Background

EGFR TKIs

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• BI 836845 is a humanized monoclonal antibody of the IgG1 isotype that binds to human

Monotherapy with EGFR tyrosine kinase inhibitors (TKIs) has been established as standard

Epidermal growth factor receptor (EGFR) acquired resistance to EGFR TKIs in the absence of other known mechanisms including

Design

This is a multicenter, open-label, Phase I clinical trial to evaluate the safety, tolerability and antitumor activity of the combination of BI 836845 and afatinib (NCT02191891). Study Table 1: Key inclusion criteria

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| Part A: MTD and/or RP2D of BI 836845 in combination with afatinib and dose-limiting toxicities during the first treatment course
| Part B: objective response (defined as a complete response [CR] or partial response [PR] according to the Response Evaluation Criteria in Solid Tumors [RECIST] version 1.1) Secondary (Part B only)
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Table 2: Key exclusion criteria

Exclusion criteria

Overall survival

Progression-free survival

Endpoints

Primary

Secondary (Part B only)

Secondary (Part B only)

Secondary (Part B only)

Secondary (Part B only)

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REFERENCES


SUMMARY

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CURRENT STATUS

This open-label, Phase I trial is currently recruiting patients in three Asian countries to evaluate the safety, tolerability and early antitumor activity of BI 836845 in combination with afatinib in patients with EGFR-mutated NSCLC progressing following prior treatment with monotherapy or doublet EGFR TKIs and in patients with squamous cell histology

This trial was initiated in October 2014 and is currently enrolling patients. Patients are being enrolled at nine trial sites in three countries (Figure 3).