Evaluation of VeriStrat®, a serum proteomic test, in the open-label, randomised, Phase III LUX-Lung 8 trial of afatinib versus erlotinib for the second-line treatment of advanced squamous cell carcinoma of the lung

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INTRODUCTION

• The Phase III, global, 1:1 randomised, open-label LUX-Lung 8 study (NCT01385651) compared the irreversible EGFR TKI, afatinib, against the reversible EGFR TKI, erlotinib, in this treatment setting (Figure 1).

• Afatinib, significantly improved overall survival (OS; Figure 2a), versus the reversible EGFR TKI, erlotinib, in this treatment setting (Figure 1).

• In the VS-G group, patients had significantly longer OS (Figure 3) and PFS (Figure 4) with afatinib versus erlotinib (Figure 4).

• In afatinib-treated patients, OS (Figure 5) and PFS (Figure 6) were significantly improved (p<0.0001) in the VS-G group compared with the VS-P group.

METHODS

VeriStrat® classification

The VeriStrat classification algorithm, developed using a training set of samples from gefitinib-treated patients with squamous cell lung cancer, was used to assess the impact of VeriStrat results on treatment outcome in patients treated with afatinib versus erlotinib.

VeriStrat® test has a strong independent stratification effect in patients with KRAS wild-type, unless 2nd line EGFR TKI sensitive mutation status.

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The benefit of afatinib over erlotinib was more pronounced in VS-G patients regardless of patient baseline characteristics

RESULTS

In the VS-G group, patients had significantly longer OS (Figure 3) and PFS (Figure 4) with afatinib versus erlotinib (Figure 4).

In afatinib-treated patients, OS (Figure 5) and PFS (Figure 6) were significantly improved (p<0.0001) in the VS-G group compared with the VS-P group.

• Multivariate analysis showed that VeriStrat was an independent predictor of OS and PFS in afatinib-treated patients, regardless of ECOG PS, best response to first-line therapy, age and race; HR were adjusted for these patient baseline characteristics. None of these characteristics showed a significant effect.

• HR (VS-G vs VS-P): 0.81 (95% CI: 0.69–0.96).

• However, there was no significant interaction between VeriStrat classification and treatment group for OS (Figure 7).

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