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

Trial Description

Title

A Long-term Follow up Study to Evaluate the Safety and Efficacy in Transplant Recipients Treated With Modified Release Tacrolimus, FK506E (MR4), Based Immunosuppression Regimen

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this study was to offer patients who had participated in one of the phase II PK or phase III studies on FK506E (MR4) the possibility to continue FK506E (MR4) until commercial availability of the drug and to record long term efficacy and safety data.

Brief Summary in Scientific Language

Only patients who have participated in one of the phase II PK or phase III studies on FK506E (MR4) and have received at least one dose of study medication will be enrolled.

Organizational Data

- DRKS-ID: **DRKS00007350**
- Date of Registration in DRKS: **2016/03/11**
- Date of Registration in Partner Registry or other Primary Registry: **2014/04/17**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2005-005714-20**
- Primary Registry-ID: **NCT02118896 (ClinicalTrials.gov)**
- Sponsor-ID: **F506-CL-0857 (Astellas Pharma Europe Ltd.)**
- Other Secondary-ID: **2005-005714-20**

Health condition or Problem studied

- Free text: **Kidney Transplantation**
- Free text: **Liver Transplantation**
- Free text: **Heart Transplantation**
- ICD10: **Z94.0 - Kidney transplant status**
- ICD10: **Z94.1 - Heart transplant status**
- ICD10: **Z94.4 - Liver transplant status**

Interventions/Observational Groups

- Arm 1: **Drug: FK506E**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Patient survival; time frame: Duration of study participation up to 6 years (i.e.

until study ends or study drug is available commercially in the country)
- Graft survival; time frame: Duration of study participation up to 6 years (i.e. until study ends or study drug is available commercially in the country)

Secondary Outcome

- Incidence of first biopsy-proven acute rejection episodes; time frame: Duration of study participation up to 6 years (i.e. until study ends or study drug is available commercially in the country)
- Time to first biopsy-proven acute rejection episodes; time frame: Duration of study participation up to 6 years (i.e. until study ends or study drug is available commercially in the country)
- Incidence of adverse events; time frame: Duration of study participation up to 6 years (i.e. until study ends or study drug is available commercially in the country)

Countries of recruitment

- US **United States**
- AU **Australia**
- AT **Austria**
- BE **Belgium**
- BR **Brazil**
- CA **Canada**
- CZ **Czech Republic**
- DK **Denmark**
- FI **Finland**
- FR **France**
- DE **Germany**
- HU **Hungary**
- IE **Ireland**
- IT **Italy**
- MX **Mexico**
- NL **Netherlands**
- NZ **New Zealand**
- PL **Poland**
- ZA **South Africa**
- ES **Spain**
- SE **Sweden**
-

CH **Switzerland**

- UK **United Kingdom**

Locations of Recruitment

- **Charite Campus Virchow Klinikum, Berlin**
- **DR MED Wolfgang Arns, Koeln**
- **Funktionsbereich Nephrologie, Frankfurt/Main**
- **Herz- und Diabeteszentrum NRW, Bad Oeynhausen**
- **Klinik und Poliklinik fuer Chirurgie, Regensburg**
- **Klinikum der Universität Regensburg, Regensburg**
- **Klinikum Rechts der Isar, Munchen**
- **Knappschaftskrankenhaus Bochum-Langendreer, Bochum**
- **Leiter Viszerale Organtransplantation, Heidelberg**
- **Medizinische Hochschule Hannover, Hannover**
- **Medizinische Klink IV, Erlangen**
- **Univ. Klinik und Poliklinik fuer Urologie, Halle**
- **Universitätklinikum Essen, Essen**
- **Universitäts-Krankenhaus Eppendorf, Hamburg**
- **Universitätsklinik Charité, Berlin**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2003/01/31**
- Target Sample Size: **850**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Patients who had already participated in the previous phase II pharmacokinetic or phase III studies with FK506E (MR4).

- Patients capable of understanding the purpose and risks of the study, who have been fully informed and given written informed consent to participate in the study.

Exclusion criteria

- Pregnant women or nursing mothers.

- Women unwilling or unable to use adequate contraception during the study.

Addresses

■ **Primary Sponsor**

Astellas Pharma Europe Ltd.

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

■ **Contact for Scientific Queries**

Astellas Pharma Europe Ltd.
Central Contact

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

■ **Contact for Public Queries**

Astellas Pharma Europe Ltd.
Central Contact

Telephone: **[---]***
Fax: **[---]***
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): **2009/10/01**

Trial Publications, Results and other documents

- Further trial documents **Link to Results on JAPIC - enter 140509 in the JapicCTI-RNo. field**

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: 1
- Last processed date by ClinicalTrials.gov: 2014/11/05

** 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.*