.v. injection of Ovasave (CATS29 – Open Label [OL]).
- Assessment of safety of different doses (placebo, 1.10^4, 1.10^6 and 1.10^7 cells).
- Assessment of safety during the 3-year long-term follow-up after 1st dose.

Methodology: An approximately 5 year, multicentre, randomised, DB, placebo-controlled, multi-dose and multi-injection, parallel groups, phase IIb study, with a duration of 129 weeks between the first patient first visit (FPFV) and last patient last visit (LPLV), and a further 124 weeks for long term safety follow up.

The study consisted of the following parts:

CATS29-DB: during which all patients were to attend a total of 9 scheduled visits, including a Screening Visit; Blood Collection Visit (for manufacture of Ovasave); 2 visits for administration of Drug Product (DP), at Week 0 (Visit 4) and Week 8 (Visit 7); and visits for safety and efficacy assessments (Week 4 [Visit 5], and Week 6 [Visit 6]).

A total of 150 mL of whole blood was collected from each patient, which was sufficient for the manufacturing to produce the required doses for the entire study.

The treatment for each group consisted of 2 i.v. injections of ovalbumin specific autologous T regulatory cells, or placebo:

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- Group A: 1.10^4 cells and 1.10^4 cells.
- Group B: 1.10^6 cells and 1.10^6 cells.
- Group C: 1.10^7 cells and 1.10^7 cells.
- Group D: placebo and placebo.

At the exit visit (Week 16 [Visit 9]), patients were to enter either the open label part (CATS29-OL) upon Investigator's recommendation, with 2 administrations of Ovasave at 1.10^6 cells dose; or the safety follow up part (CATS29-FUP) without administrations of Ovasave, for those patients who were not willing to participate in CATS29-OL.

CATS29-OL: for all groups, each patient was to attend a total of 4 scheduled visits, including 2 visits for i.v. administration of DP (Ovasave at 1.10^6 cells), at Week 16 (Visit 9) and Week 24 (Visit 11), and visits for safety and efficacy assessments.

CATS29-FUP: each patient was to attend a total of 2 scheduled visits, for follow up without administration of DP.

CATS29-Long term (LT): following completion of either CATS29-OL or CATS29-FUP, all patients would then attend a total of 6 scheduled visits, for an additional 124 weeks (28.6 months) until year 3, exit of the study.

To maximise ovalbumin presence in the diet, all patients during CATS29-DB and only the injected patients during CATS29-OL were provided with a daily diet supplement of ovalbumin for 32 weeks, starting from the day of the first administration.

Number of Patients (Planned and Analysed):

Planned: It was planned that 200 patients would be screened (Visit 1) in order to obtain 160 included patients (Visit 2 to Visit 4) and to ensure 144 patients assessable at the primary endpoint (Visit 6[Week 6]).

Analysed: Thirty-two patients were screened, 26 patients enrolled, and 7 patients were randomised and received at least 1 administration of the study treatment. The clinical trial was halted prematurely on 11 October 2016 following TxCell's decision.

Diagnosis and Main Criteria for Inclusion:

Patients meeting all of the following criteria were considered for admission to the study.

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At the Screening Visit (Visit 1):

1. Willing and able to provide written informed consent (IC).
2. Male or Female aged between 18 and 70 (inclusive) years of age.
3. CD diagnosis defined as patients with medical history of signs, symptoms and biological evidence of active bowel inflammation: documented endoscopic evidence of Crohn's diagnosis at least 1 year prior to Visit 1 (an endoscopy was to be performed if the one available was more than 1 year old at Visit 1).
4. Elevated High sensitive C-reactive protein (hs-CRP) >10 mg/L at Visit 1.
5. Calprotectin ≥250 µg/g.
6. Failure or intolerance to conventional treatments including corticosteroid, immunosuppressant and at least 1 biologic; and had not responded (primarily failure) or responded and then lost response completely (no response or need to increase the dose / secondary failure) or were intolerant to this therapy at a dose indicated for CD.
7. Documented CDAI ≥250 at Visit 1 or within the past 3 months prior to Visit 1.
8. Total white cell count ≥4.0 $x10^9$/L.
9. Platelets between 150 $x10^9$ and 600 $x10^9$/L (included).
10. Haemoglobin >8.5 g/dL.
11. Full blood count (FBC) and biochemistry without any clinically significant (CS) abnormalities except if CD related, at Investigator's discretion.
12. Normal, or no CS abnormality in the electrocardiogram (ECG) at Investigator's discretion.
13. Patients willing and able to observe an intake of ovalbumin through the ingestion of a meringue daily after the first administration until the end of the DB part and during the OL part if the patient receives additional administration.

At Visit 3 (Week -4):

1. CDAI ≥250.

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2. Evidence of inflammation by an elevated hs CRP value (>5 mg/L) or endoscopic / Magnetic Resonance Imaging (MRI) evidence of local intestinal inflammation, or elevated calprotectin (≥250 µg/g) to be confirmed before Visit 4 (first administration).

Between Visit 8 (Week 14) and Visit 9 (Week 16):

Upon Investigator recommendation, patient qualification was based on acceptable safety and tolerability profile of the IMP before continuing to receive i.v. administrations of Ovasave at a dose of 1.10^6 cells.

Test Product, Dose and Mode of Administration, Bath Number:

The test product Ovasave was an autologous product, made for each patient from their own blood. Ovasave was composed of Ova-Treg cells formulated in cryopreservation medium, which was thawed and diluted in a 100 mL bottle of 0.9% NaCl and 4% human serum albumin (HSA) immediately before administration. Each product was identified individually by the patient code with additional code.

During CATS29-DB the treatment consisted of 2 i.v. administrations of test product or placebo as follows:

- Group A: 1.10^4 cells and 1.10^4 cells.
- Group B: 1.10^6 cells and 1.10^6 cells.
- Group C: 1.10^7 cells and 1.10^7 cells.
- Group D: placebo and placebo.

All patients were followed during 16 weeks.

Patients then entered the CATS29-OL part or the CATS29-FUP part (patients who refused consent for further administration of test drug, or those who were not recommended for further injections by the Investigator).

During the CATS29-OL part, patients received 2 additional i.v. administrations of test product of 1.10^6 cells dose, for all groups. Patients who had not received the first 2 i.v. administrations during the CATS29-DB part were not given the 3rd and 4th i.v. administrations during the CATS29-OL part.

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To maximise ovalbumin presence in the diet, during CATS29-DB and CATS29-OL, patients were provided with a daily diet supplement of ovalbumin.

Duration of Treatment:

The duration of CATS29 DB was 16 weeks, with 2 i.v. administrations of test product (Groups A, B and C) or placebo (Group D) at Week 0 and Week 8.

CATS29-DB was followed by CATS29-OL, during which all patients received 2 additional i.v. administrations of test product (dose of 1.10^6 cells) at Week 16 and Week 24, or CATS29-FUP, during which there was no administration of test product. Both CATS29-OL and CATS29-FUP lasted 16 weeks.

The total treatment period therefore lasted a minimum of 16 weeks and a maximum of 32 weeks.

Patients were provided with a daily diet supplement of ovalbumin:

- During CATS29-DB (16 weeks).
- During CATS29-OL (a further 16 weeks, therefore 32 weeks in total for patients who completed both parts)

Reference therapy:

Non applicable

Criteria for Evaluation:

Efficacy:

Primary efficacy endpoint:

The primary clinical efficacy endpoint was the percentage of patients with a CDAI response (CDAI decrease from baseline ≥100 points) in the active group of 1.10^6 Ova-Treg cells, 6 weeks after 1 Ovasave administration (Week 6 [Visit 6]) compared to placebo.

Secondary efficacy endpoints:

Based on CDAI:

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- Percentage of patients with a CDAI remission (CDAI<150 points) and response 6 weeks after the second administration (Week 14) for the 4 groups.
- Percentage of patients with a CDAI response at each of the other post baseline visits for the 4 groups.
- Percentage of patients achieving a CDAI remission at each post baseline visit for the 4 groups.
- Raw value in CDAI total score at each post baseline visit for the 4 groups.
- Raw value in each CDAI sub score at each post baseline visit for the 4 groups.
- Change from baseline in CDAI total score at each post baseline visit for the 4 groups.

Based on the Steroids Sparing Effect:

- Steroid decrease from Week 8 was recorded at Week 14 (including the daily dose taken at each week between Week 8 and Week 14).
- Percentage of patient by decrease steroids dose (decrease in total of 20, 15, 10, 5 or 0 mg/day) at Week 14.

Based on Inflammatory Markers (hs-CRP, calprotectin):

- Raw value in hs CRP at each post baseline visit.
- Change from baseline in hs-CRP at each post baseline visit.
- Raw value in Calprotectin at each post-baseline visit.
- Change from baseline in Calprotectin at each post-baseline visit

Based on the Investigator's opinion on the IMP (at Week 16 and Week 32):

- Qualify the IMP (very satisfactory / satisfactory / unsatisfactory / very unsatisfactory).
- Would you like to test the IMP again? (Yes/No).

Safety:

General Safety:

- Adverse Events

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The type and incidence of adverse events (AEs) and serious adverse events (SAEs) were recorded at all visits and coded according to the medical dictionary for regulatory activities (MedDRA) criteria. Abnormal laboratory results constituted an AE, and were reported as such, if they are considered abnormal within the pathology of this study population.

- Laboratory data

  Laboratory assessments including blood samples for full haematology, clinical chemistry and qualitative urinalysis were performed for all visits during CATS29-DB, CATS29-OL and CATS29-FUP and at Week 40 (Visit 14) and Week 52 (Visit 15) of CATS29-LT for some haematology, biochemical parameters and hs-CRP.

- Vital signs and physical examination

  Heart rate (HR), blood pressure (BP) and a complete clinical examination of the patient was performed at all visits during the study (except the Blood Collection Visit [Visit 2]). During dosing visits, vital signs were assessed pre-dose, during administration of the DP and post-dose.

- ECG

  A 6 lead or 12 lead ECG was performed at the Screening Visit (Visit 1), Pre-entry Visit (Visit 3), and Week 0 (pre and post dose [Visit 4]).

- Toxoplasmosis, Epstein-Barr virus (EBV) and cytomegalovirus (CMV) serologies and virus load

  EBV and CMV serologies were assessed at Screening Visit (Visit 1), Week 0 pre-dose (Visit 4), Week 8 pre-dose (Visit 7), Week 16 pre-dose (Visit 9) and Week 32 (Visit 13). Virus load assessments for EBV and CMV were performed systematically at the subsequent visit if the patient's serology for EBV or CMV was previously shown to be positive.

  Toxoplasmosis serology was assessed at the Screening Visit (Visit 1), Week 0 pre-dose (Visit 4) and Week 16 (Visit 9).

- Endoscopy and MRI

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A colonoscopy or recto sigmoidoscopy was performed in all patients, at Week -14 (Visit 1) if the previous one had been performed more than 1 year prior to Week -14.

A colonoscopy, recto sigmoidoscopy or MRI was performed in patients at Week 4 (Visit 3) to confirm the presence of local intestinal inflammation (if hs-CRP or calprotectin were not within specifications), and at Week 14 (Visit 8) to assess the impact of Ovasave.

- Full serology characterisation:

  At the Screening Visit (Visit 1) and Blood Collection Visit (Visit 2), serology parameters were assessed for human immunodeficiency virus (HIV), hepatitis B and C, human T-lymphotropic virus (HTLV) and syphilis.

- Blood qualification for manufacturing:

  This included evaluation of serology parameters (for HIV, hepatitis B and C, HTLV and syphilis) and viral genomic analysis (for HIV and hepatitis C).

- Elispot: QuantiFERON® TB Gold or T Spot®.TB

  A QuantiFERON® or a T Spot®.TB was performed at the Screening Visit (Visit 1) in order to detect tuberculosis (TB).

- Urine pregnancy test

  All female patients had a urine pregnancy tests at the Screening Visit (Visit 1).

  During CATS29-DB and CATS29-FUP, all female patients had a urine pregnancy test before each administration of IMP at Week 0 (Visit 4), Week 8 (Visit 7) and Week 16 (Visit 9).

  During CATS29-DB and CATS29-OL, all female patients had a urine pregnancy test before each administration of IMP at Week 0 (Visit 4), Week 8 (Visit 7), Week 16 (Visit 9), Week 24 (Visit 11) and Week 32 (Visit 13).

- HLA Class I typing

  Human leukocyte antigen (HLA)-Class I typing was performed on a blood sample at the Blood Collection Visit (Visit 2), and on a sample of Ovasave at the end of

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manufacturing. This control was performed to ensure that the Ova-Treg cells belonged to the blood donor and assert its autologous attribute.

- Serum bank constitution

  A serum bank was constituted if other dosages were required during and/or after the study, and the serum would be stored for 5 years according to regulatory requirements.

Specific safety - reactions to the Drug Product:

Acute reactions: defined as at least one of the following signs and symptoms occurring during or within 2 hours of the administration of the IMP.

- Hypotension.
- Urticaria.
- Flushing.
- Facial or hand oedema.
- Throat tightness, oral cavity or lip oedema.
- Headache.
- Shortness of breath.

Delayed reactions: defined as at least 2 of the following 4 signs or symptoms occurring within 1 to 14 days following the administration of the IMP.

- Rash.
- Fever (more than 38°C).
- Polyarthralgias.
- Myalgias

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- **Other assessments and endpoints:**

  Immuno-monitoring:

  - Change from baseline at each post baseline visit, for monocytes.
  - Change from baseline at each post baseline visit, for Ova proliferation and Tetanus toxoid (TT) proliferation (index).

- Based on IBDQ questionnaire:
  - Raw value in the IBDQ total score at each post baseline visit.
  - Change from baseline in the IBDQ total score at each post baseline visit.
  - Percentage of patients with an IBDQ response (IBDQ increase from baseline ≥16 points) at each post baseline visit for the 4 groups.

Statistical Methods:

The sample size calculation was based on the primary efficacy endpoint (CDAI response 6 weeks after the 1st administration of DP), for which 36 patients were required to demonstrate the superiority of Ovasave 1.10^6 cells dose over placebo. By including the same number of patients in the other two dose groups (Ovasave 1.10^4 cells and 1.10^7 cells), which were assessed as secondary objectives, a total of 144 patients were deemed necessary.

As the study was terminated early, planned statistical analyses were not carried out. All data collected for the 7 patients randomised and treated in the study were presented in by-patient listings.

Summary – Conclusions:

Demographics and Other Baseline Characteristics:

The race of the treated patients was white (6 patients) or not recorded (1 patient), 3 patients were female and 4 patients were male, ranging in age from 21 to 49 years.

Efficacy conclusions:

Patient A24-001 was the only patient treated with Ovasave 1.10^6 cells dose during CATS29-DB, and did not achieve CDAI response at Week 6. Neither Patient A14-003 nor

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Patient A25-002, who were treated with placebo during CATS29-DB achieved CDAI response at Week 6.

Regarding the secondary efficacy endpoints based on CDAI, none of the 4 patients who had CDAI scores recorded at Baseline and Week 14 achieved CDAI response or remission at Week 14; Patient A25-002 (placebo group during CATS29-DB) achieved CDAI response at Week 4, Week 16 and Week 32; Patient A14-004 (Ovasave 1.10^7 cells dose during CATS29-DB) achieved CDAI response at Week 6 and Week 8; Patient A14-003 (placebo group during CAT29-DB) had a CDAI score of response and CDAI score of remission compatible with a response and a remission respectively at Week 18 during an unscheduled visit; and Patient A25-002 (placebo group during CATS29-DB) achieved CDAI remission at Week 4.

Neither of the patients in the placebo group during CATS29-DB achieved IBDQ response. One patient in each treated group achieved IBDQ response at one time point at least. No IBDQ remission was reported for any patient in the treated groups.

The changes from baseline in conventional monocytes were clinically not significant (NS). Clinical interpretation of changes over time in blood concentrations of pro-inflammatory monocytes or conventional monocytes was difficult due to the small number of patients in the study. No significant changes were observed in the index of peripheral blood mononuclear cell (PBMC) proliferation. Taken together, these results suggest that the treatment did not induce systemic immunosuppression.

Safety conclusions:

Overall there were 31 treatment emergent adverse events (TEAEs) in 6 of the treated patients (2 patients in placebo group during CATS29-DB; 2 patients in Ovasave 1.10^4 cells dose group during CATS29-DB; 1 patient in Ovasave 1.10^6 cells dose group during CATS29-DB; and 1 patient in Ovasave 1.10^7 cells dose group during CATS29-DB). Administration of the DP was permanently stopped due to related AEs in 2 patients (one of whom received placebo) and 3 patients experienced acute reactions to the DP. Adverse events were most frequently reported in the System Organ Class (SOC) Gastrointestinal disorder (6 AEs in 4 patients), General disorders and administration site conditions (5 AEs in 2 patients) and the SOC Nervous System disorders (5 AEs in 2 patients). The Preferred Terms (PTs) reported more than once were dizziness (3 AEs in 2 patients); fatigue, feeling

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hot, tachycardia and nasopharyngitis (2 AEs in the same patient for each PT); and headache and erythema (2 AEs in 2 patients for each PT).

Seven SAEs were recorded in 4 patients during the trial, of which 2 SAEs were related to the DP (PTs – CD [patient in the placebo group during CATS29-DB] and anaphylactic reaction [patient in the Ovasave 1.10^4 cells dose group during CATS29-DB]).

Clinically significant abnormalities without clinically significant changes were reported in 2 patients (for haematology and clinical chemistry in 1 patient, and for urinalysis in 1 patient).

Conclusion:

Due to manufacturing challenges and premature termination of the study, the limited clinical data obtained in this study does not allow for any firm conclusion on either efficacy or safety profile.

Date of Report: 06 October 2017