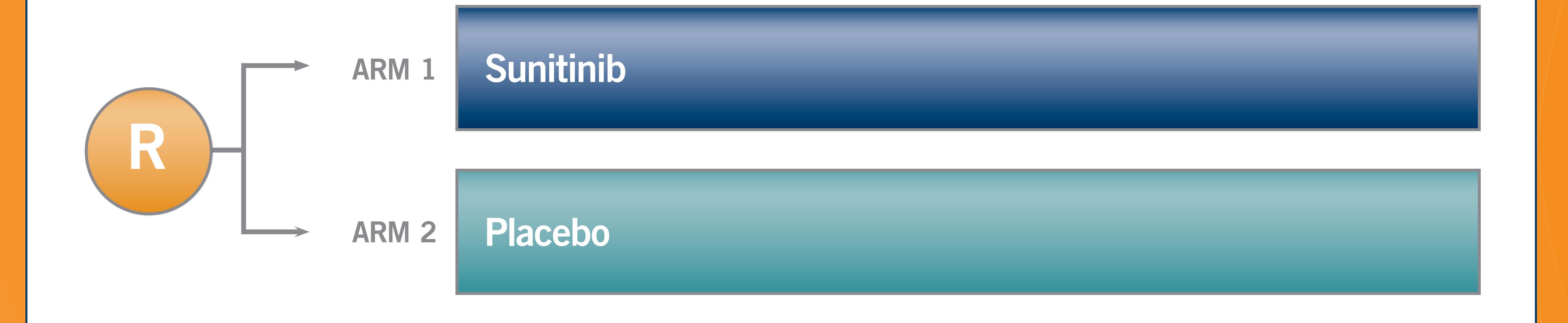
62LGB-30607

Sunitinib as maintenance therapy in treating Stage III or Stage IV NSCLC previously treated with combination chemotherapy

- Study start date: June 2008 (Target N = 244)
- Eligibility: Primary Stage IIIB or IV NSCLC; not a candidate for chemoradiation therapy; must have received 1 prior first-line chemotherapy regimen that included 4 courses of platinum-based doublet chemotherapy ± bevacizumab; ECOG PS 0-1



Principal Investigator: Mark A Socinski, MD ClinicalTrials.gov Identifier: NCT00693992



DR SOCINSKI

I'm biased because I'm the Pl of this trial. I believe the value of this trial is that sunitinib is a

VEGFR TKI and we have not conducted a true maintenance trial to date of an anti-angiogenic agent. We all use bevacizumab as maintenance therapy, but it's never been evaluated in a pure maintenance trial. The problem with sunitinib is it has "fallen off the map" in lung cancer because of the negative Phase III data in combination with erlotinib in this setting. The other issue is that the trial started up when the maintenance story with pemetrexed and erlotinib was coming out, so the trial has had accrual problems.



DR GOVINDAN

Mark Socinski and I observed an 8% to 10% response rate with sunitinib in advanced NSCLC,

and some evidence indicates that it increases progression-free survival when added to erlotinib. The question is, where does it fit into the management of NSCLC? Could that be used as maintenance therapy? The current study is being conducted through the CALGB. It's unclear to me whether sunitinib will be an active drug in an unselected group of patients with lung cancer, but conducting this study in a maintenance setting is reasonable and we have enrolled patients on the trial.

The 10th Annual

Winter Lung Cancer

Conference

