A Study Comparing SB8 and Avastin® in Patients With Advanced Non-squamous Non-small Cell Lung Cancer

Purpose

This study is designed to establish biosimilarity of SB8, a proposed biosimilar product of bevacizumab, to EU-sourced bevacizumab, in patients with metastatic or recurrent non-squamous non-small cell lung cancer (NSCLC).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung Cancer</td>
<td>Drug: Bevacizumab</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Non-small Cell Lung Cancer</td>
<td>Drug: SB8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug: Carboplatin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug: Paclitaxel</td>
<td></td>
</tr>
</tbody>
</table>

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Phase 3, Randomised, Double-blind Study to Compare the Efficacy, Safety, PK and Immunogenicity Between SB8 (Proposed Bevacizumab Biosimilar) and Avastin® in Subjects With Metastatic or Recurrent Non-squamous Non-small Cell Lung Cancer

Resource links provided by NLM:
Genetics Home Reference related topics: lung cancer
MedlinePlus related topics: Cancer Lung Cancer
Drug Information available for: Paclitaxel Carboplatin Bevacizumab
U.S. FDA Resources

Further study details as provided by Samsung Bioepis Co., Ltd.:

Primary Outcome Measures:
- Best Objective Response Rate by 24 weeks [ Time Frame: 24 weeks from randomisation ] [ Designated as safety issue: No ]
  Any PR or CR prior to the 24th week will be marked as response

Secondary Outcome Measures:
- Progression Free Survival [ Time Frame: from the date of randomisation to the date of disease progression or death up to 12 months from randomisation of the last subject ] [ Designated as safety issue: No ]
- Overall Survival [ Time Frame: from the date of randomisation to the date of death up to 12 months from randomisation of the last subject ] [ Designated as safety issue: No ]
- Duration of Response [ Time Frame: from documented tumour response until disease progression up to 12 months from randomisation of the last subject ] [ Designated as safety issue: No ]
Incidence of Treatment-related Adverse Events using CTCAE v4.03 [Time Frame: AEs will be reported from the time the informed consent form (ICF) is signed until the EOT visit. The expected EOT visit for a final subject is approximately 30 months from study initiation.]

After the end of treatment (EOT) visit, SAEs should be reported to the Sponsor if the Investigator becomes aware of them.

Pharmacokinetics: Trough Level [Ctrough] [Time Frame: Up to 21 weeks (Cycle 1,3,5 and 7. Each cycle is 21 days.)]

Pharmacokinetics: Maximum Plasma Concentration [Cmax] [Time Frame: Up to 21 weeks (Cycle 1,3,5 and 7. Each cycle is 21 days.)]

Immunogenicity Assessments (Anti-drug Antibodies) [Time Frame: Up to 21 weeks (Cycle 1,3,5, 7 and EOT visit. Each cycle is 21 days. The expected EOT visit for a final subject is approximately 30 months from study initiation.)]

Immunogenicity Assessments (Neutralizing Antibodies) [Time Frame: Up to 21 weeks (Cycle 1,3,5, 7 and EOT visit. Each cycle is 21 days. The expected EOT visit for a final subject is approximately 30 months from study initiation.)]

Other Outcome Measures:

Best Objective Response Rate by 11 and 17 weeks [Time Frame: 11 weeks and 17 weeks from randomisation]

Estimated Enrollment: 678
Study Start Date: June 2016
Estimated Study Completion Date: December 2018
Estimated Primary Completion Date: June 2018 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Comparator: Bevacizumab (Avastin)</td>
<td>Drug: Bevacizumab</td>
</tr>
<tr>
<td>Avastin® + Carboplatin/Paclitaxel</td>
<td>Avastin® 15 mg/kg IV every 3 weeks on Day 1</td>
</tr>
<tr>
<td></td>
<td>Other Name: Avastin®</td>
</tr>
<tr>
<td></td>
<td>Drug: Carboplatin</td>
</tr>
<tr>
<td></td>
<td>Carboplatin AUC 6 IV every 3 weeks on Day 1 for 4-6 cycles</td>
</tr>
<tr>
<td></td>
<td>Drug: Paclitaxel</td>
</tr>
<tr>
<td></td>
<td>Paclitaxel 200 mg/m2 IV every 3 weeks on Day 1 for 4-6 cycles</td>
</tr>
<tr>
<td></td>
<td>Other Name: Taxol</td>
</tr>
</tbody>
</table>

| Experimental: SB8 (A proposed bevacizumab biosimilar) | Drug: SB8                                                                            |
| SB8 + Carboplatin/Paclitaxel                          | SB8 15 mg/kg IV every 3 weeks on Day 1                                                |
|                                                       | Other Name: SB8 (A proposed bevacizumab biosimilar)                                  |
|                                                       | Drug: Carboplatin                                                                    |
|                                                       | Carboplatin AUC 6 IV every 3 weeks on Day 1 for 4-6 cycles                            |
|                                                       | Drug: Paclitaxel                                                                     |
|                                                       | Paclitaxel 200 mg/m2 IV every 3 weeks on Day 1 for 4-6 cycles                        |
|                                                       | Other Name: Taxol                                                                   |

Detailed Description:
Standard efficacy parameters, safety profiles, pharmacokinetics and immunogenicity will be compared between SB8 and bevacizumab.

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
1. Aged ≥ 18 years
2. ECOG performance status of 0-1
3. Histologically-confirmed metastatic or recurrent non-squamous non-small cell lung cancer
4. At least one measurable lesion according to RECIST v1.1.
5. Able to receive bevacizumab, carboplatin and paclitaxel based on adequate laboratory and clinical parameters

Exclusion Criteria:
1. Diagnosis of small cell carcinoma of the lung or squamous cell carcinoma
2. Sensitizing EGFR mutations or ALK rearrangements
3. Increased risk of bleeding determined by investigator based on radiographic / clinical findings
4. History of systemic chemotherapy administered in the first-line setting for metastatic or recurrent disease of NSCLC.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02754882

Contacts
Contact: Samsung Bioepis Information Center +82 32 455 6711

Locations
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Sponsors and Collaborators
Samsung Bioepis Co., Ltd.

Investigators
Principal Investigator: Martin Reck, M.D. LungenClinic Grosshansdorf, Germany

More Information
Responsible Party: Samsung Bioepis Co., Ltd.
ClinicalTrials.gov Identifier: NCT02754882 History of Changes
Other Study ID Numbers: SB8-G31-NSCLC
Study First Received: March 24, 2016
Last Updated: July 31, 2016
Health Authority: Russia: Ministry of Health of the Russian Federation
Germany: Ministry of Health
Korea: Ministry of Food and Drug Safety

Individual Participant Data
Plan to Share IPD: No

Keywords provided by Samsung Bioepis Co., Ltd.:
NSCLC
bevacizumab
avastin

Additional relevant MeSH terms:
Lung Neoplasms
Carcinoma, Non-Small-Cell Lung
Respiratory Tract Neoplasms
Thoracic Neoplasms
Neoplasms by Site
Neoplasms
Lung Diseases
Respiratory Tract Diseases
Carcinoma, Bronchogenic
Bronchial Neoplasms
Paclitaxel
Albumin-Bound Paclitaxel
Bevacizumab

ClinicalTrials.gov processed this record on September 26, 2016

https://clinicaltrials.gov/ct2/show/NCT02754882?term=SB8-G31&rank=1