KURZPROTOKOLL
Lipo-MERIT

Öffentlicher Titel	Phase I Studie zum Impfstoff Lipo-MERIT bei Patienten mit fortgeschrittenem Melanom
Wissenschaftl. Titel	Clinical first-in-human dose escalation study evaluating the safety and tolerability of intravenous administration of a tetravalent RNA-lipoplex cancer vaccine targeting the tumor-associated antigens NY-ESO-1, tyrosinase, MAGE-A3, and TPTE in patients with advanced melanoma
Kurztitel	Lipo-MERIT
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, einarmig
Studienphase	Phase I
Erkrankung	Haut: Hautkrebs: Schwarzer Hautkrebs (Malignes Melanom) - Zweitlinie oder höher
Einschlusskriterien	- Cohort I: stage IV malignant melanoma (AJCC 2009 melanoma classification) - Cohorts II-VI (after DSMB release): stage IIC, IIIA-C, or stage IV of malignant melanoma (AJCC 2009 melanoma classification) - Therapy only for subjects not eligible or declining any other available approved therapy after all available treatment options have been transparently disclosed (to be documented!) Expression of either one of the selected TAA confirmed by RT-PCR analysis from FFPE - >= 18 years of age - Written informed consent - ECOG performance status (PS) 0-1 - Life expectancy > 6 months - WBC >= 3x10^9/L - Haemoglobin >= 10 g/dL - Platelet count >= 100,000/mm³ - LDH level < 2.0 x ULN - ALT/AST < 3 x ULN (except patients with liver metastasis) - Negative pregnancy test (measured by -HCG) for females with childbearing age
Ausschlusskriterien	- Pregnancy or breastfeeding - Primary ocular melanoma - Concurrence of a second malignancy other than squamous or basal cell carcinoma, non-active prostate cancer or cervical carcinoma in situ or non-active treated urothelial carcinoma - Brain metastases - Post-splenectomy patients - Known or symptomatic pleural effusions and/or ascites - Known hypersensitivity to the active substance or to any of the excipients - A serious local infection (e. g. cellulitis, abscess) or systemic infection (e. g. pneumonia, septicemia) which requires systemic antibiotic treatment within 2 weeks prior to the first dose of study medication - Positive test for acute or chronic active hepatitis B or C infection, acute EBV, or acute CMV - Clinically relevant autoimmune disease - Systemic immune suppression: HIV disease; Use of chronic oral or systemic steroid medication (topical or inhalational steroids are permitted); Other clinical relevant systemic immune suppression - Symptomatic congestive heart failure (NYHA 3 or 4) - Unstable angina pectoris

- Radiotherapy and minor surgery within 14 days prior to the first administration of study treatment
- Myelosuppressive chemotherapy within 14 days and after reconstitution of blood values prior to the first administration of study treatment
- Ipilimumab within 28 days prior to the first administration of study treatment
- Interferon, major surgery,vaccination, and other investigational agents within 28 days or 5 half-life's depending on what gives the longer range before the first treatment
- Approved BRAF inhibitors Vemurafenib or Dabrafenib as well as the approved MEK inhibitor Trametinib in patients of the dose escalation cohorts. Concomitant treatment with approved BRAF inhibitors or MEK inhibitor is allowed for patients included in one of the two expanded dose cohorts, after analysis of safety data collected for the dose escalation cohorts and DSMB approval.Local radiation will be allowed as concurrent treatment.
- Fertile males and females who are unwilling to use a highly effective method of birth control (less than 1% per year, e.g. condom with spermicide, diaphragm with spermicide, birth control pills, injections, patches or intrauterine device) during study treatment and 28 days after the last dose of study treatment
- Presence of a serious concurrent illness or other condition (e. g. psychological, family, sociological, or geographical circumstances) that does not permit adequate follow-up and compliance with the protocol

Alter	18 Jahre und älter
Fallzahl	42
Sponsor	BioNTech AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02410733 EudraCT 2013-001646-33