

## Companion test for lung cancer compound, 2/13:112

Qiagen has submitted to the FDA its Therascreen EGFR RGQ PCR kit as a proposed companion diagnostic test to guide treatment with afatinib, an investigational oncology compound developed by Boehringer Ingelheim. The FDA has accepted afatinib for filing and granted it priority review as a proposed treatment for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with an EGFR mutation detected by an FDA-approved test.

Qiagen submitted a premarket approval application for use of Therascreen to determine which NSCLC patients would potentially be eligible for treatment with afatinib. The companion diagnostic test was developed in collaboration with Boehringer Ingelheim. A version of the Therascreen EGFR test has already been CE-marked and is available in Europe. The test is also approved in Japan.

The submission of the afatinib registration is supported by the findings of Boehringer's LUX-Lung 3 study, a large phase-three trial conducted in untreated patients with locally advanced or metastatic NSCLC with a confirmed EGFR mutation-positive status, using Therascreen EGFR.

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