

KURZPROTOKOLL **LSK_AM301**

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 Metastatic 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	<ul style="list-style-type: none">- Male or female \geq 18 years of age.- Documented primary diagnosis of histologic- or cytologic-confirmed adenocarcinoma of the stomach or gastroesophageal junction- Locally advanced unresectable or metastatic disease that has progressed since last treatment.- One or more measurable or nonmeasurable evaluable lesions per RECIST 1.1.- 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- Disease progression within 6 months after the last treatment.- Adequate bone-marrow, renal and liver function.- Eastern Cooperative Oncology Group (ECOG) performance status of \leq 1.- Expected survival of \geq 12 weeks, in the opinion of the investigator.- Ability to swallow the investigational product tablets.- 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.- Ability and willingness to comply with the study protocol for the duration of the study and with follow-up procedures.
Ausschlusskriterien	<ul style="list-style-type: none">- Malignancies other than adenocarcinoma of the stomach or gastroesophageal junction (including hematologic malignancies) within 3 years.- CNS metastases as shown by radiology records or clinical evidence of symptomatic CNS involvement in the last 3 months prior to randomization.- 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.).- 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.- 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.- Previous treatment with Apatinib.- Known hypersensitivity to Apatinib or components of the formulation.

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- 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 \geq 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.

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