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

Trial Description

Title

A Multicenter 26-Week Extension Study to Evaluate the Safety and Clinical Effects of Prolonged Exposure to Two Doses of EVP-6124, an Alpha-7 Nicotinic Acetylcholine Receptor Agonist, as an Adjunctive Pro-cognitive Treatment in Subjects With Schizophrenia on Chronic Stable Atypical Antipsychotic Therapy

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**This study is being conducted to further investigate the safety of prolonged exposure to
EVP-6124 in subjects with Schizophrenia receiving a stable dose of an atypical antipsychotic
who completed double-blind treatment on studies EVP-6124-015 and EVP-6124-016.**

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00006777**
- Date of Registration in DRKS: **2014/10/01**
- Date of Registration in Partner Registry or other Primary Registry: **2012/10/19**
- 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): **2012-003228-19**
- Primary Registry-ID: **NCT01714713 (ClinicalTrials.gov)**
- Sponsor-ID: **EVP-6124-017 (FORUM Pharmaceuticals Inc)**
- Other Secondary-ID: **2012-003228-19**

Health condition or Problem studied

- Free text: **Schizophrenia**
- Free text: **Impaired Cognition**
- ICD10: **F20.9 - Schizophrenia, unspecified**

Interventions/Observational Groups

- Arm 1: **Drug: EVP-6124**

Characteristics

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

Primary Outcome

- Safety and Tolerability of EVP-6124 or Placebo in Subjects with Schizophrenia; time frame: Baseline through Day 182 or Early Termination; All adverse experiences spontaneously reported by subject and/or observed by investigator and repeated clinical evaluation of physical examinations, vital signs, 12-lead ECG (electrocardiogram), ambulatory ECG, and laboratory tests (hematology/blood/chemistry/urinalysis)

Secondary Outcome

- Change from Baseline in the Clinical Global Impression (CGI) - Severity (CGI-S) to Day 182; time frame: Baseline to Day 182 or Early Termination
- Change from Baseline in the Clinical Global Impression (CGI) - Change (CGI-C) to Day 182; time frame: Baseline to Day 182 or Early Termination
- Change from Baseline in the EuroQol-5D (EQ-5D-5L) to Day 182; time frame: Baseline to Day 182 or Early Termination
- Change from Baseline in the Columbia Suicide Severity Rating Scale (C-SSRS) to Day 182; time frame: Baseline to Day 182 or Early Termination
- Change from Baseline in the Client Socio-Demographic and Service Receipt Inventory-European Version (CSSRI-EU) to Day 182; time frame: Baseline to Day 182 or Early Termination

Countries of recruitment

- US **United States**
- CA **Canada**
- CO **Colombia**
- DE **Germany**
- IT **Italy**
- RO **Romania**
- RU **Russian Federation**
- SG **Singapore**
- ES **Spain**
- UA **Ukraine**

Locations of Recruitment

- **Berlin**
- **Dusseldorf**
- **Leipzig**
- **Stralsund**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2013/06/30**
- Target Sample Size: **1050**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **50 Years**

Additional Inclusion Criteria

- Completion of the Day 182 visit in a previous 26-week double-blind study (EVP-6124-015 or EVP-6124-016).

- Subject has signed informed consent for this extension study, indicating that the subject understands the purpose of and procedures required for the study, before the initiation of any extension study specific procedures. Subjects who are unable to provide informed consent will not be included in the study

- No clinically significant changes in the subject's medical status during the participation in EVP-6124-015 or EVP-6124-016. Any significant changes in health care status and their impact on subject eligibility will be reviewed by the investigator and sponsor on a case-by-case basis.

- In the opinion of the investigator, the extension treatment is in the best interest of the subject.

- Fertile, sexually active subjects (men and women) must use an effective method of contraception during the study. Females and the female partners of male must be surgically sterile (hysterectomy or bilateral tubal ligation), postmenopausal for at least 1 year, willing to practice adequate methods of contraception if of childbearing potential (defined as consistent use of combined effective methods of contraception [including at least one barrier method]). Female subjects must have a negative urine pregnancy test predose on Day 1.

Exclusion criteria

- Significant risk for suicidal or violent behavior, as determined by the investigator.
Significant risk for suicidal behavior is defined as 1) suicidal ideation as endorsed on items 4 and 5 of the Columbia-Suicide Severity Rating Scale (C-SSRS); 2) suicidal behaviors detected by the C-SSRS; or 3) psychiatric interview and examination.

- Adverse events from the previous study (EVP-6124-015 or EVP-6124-016)

**that have not
resolved, are of moderate or greater severity and judged to be possibly related or
related to study drug and are thought by the investigator to be contraindications to
study participation.**

**- Any condition which would make the subject, in the opinion of the investigator,
unsuitable for the study.**

- Female subjects who are pregnant.

**- Subjects who received any other investigational treatment during participation in
either EVP-6124-015 or EVP-6124-016 other than assigned study medication.**

Addresses

- **Primary Sponsor**

  FORUM Pharmaceuticals Inc

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Scientific Queries**

  INC Research, LLC

  Telephone: **450.682.6226**
  Fax: **[---]***
  E-mail: **SM_EVP-6124-CIAS_ctgov at INCResearch.com**
  URL: **[---]***
- **Contact for Public Queries**

  INC Research, LLC

  Telephone: **450.682.6226**
  Fax: **[---]***
  E-mail: **SM_EVP-6124-CIAS_ctgov at INCResearch.com**
  URL: **[---]***
- **Collaborator, Other Address**

  INC Research

Collaborator, Other Address

INC Research

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 ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

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: 2
- Last processed date by ClinicalTrials.gov: 2014/09/29

** 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.*