

KURZPROTOKOLL
IO102-012

Öffentlicher Titel	Phase I/II Studie zu IO102 plus Pembrolizumab als Erstlinientherapie beim metastasierten nicht-kleinzelligen Lungenkarzinom
Wissenschaftl. Titel	An Open-label, Randomized, Phase I/II Trial Investigating the Safety and Efficacy of IO102 in Combination with Pembrolizumab, with or without Chemotherapy, as First-line Treatment for Patients with Metastatic Non-Small Cell Lung Cancer
Kurztitel	IO102-012
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase II
Erkrankung	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Erstlinie
Einschlusskriterien	- histologically or cytologically confirmed metastatic NSCLC (Cohort A) or non-squamous NSCLC (Cohort B), who have not received prior treatment for metastatic NSCLC - No known sensitizing EGFR or ALK mutations - Solitary metastases must be biopsied to confirm the diagnosis metastasis from NSCLC
Ausschlusskriterien	- prior treatment with a checkpoint inhibitor of e.g PD1/PD-L1/PD-L2, CTLA4, OX-40, and/or CD137 - prior systemic anti-cancer therapy in the first line setting for the participant's metastatic disease (treatment with chemotherapy and/or radiation as part of neoadjuvant/adjuvant therapy is allowed as long as completed at least 6 months prior to diagnosis of metastatic disease).
Alter	18 Jahre und älter
Prüfzentren	Universitätsmedizin Frankfurt (Geschlossen) Medizinische Klinik I, Pneumologie/Allergologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. med. Wolfgang Gleiber Tel: 069 6301-6337 Fax: 069 6301-7391 Pneumo.studien@unimedizin-ffm.de
Sponsor	IO Biotech Aps
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03562871 (primäres Register) EudraCT 2018-000139-28