***PLEASE NOTE:*** *This study has been imported from ClinicalTrials.gov without additional data checks.*

## Trial Description

### Title

**Ph3,DB/DD,Multi-Ctr,Pros,Rand Study-Efficacy and Safety of LCP-Tacro™ Tablets, QD, Compared to Prograf® Capsules,BID, in Combination With Mycophenolate Mofetil for Acute Allograft Rejection in De Novo Kidney Transplant**

### Trial Acronym

**LCPTacro3002**

### URL of the trial

**[---]***

### Brief Summary in Lay Language

**This study will evaluate the efficacy and safety of LCP-Tacro (tacrolimus) Tablets administered once-a-day compared to Prograf (tacrolimus) Capsules twice-a-day as immunosuppression for the prevention of organ rejection in newly transplanted adult kidney transplant recipients. Patients will be treated for a 12 month study period followed by a 12 month, blinded extension treatment period To show that LCP-Tacro Tablets are clinically similar to Prograf Capsules in the prevention of acute rejection.**

### Brief Summary in Scientific Language

**This is a two-armed parallel group, prospective, randomized, double-blind, double-dummy,multicenter Phase 3 clinical study to establish the efficacy and safety of LCP-Tacro Tablets (tacrolimus, LifeCycle Pharma A/S, Hørsholm, Denmark) once daily for the prevention of allograft rejection in de novo adult male and female recipients of a primary or secondary kidney transplant evaluated by a combined efficacy endpoint comprised of acute rejection, graft loss and patient loss. The trial is designed to determine if the test drug, LCP-Tacro, is not inferior to an unacceptable extent to the reference compound, Prograf. Recipients of a kidney transplant who sign an informed consent form and fulfill all other inclusion and exclusion criteria will be randomly assigned to once-daily**

**therapy with**
**LCP-Tacro Tablets or to twice-daily therapy with Prograf Capsules (tacrolimus, Astellas**
**Pharma US, Inc., Deerfield, IL), each concomitantly administered with mycophenolate mofetil**
**(MMF) and corticosteroids. All patients will also receive interleukin-2 (IL-2) receptor**
**antagonist (e.g.,Simulect®, basiliximab; Novartis Pharmaceuticals, East Hanover, NJ).**
**Following screening,transplantation, and randomization, study visits will be conducted over**
**a 12-month treatment period; with additional visits during a 12 month extension period on**
**treatment and a follow-up safety assessment by visit or telephone interview 30 days after**
**withdrawal from study drug.**

## Organizational Data

- DRKS-ID: **DRKS00006514**
- Date of Registration in DRKS: **2015/03/13**
- Date of Registration in Partner Registry or other Primary Registry: **2010/08/23**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

## Secondary IDs

- Primary Registry-ID: **NCT01187953 (ClinicalTrials.gov)**
- Sponsor-ID: **LCP-Tacro-3002 (Veloxis Pharmaceuticals)**

## Health condition or Problem studied

- Free text: **Renal Failure**
- ICD10: **N18 - Chronic kidney disease**

## Interventions/Observational Groups

- Arm 1: **Drug: Prograf (tacrolimus)**
- Arm 2: **Drug: LCP-Tacro**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, caregiver, investigator/therapist, assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

### Primary Outcome

**- The Primary Efficacy Endpoint for the Study is the Proportion of Treatment Failures Within 12 Months After Randomization to Study Drug.; time frame: 360 days; Treatment failure is a composite endpoint; a patient is considered a treatment failure if the patient experienced any of the following events during this period: death, graft failure, BPAR (Banff grade ≥1A) or lost to follow-up.**

### Secondary Outcome

**- For the 24-month Analysis, the Endpoint Includes Additional Treatment Failures That Occurred During the 12-month Treatment Extension Period, up to Day 734 After the Randomization Date.; time frame: 734 days; Treatment failure is a composite endpoint; a patient is considered a treatment failure if the patient experienced any of the following events during this period (day 1 to day 734): death, graft failure, BPAR (Banff grade ≥1A) or lost to follow-up.**

## Countries of recruitment

- US **United States**
- AR **Argentina**
- AU **Australia**
- BR **Brazil**
- FR **France**
- DE **Germany**
- IT **Italy**
- KR **Korea, Republic of**
- MX **Mexico**
- NZ **New Zealand**

- PL **Poland**
- RS **Serbia**
- SG **Singapore**
- ES **Spain**
- SE **Sweden**

## Locations of Recruitment

- **Clinical Site 49137, Berlin**
- **Clinical Site 49139, Essen**

## Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/09/30**
- Target Sample Size: **540**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

### Additional Inclusion Criteria

**1. informed consent**

**2. 18 and 70 years, inclusive**

**3. receiving primary or secondary renal allograft from a deceased donor or non-human leukocyte antigen (HLA) identical living donor**

**4. no known contraindications to the administration of IL-2 receptor antagonist induction therapy, MMF, corticosteroids or tacrolimus**

**5. negative pregnancy test**

**6. Negative cross match test, and compatible (A, B, AB or O) blood type**

**7. Able to swallow tablets and capsules**

**Exclusion criteria**

**1. Recipients of any non-renal transplant (solid organ or bone marrow) ever**

**2. Panel reactive antibody (PRA) >30%**

**3. Patients with any condition that may affect study drug absorption (e.g. gastrectomy or clinically significant diabetic gastroenteropathy)**

**4. Body mass index (BMI) 18 kg/m2**

**5. History of alcohol abuse**

**6. History of recreational drug abuse**

**7. Screening 12-lead electrocardiogram (ECG) demonstrating clinically relevant abnormalities**

**8. WOCBP who are either pregnant, lactating, planning to become pregnant**

**9. Patients with an oral temperature (prior to study drug dosing) of 38.0 ºC (100.4 ºF) or higher**

**10. Patients with clinically significant active infections**

**11. Patients with a known hereditary immunodeficiency**

**12. Patients with malignancies or with a history of malignancies (within the last 5 years)**

**13. Patients who are receiving or expect to receive sirolimus, everolimus, azathioprine,or cyclophosphamide within 3 months prior to enrollment**

**14. Patients with evidence of clinically significant disease (e.g., cardiac, gastrointestinal or hepatic disorders)**

**15. Patients with reversible cardiac ischemia (history of untreated reversible ischemia on stress test)**

**16. Patients with clinically symptomatic congestive heart failure or documented ejection fraction of less than 45%**

**17. Patients with significant chronic obstructive pulmonary disease, pulmonary restrictive disease or significant pulmonary hypertension**

**18. Treatment with an investigational drug, device or regimen within 1 year preceding the first dose of study drug**

**19. Patients who are unwilling to refrain from consumption of grapefruit or grapefruit containing juices**

**20. Patients receiving concomitant drugs that may affect concentrations of tacrolimus in whole blood, as listed in Appendix 2**

**21. Laboratory variables that are abnormal (outside laboratory reference range) and clinically relevant, as judged by the Investigator**

**22. Patients with positive results of any of the following serological tests: human immunodeficiency virus (HIV)-1 antibody, hepatitis B virus (HBV) surface antigen (HBsAg), anti-hepatitis B core antibody (HBcAb), and anti-hepatitis C virus (HCV)antibody (HCV Ab).**

**23. Patients who experienced graft loss within 1 year of transplant, due to acute rejection or due to BK nephropathy**

**24. Patients having experienced focal segmental glomerulosclerosis (FSGS)**

**25. Donor with positive serological test result for HIV-1, HBV or HCV**

**26. Donor with history of malignant disease (current or historical)**

**27. Centers for Disease Control and Prevention high-risk donor**

**28. Patients with mental dysfunction or inability to cooperate with the study**

**29. Cold ischemia time >30 hours**

**29. Non-heart-beating donor**

## Addresses

- **Primary Sponsor**

  **Veloxis Pharmaceuticals**

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Scientific Queries**

  **VP, Clinical Operations**
  **Alan Glicklich**

**Contact for Scientific Queries**

**VP, Clinical Operations**
**Alan Glicklich**

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URL: **[---]***

- **Contact for Public Queries**

**VP, Clinical Operations**
**Alan Glicklich**

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E-mail: **[---]***
URL: **[---]***

## Sources of Monetary or Material Support

- **[---]***

**Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor**

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/03/01**

## Trial Publications, Results and other documents

## Additional Trial Attributes

- *Urological disease:* ***other***
- *If other, please specify:* ***[---]****

*If other, please specify:* ***[---]****

- *Onset of therapy:* ***[---]****
- *If other, please specify:* ***[---]****
- *If other, please specify:* ***Renal Transplantation***
- *Study recommendations:* ***[---]****
- *If other, please specify:* ***[---]****
- *German director of clinical investigation:*

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- *Further contact:*

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- *Function of contact:* ***[---]****
- *Non-interventional study:* ***[---]****
- *Stage:* ***[---]****

*The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.*
*- Translation on version: 12*
*- Last processed date by ClinicalTrials.gov: 2016/01/14*

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*