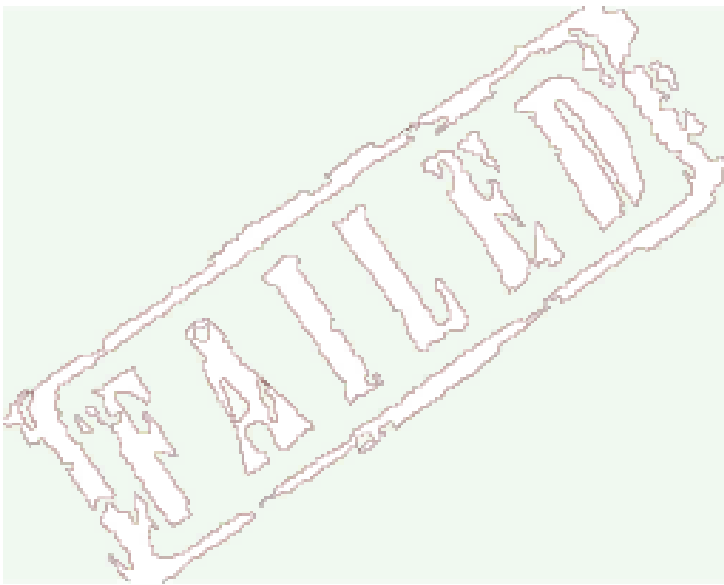


Pfizer trial of cancer drug INLYTA is a failure

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Singapore: Pfizer has revealed that its phase III study of INLYTA (axitinib) did not meet the primary endpoint of demonstrating statistically significantly longer progression-free survival (PFS), as compared to sorafenib, in treatment-naïve patients with advanced renal cell carcinoma (RCC). Adverse events for INLYTA were generally consistent with previous findings.

Dr Mace Rothenberg, senior VP, clinical development and medical affairs, oncology business unit, Pfizer, said that, "We narrowly missed the primary endpoint in this trial. We are analyzing the study findings to determine whether further evaluation of INLYTA in specific sub-populations of treatment-naïve patients with advanced RCC would be warranted."

Earlier this year, INLYTA was approved for patients with previously treated advanced RCC in the US, EU, Japan, Switzerland, Canada, Korea, and Australia. In its registrational phase III AXIS trial, INLYTA significantly extended PFS with a median PFS of 6.7 months as compared to 4.7 months for those treated with sorafenib. The differences in PFS observed in the subgroups in the AXIS trial favored INLYTA over sorafenib, including in the 'either good performance status' (ECOG PS 0) and 'intermediate performance status' (ECOG PS 1) subgroups.

Pfizer is also investigating axitinib in the AGILE 1046 study, a randomized phase II clinical trial in treatment-naïve patients with advanced RCC. Blinded efficacy data from this ongoing study were presented at ASCO earlier this year.

Axitinib is also being studied in a randomized phase II clinical trial for the treatment of hepatocellular carcinoma (HCC), which

is currently closed to enrollment. Additionally, under a collaborative development agreement between Pfizer and SFJ Pharma, a phase III clinical trial in Asia studying axitinib for adjuvant treatment of patients at high risk of recurrent RCC following nephrectomy (kidney removal) is also being conducted.