# *KURZPROTOKOLL*
# *LSK_AM301*

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| **Öffentlicher Titel** | Phase III Studie zu Apatinib bei fortgeschrittenem oder metastasiertem Magenkrebs |
| **Wissenschaftl. Titel** | A Prospective, Randomized, Double-Blinded, Placebo-Controlled, Multinational, Multicenter, Parallel-group, Phase III Study to Evaluate the Efficacy and Safety of Apatinib plus Best Supportive Care (BSC) compared to Placebo plus BSC in Patients with Advanced or Metastastic Gastric Cancer |
| **Kurztitel** | LSK_AM301 |
| **Studienart** | multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig |
| **Studienphase** | Phase III |
| **Erkrankung** | Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Zweitlinie oder höher |
| **Einschlusskriterien** | - Male or female >= 18 years of age.<br>- Documented primary diagnosis of histologic- or cytologic-confirmed adenocarcinoma of the stomach or gastroesophageal junction<br>- Locally advanced unresectable or metastatic disease that has progressed since last treatment.<br>- One or more measurable or nonmeasurable evaluable lesions per RECIST 1.1.<br>- Failure or intolerance to at least two prior lines of standard chemotherapies with each containing one or more of the following agents: a) fluoropyrimidine (IV 5-FU capecitabine, or S-1); b) platinum (cisplatin or oxaliplatin); c) taxanes (paclitaxel or docetaxel) or epirubicin; d) irinotecan; e) trastuzumab in case of HER2-positive; f) ramucirumab<br>- Disease progression within 6 months after the last treatment.<br>- Adequate bone-marrow, renal and liver function.<br>- Eastern Cooperative Oncology Group (ECOG) performance status of <= 1.<br>- Expected survival of >= 12 weeks, in the opinion of the investigator.<br>- Ability to swallow the investigational product tablets.<br>- Female patients with negative pregnancy test at Screening and use of acceptable method of birth control for study duration, unless surgically sterile or postmenopausal for at least 1 year prior to Screening.<br>- Ability and willingness to comply with the study protocol for the duration of the study and with follow-up procedures. |
| **Ausschlusskriterien** | - Malignancies other than adenocarcinoma of the stomach or gastroesophageal junction (including hematologic malignancies) within 3 years.<br>- CNS metastases as shown by radiology records or clinical evidence of symptomatic CNS involvement in the last 3 months prior to randomization.<br>- Cytotoxic chemotherapy, surgery, immunotherapy, radiotherapy or other targeted therapies within 4 weeks (6 weeks in cases of ramucirumab, mitomycin C, nitrosourea, lomustine; 2 weeks in case of biopsy) prior to randomization (Adjuvant radiotherapy given to local area for non-curative symptom relief is allowed until 2 weeks before randomization.).<br>- Therapy with clinically significant systemic anticoagulant or antithrombotic agents within 7 days prior to randomization that may prevent blood clotting and, in the investigator's opinion, could place the subject at risk.<br>- Patients who had therapeutic paracentesis of ascites (> 1L) within the 3 months prior to starting study treatment or who, in the opinion of the investigator, will likely need therapeutic paracentesis of ascites (> 1L) within 3 months of starting study treatment.<br>- Previous treatment with Apatinib.<br>- Known hypersensitivity to Apatinib or components of the formulation. |

- Concomitant treatment with strong inhibitors or inducers of CYP3A4, CYP2C9 and CYP2C19.
- Active bacterial infections.
- Substance abuse or medical, psychological, or social conditions that may interfere with the patient's participation in the study or evaluation of the study results.
- Participation in any other clinical trial within 4 weeks prior to randomization.
- Pregnant or breast-feeding women.
- History of drug or alcohol abuse within past 5 years.
- Medical or psychiatric illnesses that, in the investigator's opinion, may impact the safety of the subject or the objectives of the study.
- History of uncontrolled hypertension (Blood pressure >= _140/90 mmHg and change in antihypertensive medication within 7 days prior to randomization) that is not well managed by medication and the risk of which may be precipitated by a VEGF inhibitor therapy.
- Known history of symptomatic congestive heart failure (New York Heart Association III-IV), symptomatic or poorly controlled cardiac arrhythmia, complete left bundle branch block, bifascicular block, or any clinically significant ST segment and/or T-wave abnormalities, QTcF > 450 msec prior to randomization.
- Prior major surgery or fracture within 3 weeks prior to randomization or presence of any non-healing wound.
- History of bleeding diathesis or clinically significant bleeding within 14 days prior to randomization.
- History of clinically significant thrombosis within the past 3 months prior to randomization that, in the investigator's opinion, may place the patient at risk of side effects from anti-angiogenesis products.
- History of gastrointestinal bleeding, gastric stress ulcerations, or peptic ulcer disease within the past 3 months prior to randomization that, in the investigator's opinion, may place the patient at risk of side effects from anti-angiogenesis products.
- Myocardial infarction or unstable angina pectoris within 6 months prior to randomization.
- History of severe adverse events, in the investigator's opinion, related to ramucirumab.
- History of other significant cardiovascular diseases or vascular diseases within the last 6 months prior to randomization that, in the investigator's opinion, may pose a risk to the patient on VEGF inhibitor therapy.
- History of clinically significant glomerulonephritis, biopsy-proven tubulointerstitial nephritis, crystal nephropathy, or other renal insufficiencies.
- Gastrointestinal malabsorption, or any other condition that in the opinion of the investigator might affect the absorption of the study drug.

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| **Alter** | 18 Jahre und älter |
| **Sponsor** | LSK BioPartners Inc. |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT03042611<br>EudraCT 2016-003984-20 |