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

## Trial Description

### Title

**An International, Randomized, Double-Blinded, Phase 3 Efficacy Study of XL184 Versus Placebo in Subjects With Unresectable, Locally Advanced, or Metastatic Medullary Thyroid Cancer**

### Trial Acronym

**EXAM**

### URL of the trial

**[---]***

### Brief Summary in Lay Language

**The purpose of this research study is to evaluate the progression-free survival (PFS) with
XL184 as compared with placebo (an inactive substance) in subjects with unresectable,
locally advanced, or metastatic medullary thyroid cancer (MTC). Subjects will be randomized
to receive XL184 or placebo in a 2:1 ratio. XL184 is an investigational drug that inhibits
VEGFR2, MET and RET, kinases implicated in tumor formation, growth and migration.**

**The Clinical Steering Committee for this study, comprised of study doctors who specialize in
medullary thyroid cancer, has provided guidance regarding the design of the study. The
committee includes: Douglas Ball, MD, Barry Nelkin, PhD, Martin Schlumberger, MD and Steven
Sherman, MD.**

### Brief Summary in Scientific Language

**[---]***

## Organizational Data

- DRKS-ID: **DRKS00005513**
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Date of Registration in DRKS: **2014/01/16**

- Date of Registration in Partner Registry or other Primary Registry: **2008/06/23**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

## Secondary IDs

- Primary Registry-ID: **NCT00704730 (ClinicalTrials.gov)**
- Sponsor-ID: **XL184-301 (Exelixis)**

## Health condition or Problem studied

- Free text: **Thyroid Cancer**
- ICD10: **C73 - Malignant neoplasm of thyroid gland**

## Interventions/Observational Groups

- Arm 1: **Drug: XL184**
- Arm 2: **Drug: Placebo**

## Characteristics

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

### Primary Outcome

**- To evaluate progression-free survival (PFS) with XL184 as compared with placebo in subjects with unresectable, locally advanced, or metastatic medullary thyroid cancer (MTC); time frame: Assessed at periodic visits**

### Secondary Outcome

**- To evaluate overall survival (OS) with XL184 as compared with placebo; time frame: Assessed as applicable**
**- To evaluate the objective response rate (ORR) and duration of response in subjects with measurable disease with XL184 as compared with placebo; time frame: Assessed at periodic visits**
**- To evaluate the safety and tolerability of XL184; time frame: Assessed at periodic visits**
**- To assess the pharmacokinetics and pharmacodynamic effects of XL184; time frame: Assessed at periodic visits**

## Countries of recruitment

- US **United States**
- AT **Austria**
- BE **Belgium**
- BR **Brazil**
- CA **Canada**
- CL **Chile**
- DK **Denmark**
- FR **France**
- DE **Germany**
- GR **Greece**
- IN **India**
- IL **Israel**
- IT **Italy**
- KR **Korea, Republic of**
- NL **Netherlands**
- PE **Peru**
- PL **Poland**
- PT **Portugal**
- RU **Russian Federation**
-

SA **Saudi Arabia**

- ES **Spain**
- SE **Sweden**
- CH **Switzerland**
- UK **United Kingdom**

## Locations of Recruitment

- **Klinik fuer Nuklearmedizin des Universitaetsklinikums Essen, Essen**
- **Gemeinschaftspraxis, Heidelberg**
- **Universitaetsklinikum Leipzig, Leipzig**
- **Johannes-Gutenberg Universitaet Mainz, Mainz**
- **Klinikum der Ludwig-Maximilians-Universitaet Muenchen, Muenchen**
- **Ludwig-Maximilians-Universitaet Muenchen, Muenchen**
- **Universitaetsklinikum Tuebingen, Tuebingen**
- **Universitaetsklinikum Wuerzburg, Wuerzburg**

## Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2008/06/30**
- Target Sample Size: **315**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**- The subject has a histologically confirmed diagnosis of MTC that is cannot be removed**
**by surgery, is locally advanced, or has spread in the body.**

**- The subject is at least 18 years old.**

**- The subject has an ECOG (Eastern Cooperative Oncology Group)**

**performance status ≤ 2.**

**- The subject has documented worsening of disease (progressive disease) at screening**
**compared with a previous CT scan or MRI image done within 14 months of screening.**

**- The subject has recovered from clinically significant adverse events (side effects)**
**due to any other medications that were administered prior to randomization.**

**- The subject has adequate organ and bone marrow function.**

**- Subjects who are sexually active (male and female) must agree to use medically**
**accepted methods of contraception during the course of the study and for 3 months**
**following discontinuation of study treatments.**

**- The subject has no other diagnosis of cancer (unless non-melanoma skin cancer, an**
**early form of cervical cancer, or another cancer diagnosed ≥ 2 years previously) and**
**currently has no evidence of malignancy (unless non-melanoma skin cancer or an early**
**form of cervical cancer).**

**- Female subjects of childbearing potential must have a negative pregnancy test at**
**screening.**

**Exclusion criteria**

**- The subject has received prior treatment for their cancer within 4 weeks of**
**randomization (6 weeks for nitrosoureas or mitomycin C).**

**- The subject has received radiation to ≥ 25 % of bone marrow.**

**- The subject has received treatment with other investigational agents (unapproved**
**therapies) within 4 weeks of randomization.**

**- The subject has received treatment with XL184.**

**- The subject has brain metastases or spinal cord compression, unless completed**
**radiation therapy ≥ 4 weeks prior to randomization and stable without steroid and**
**without anti-convulsant treatment for ≥ 10 days.**

**- The subject has a history of clinically significant episodes of vomiting blood or a**
**recent history of vomiting > 2.5 mL (about 1/2 teaspoon) of red blood**

**- The subject has serious illness other than cancer**

**- The subject is pregnant or breastfeeding.**

**- The subject has an active infection requiring ongoing treatment.**

**- The subject is incapable of understanding and complying with the protocol or unable to provide informed consent.**

## Addresses

■ **Primary Sponsor**

**Exelixis**

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 continuing**

■ 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: 2013/12/01*

*Please note:*
*There are additional attributes available concerning this trial. To open an extended view please click here.*