# *KURZPROTOKOLL*
# *ECLIPSE (EFC11553)*

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| **Öffentlicher Titel** | Studie zu Gemcitabin/Carboplatin mit oder ohne Iniparib bei unbehandeltem, squamösem NSCLC im Stadium IV |
| **Wissenschaftl. Titel** | Randomized Phase 3 Trial of Gemcitabine/Carboplatin With or Without Iniparib (SAR240550) (a PARP1 Inhibitor) in Subjects With Previously Untreated Stage IV Squamous Non-Small-Cell Lung Cancer (NSCLC) |
| **Kurztitel** | ECLIPSE (EFC11553) |
| **Studienart** | multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT) |
| **Studienphase** | Phase III |
| **Erkrankung** | Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Erstlinie |
| **Ziele** | - overall survival<br>- progression free survival |
| **Einschlusskriterien** | - 1. Newly diagnosed, stage IV squamous cell lung cancer. This includes patients who present with disseminated metastases, and those with a malignant pleural or pericardial effusion (i.e., formerly stage IIIB in the 6th TNM staging system).<br>- 2. Patients who have received prior adjuvant therapy for early-stage lung cancer are eligible if at least 12 months have elapsed from that treatment.<br>- 3. Histologically confirmed squamous cell bronchogenic carcinoma. Patients whose tumors contain mixed non-small cell histologies are eligible, as long as squamous carcinoma is the predominant histology. Mixed tumors with small cell anaplastic elements are not eligible. Cytologic specimens obtained by brushings, washings, or needle aspiration of the defined lesion are acceptable.<br>- 4. Patients with previous radiotherapy as definitive therapy for locally advanced non-small cell lung cancer are eligible, as long as the recurrence is outside the original radiation therapy port. Radiation therapy must have been completed >4 weeks prior to the initiation of study treatment. Patients who have received chemo/radiation for locally advanced NSCLC are not eligible. Patients who have received palliative radiation therapy for symptomatic metastases must have completed treatment >14 days prior the initiation of the study treatment.<br>- 5. Presence of evaluable (measureable or non-measurable) disease.<br>- 6. ECOG Performance Status of 0 or 1.<br>- 7. Laboratory values as follows:<br>- o Absolute neutrophil count (ANC) >1,500/microL and platelets >100,000/microL (72 hours prior to initial treatment).<br>- o Hemoglobin >9 g/dL (Note: Patients may be transfused or receive erythropoietin to maintain or exceed this level).<br>- o Bilirubin < ULN.<br>- o Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) 2.5 times the upper limit of normal if no liver involvement or 5 times the upper limit of normal with liver involvement.<br>- o Creatinine <2.0 mg/dL, or creatinine clearance >40 mL/min (as calculated by the Cockcroft-Gault method.<br>- 8. Women of childbearing potential must have a negative serum pregnancy test performed within 7 days prior to start of treatment. Women of childbearing potential or men with partners of childbearing potential must use effective birth control measures during treatment and at least 6 months after the last dose of the study treatment. If a woman becomes pregnant or suspects she is pregnant while participating in this study, she must agree to inform her treating physician immediately. Sexually active men must agree to use a medically acceptable form of birth control during treatment and at least 6 months after the last dose. If a female partner becomes pregnant during the course of the study the treating physician should be informed immediately. |

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| | - 9. >18 years of age.<br>- 10. Ability to understand the nature of this study, give written informed consent, and comply with study requirements.<br>- 11. Patients entering this study must be willing to provide tissue from a previous tumor biopsy (if available) for correlative testing. An exception to this is when the national/local regulations prohibits some of the key activities of this research like the export of samples to third countries, storage of coded samples or global gene expression profiling without a pre-specified list of target genes. If tissue is not available, a patient will still be eligible for enrollment into the study. |
| **Ausschlusskriterien** | - 1. Prior treatment with gemcitabine, carboplatin (except in the adjuvant setting), or Iniparib.<br>- 2. Past or current history of neoplasm other than the entry diagnosis, with the exception of treated non-melanoma skin cancer or carcinoma in-situ of any primary site, or invasive cancers treated definitively, with treatment ending >5 years previously and no evidence of recurrences.<br>- 3. A history of cardiac disease, as defined by:<br>- o Malignant hypertension<br>- o Unstable angina<br>- o Congestive heart failure<br>- o Myocardial infarction within the previous 6 months<br>- o Symptomatic, unstable or uncontrolled, cardiac arrhythmias. Patients who have stable, rate-controlled atrial fibrillation are eligible for study enrollment.<br>- 4. Active brain metastases. Patients with treated brain metastases are eligible, if (1) radiation therapy was completed at least 2 weeks prior to study entry; (2) follow-up scan shows no disease progression; and (3) patient does not require steroids.<br>- 5. Women who are pregnant or lactating.<br>- 6. Any serious, active infection (> Grade 2) at the time of treatment.<br>- 7. A serious underlying medical condition that would impair the ability of the patient to receive protocol treatment.<br>- 8. A major surgical procedure, or significant traumatic injury 28 days of beginning treatment, or anticipation of the need for major surgery during the course of the study.<br>- 9. Uncontrolled or intercurrent illness including, that in the opinion of the investigator may increase the risks associated with study participation or administration of the investigational products, or that may interfere with the interpretation of the results.<br>- 10. History of any medical or psychiatric condition or laboratory abnormality that, in the opinion of the investigator, may increase the risks associated with the study participation or administration of the investigational products, or that may interfere with the interpretation of the results.<br>- 11. Known or suspected allergy/hypersensitivity to any agent given in the course of this trial. The above information is not intended to contain all considerations relevant to a patient's potential participation in a clinical trial. |
| **Alter** | 18 Jahre und älter |
| **Sponsor** | Sanofi Aventis GmbH (Hauptsponsor) |
| **Förderer** | Sanofi Aventis GmbH |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT01082549 (primäres Register)<br>EudraCT 2010-019255-22 |
| **Therapie** | Gemcitabine Carboplatin Iniparib |