Typcial and atypical Lung carcinoids, therapy naïve, first line therapy

AIO-NET-0116/ass: A Phase 3, prospective, randomized, double-blind, multi-center study of the efficacy and safety of lanreotide Autogel/Depot 120 mg plus BSC vs. placebo plus BSC for tumour control in subjects with well differentiated, metastatic and/or unresectable, typical or atypical, lung neuroendocrine tumours. (SPINET-Trial)

AIO-assoziierte Studie

Studiennummer/-Code:	AIO-NET-0116/ass - SPINET-Trial
Status:	Rekrutierung beendet
Rekrutierungszeitraum	2016 - 2019
Weitere Zentren:	sind leider nicht mögilch
Letzte Aktualisierung	Oktober 2018

Sponsor Name	IPSEN Biopharmaceuticals Contact: • Philipp Hoffmanns, Director Global Medical Affairs, philipp.hoffmanns@ipsen.com • Elodie Blouquit, Global Project Leader, elodie.blouquit.ext@ipsen.com
Study sites in Germany	• Zentralklinik Bad Berka GmbH Principal Investigator: Dieter Hoersch • Evangelische Lungenklinik Berlin Principal Investigator: Christian Grohe • Charite Universitätsmedizin Berlin, Campus Virchow-Klinikum Principal Investigator: Marianne Pavel • Universitätsklinikum Essen Principal Investigator: Harald Lahner • Johann Wolfgang Goethe-Universitätsklinikum Frankfurt Principal Investigator: Jörg Bojunga
Study Objectives	Objectives Primary Objective • To compare the antitumour efficacy of LAN monotherapy plus BSC every 28 days versus placebo plus BSC, in terms of progression free survival (PFS), measured by central review using Response Evaluation Criteria in Solid Tumours (RECIST) v1.1 criteria, every 12 weeks Secondary Efficacy Objectives • To compare the objective response rate (ORR) of LAN monotherapy plus BSC every 28 days versus placebo plus BSC, as assessed by RECIST v 1.1 criteria (proportion of subjects with a best overall response of partial response (PR) or complete response (CR)), • To compare the overall survival (OS) of subjects randomised to LAN monotherapy plus BSC every 28 days versus subjects randomised to placebo plus BSC, • To compare time to treatment failure (Kaplan Meier estimates) of LAN monotherapy plus BSC every 28 days versus placebo plus BSC, • To compare the changes from Baseline in the biomarker chromogranin A (CgA),

	• To describe the change in Quality of Life (QoL) from baseline, as assessed by the EORTC QLQ-C30 questionnaire, • To describe the time to deterioration of QoL (using EORTC QLQ-C30), • To describe the changes in urinary 5-hydroxyindoleacetic acid (5-HIAA) in subjects with elevated urinary 5-HIAA (≥2 x ULN) at Baseline, • To assess the pharmacokinetics (PK) of LAN
Study Timelines	Start: Feb 2016 Estimated completion date: August 2019
Study Design	This is a Phase 3, prospective, multi-center, randomized, double-blind study evaluating the efficacy and safety of LAN plus BSC vs. placebo plus BSC for the treatment of well-differentiated typical or atypical, metastatic and/or unresectable lung NETs. The study contains two phases, the DB Phase, and the OL Extension Phase. The DB Phase will include: Screening, Baseline and Treatment periods and the Extension Phase will consist of two periods: Treatment Period and Follow-Up Period.
Number of Patients	Aktuell eingeschlossen: 1 Patient (Stand Okt. 2016)
Study Population	Study population will consist of 216 eligible subjects who meet the selection criteria specified below: Inclusion criteria (selected) (1) Have metastatic and/or unresectable pathologically confirmed well-differentiated, typical or atypical neuroendocrine tumour of the lung, (2) Histologic evidence of well differentiated NETs of the lung (typical and atypical according to the WHO criteria evaluated locally), (3) Has a mitotic index <2 mitoses/2 mm^2 for typical carcinoid (TC) and <10 mitoses/2 mm^2 and/or foci of necrosis for atypical carcinoid (AC), (4) At least one measurable lesion of the disease on imaging (CT or MRI; RECIST v1.1), (5) Positive somatostatin receptor imaging (SRI) (Octreoscan® ≥ grade 2 Krenning scale; Ga-PET scan: uptake greater than liver background), Exclusion criteria (selected) (1) Poorly differentiated or high grade carcinoma, or patients with neuroendocrine tumors not of lung origin are excluded (2) Has been treated with an Somatostatin analogs (SSA) at any time prior to randomization, except if that treatment was for less than 15 days (e.g. peri-operatively) of short acting SSA or one dose of long acting SSA and the treatment was received more than 6 weeks prior to randomization (3) Has been treated with Peptide receptor radionuclide therapy (PRRT) at any time prior to randomization (4) Has been treated with more than two lines of cytotoxic chemotherapy or molecular targeted therapy or interferon for Lung NET
Study Treatment	Lanreotide Autogel/Depot 120mg (LAN) plus BSC every 28 days administered via deep subcutaneous (s.c.) injection until disease progression confirmed centrally, development of unacceptable toxicity or premature withdrawal for any reason. OR Placebo plus BSC every 28 days administered via deep s.c. injection until disease progression confirmed centrally, development of unacceptable toxicity or premature withdrawal for any reason.