



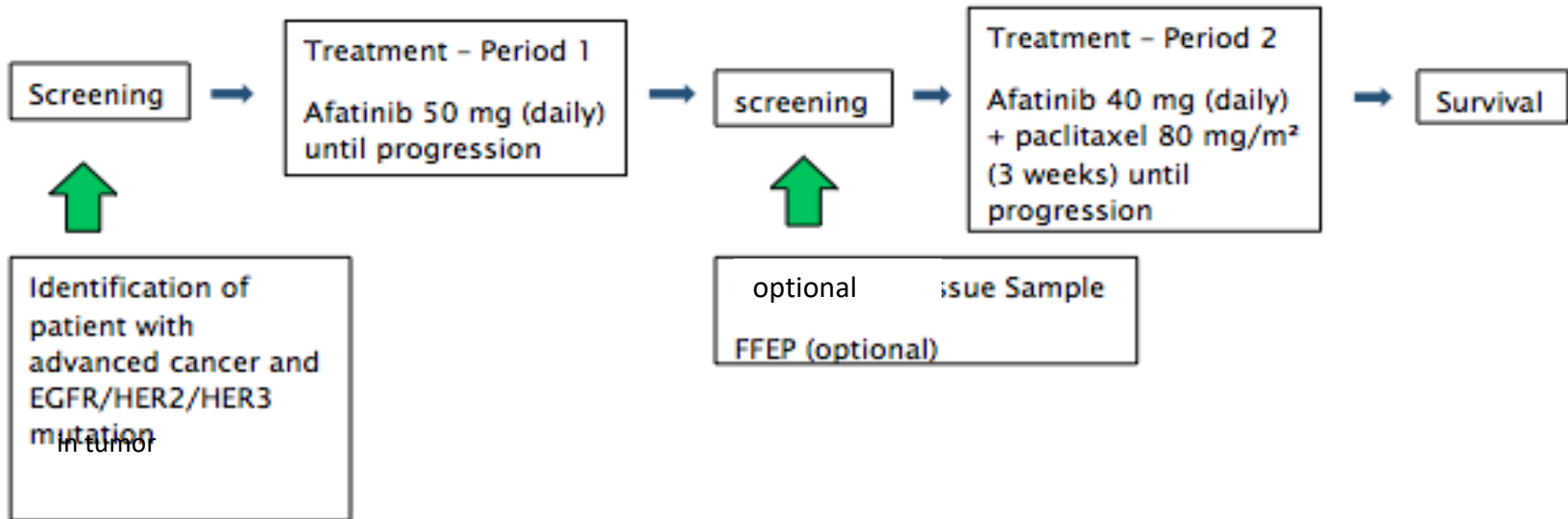
An open explorative phase II, open label study, of  
afatinib in the treatment of advanced cancer  
carrying an EGFR, HER2 or HER3 mutation  
A BSMO Precision 2 study

Lore Decoster  
UZ Brussel

# Study rationale

- Multi-center phase II study to evaluate the effect of afatinib in three cohorts of patients with advanced cancer
  - Cohort 1: EGFR mutation (excl NSCLC)
  - Cohort 2: HER2 mutation
  - Cohort 3: HER3 mutation

# Study design



The identification of mutations is NOT part of the protocol

# Study objectives

- Primary:
  - Response rate in each cohort
- Secundair
  - PFS
  - Toxicity
  - Respons and PFS after addition of paclitaxel at time of progression
  - OS

# Statistics

- Simon 2 stage design for each cohort
  - 1<sup>e</sup> step 10 pts
  - In case of  $\geq 1$  CR/PR then additional 19 pts

# Huidige inclusie (21/11/2019)

- Totaal 20 patiënten
  - 15 in HER2 cohorte
    - Interim analysis after 10 pts demonstrated 2 PRs
    - Synergy with paclitaxel
  - 4 in EGFR cohorte
  - 1 in HER3 cohorte

# Case report

- HER2 mutated NSCLC

