KURZPROTOKOLL
IMPULSE MGN1703-C03

Öffentlicher Titel	Phase II Erhaltungsstudie mit MGN1703 bei Patienten mit fortgeschrittenem SCLC
Wissenschaftl. Titel	Randomized Clinical Study of Maintenance Therapy with Immunomodulator MGN1703 in Patients with Extensive Disease Small Cell Lung Cancer after Platinum-Based First-Line Therapy
Kurztitel	IMPULSE MGN1703-C03
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase II
Erkrankung	Lunge: Lungenkrebs: Kleinzelliges Lungenkarzinom (SCLC) - Zweitlinie oder höher
Ziele	- The overall purpose of the study is to evaluate efficacy and safety of MGN1703 administered twice weekly s.c. as switch maintenance treatment in patients with extensive disease SCLC who achieved at least PR following platinum-based first-line chemotherapy
Einschlusskriterien	- 1. Male and female patients with extensive disease SCLC >= 18 years of age receiving platinum-based first-line chemotherapy; - 2. Histology of SCLC or mixed histology of SCLC if SCLC histology is at least 80%; - 3. Completion of 4 cycles of first-line therapy with a platinum-based regimen and no other prior chemotherapy; - 4. Documented evidence of tumor response (PR or CR) as assessed by the investigator at the end of the fourth cycle of platinum-based first-line chemotherapy using CT or magnetic resonance imaging (MRI) scan; - 5. Brain metastases are allowed only after cranial irradiation, if asymptomatic and not requiring continuous treatment with steroids or anticonvulsants. MRI of the brain should be performed in all patients at Screening; - 6. ECOG performance status 0 or 1; - 7. Adequate organ function with total bilirubin, lactate dehydrogenase [LDH], alkaline phosphatase [AP], albumin, creatinine, urea, electrolytes, and coagulation parameters <= 1.5 × upper limit of normal (ULN), and with aspartate aminotransferase [AST] and ALT <= 2.5 × ULN in the absence of liver metastases or <= 5.0 × ULN in the presence of liver metastases; - 8. Adequate hematological parameters: absolute neutrophil count >= 1.5 × 109/L; platelet count >= 100 × 109/L; leukocyte count >= 3.0 × 109/L; lymphocytes >= 1.0 × 109/L; hemoglobin >= 9.0 g/dL or 5.59 mmol/L; - 9. Male patients who have had vasectomy, and female patients who are not of childbearing potential (i.e. who are post-menopausal for at least 24 consecutive months or who have undergone surgical sterilization [hysterectomy, bilateral tubal ligation, or bilateral oophorectomy]). Male and female patients with reproductive potential can be included if they are using an effective means of contraception with a failure rate of less than 1% per year throughout the study, e.g. established use of oral, implanted, or injected hormonal contraceptives; placement of intra-uterine device or intra-uterine system; or use of barrier methods such as condom or diaphragm together with spermicide product; - 10. Negative serum pregnancy test in women of childbearing potential; - 11. Signed informed consent form (ICF).
Ausschlusskriterien	- 1. Patients with no evidence of tumor response (PR or CR) at the end of the fourth cycle of platinum-based chemotherapy; - 2. Clinically significant concomitant diseases or conditions, which, in opinion of the investigator, would lead to an unacceptable risk for the patient to participate in the study; - 3. Prior or current other malignancy, except adequately treated superficial bladder cancer, basal or squamous cell carcinoma of the skin, or other cancer for which the patient has been disease free for more than 3 years;

- 4. History of carcinomatous meningitis;
- 5. Prior or current paraneoplastic syndrome related to SCLC;
- 6. Active or uncontrolled infections at the time of randomization;
- 7. Severe anemia requiring repeated blood cell transfusion;
- 8. History of autoimmune disease or immune deficiency;
- 9. Known hypersensitivity to oligonucleotides or excipients of the formulation;
- 10. Pregnant and/or nursing;
- 11. Chronic systemic immune therapy or immunosuppressant medication other than steroids within the last 6 weeks prior to study treatment; or continuous treatment with systemic steroids within the last 2 weeks prior to study treatment;
- 12. Use of antibiotic therapy within the last 2 weeks prior to study treatment;
- 13. Concurrent use of molecular targeted therapy;
- 14. HIV seropositivity or active hepatitis B or C infection;
- 15. Planned major surgery during the study, except for thoracotomy;
- 16. Participation in another clinical study with other investigational drugs within 28 days prior to study treatment, or treatment with any anti-cancer investigational drug within 12 months prior to study treatment;
- 17. Vaccination within 1 month prior to study treatment;
- 18. Any medical, mental, psychological or psychiatric condition that in the opinion of the investigator would not permit the patient to complete the study or understand the patient information;
- 19. Presence of drug and/or alcohol abuse.

Alter	18 Jahre und älter
Fallzahl	100
Prüfzentren	**Universitätsklinikum Frankfurt** (Rekrutierung beendet) Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Sabine Hug Tel: 069 6301-6353 Fax: 069 6301-7463 s.hug@em.uni-frankfurt.de
Sponsor	Mologen AG
Förderer	Mologen AG
Registrierung in anderen Studienregistern	EudraCT 2013-003503-19
Anmerkung	Primary end point: Overall survival from the date of randomization