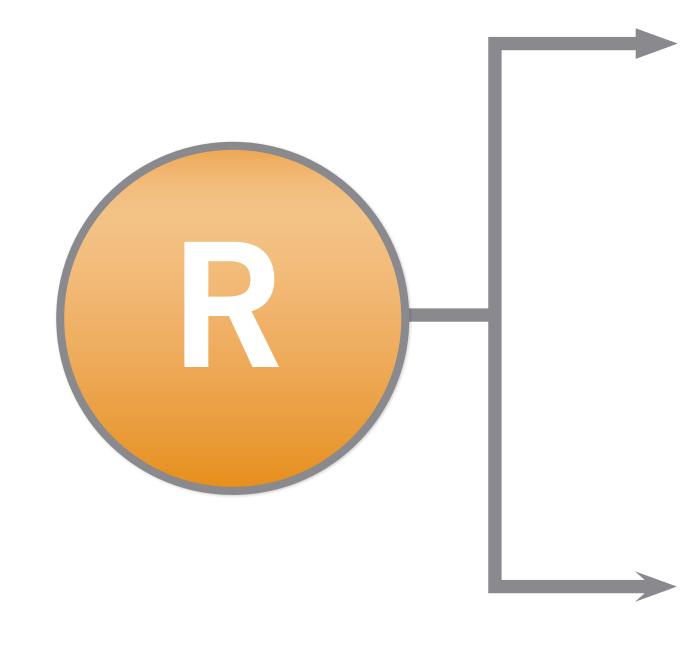
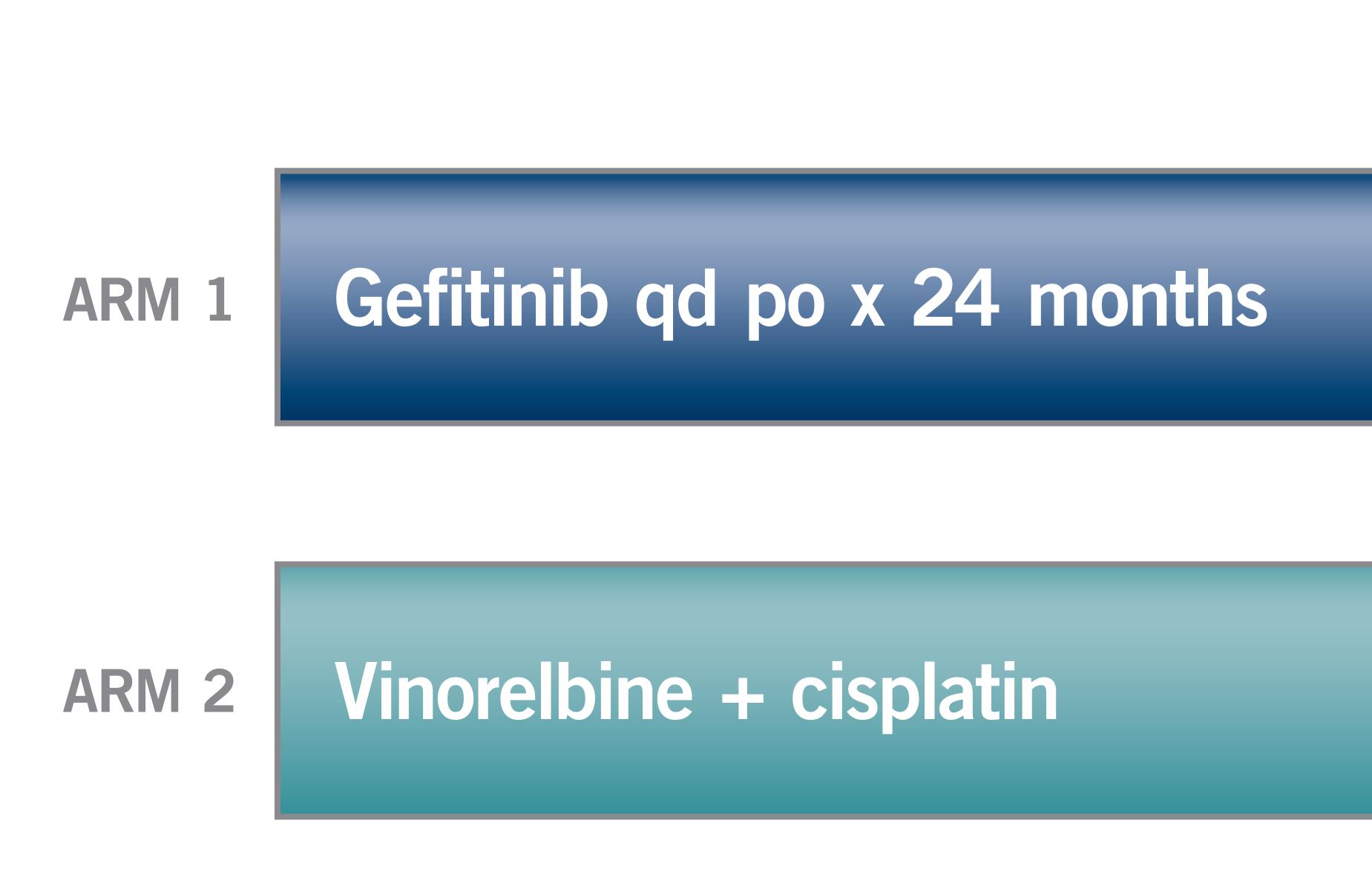
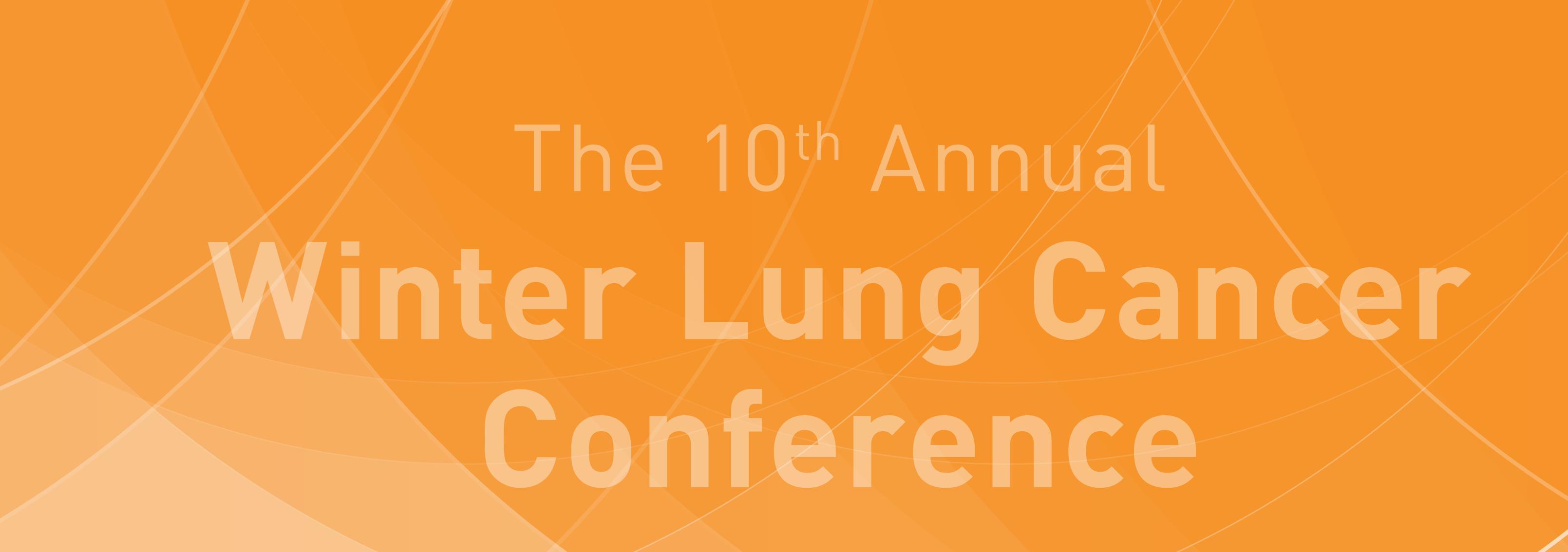
A Phase III trial of gefitinib versus vinorelbine/platinum as adjuvant treatment for Stage II-IIIA (N1-N2) NSCLC with EGFR mutation • Estimated primary completion: August 2016 (Target N = 220) • Eligibility: Stage II-IIIA (N1-N2) NSCLC with EGFR exon 19 deletions and exon 21 L858R activating mutation; within 3-6 weeks of complete resection



Study Chair: Xue-Ning Yang, MD Principal Investigator: Yi-Long Wu, MD ClinicalTrials.gov Identifier: NCT01405079







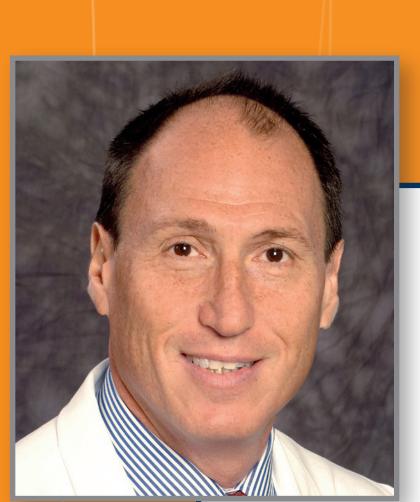


DR GOVINDAN

This Phase III study of gefitinib versus vinorelbine/platinum in patients with Stage II and

IIIA NSCLC with EGFR mutations is a nice study. This is a big question that we have to ask. Sadly, this is a small study that may not provide us with a definitive answer, but we don't know whether patients with EGFR mutations are better off with EGFR therapy or chemotherapy.

I am planning a Phase III study through all the cooperative groups that will randomly assign patients to erlotinib or placebo after adjuvant chemotherapy for patients with EGFR-mutant NSCLC, but a question the study won't ask is, do these patients even need chemotherapy? Why can't we simply administer an EGFR tyrosine kinase inhibitor? That's why the Chinese study is important.



DR LILENBAUM

The question being addressed in this trial is incredibly important. The few data that exist on this particular topic have

not been encouraging, with perhaps one exception, and to evaluate these treatments in a randomized fashion is absolutely crucial.

