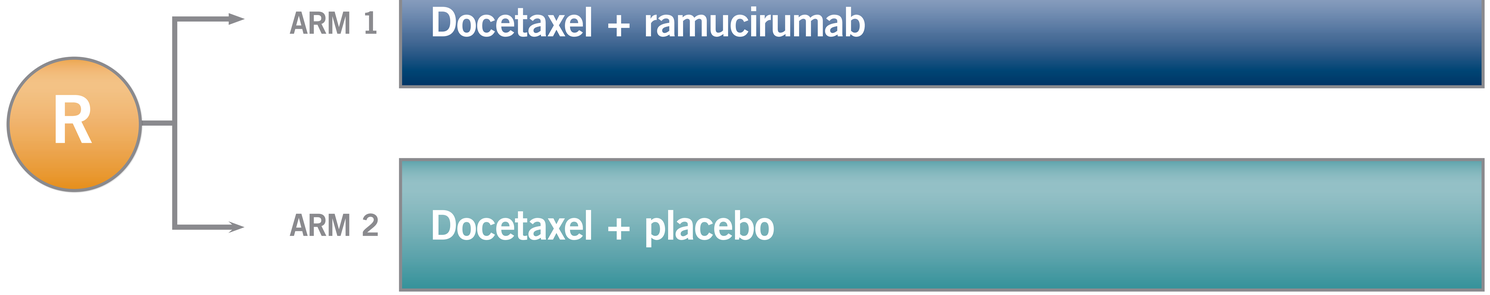
NCT01168973

A Phase III randomized trial of docetaxel and ramucirumab versus docetaxel and placebo for Stage IV NSCLC with disease progression after 1 prior platinum-based therapy

- Estimated primary completion: April 2015 (Target N = 1,242)
- Eligibility: Stage IV NSCLC with disease progression during or after 1 prior first-line platinum-based chemotherapy with or without maintenance therapy; prior bevacizumab as first-line and/or maintenance therapy allowed; ECOG PS 0-1



Study Director: Eli Lilly and Company
ClinicalTrials.gov Identifier: NCT01168973

DR GOVINDAN

This is a conceptually interesting question evaluating chemotherapy with or without the anti-VEGF antibody ramucirumab as second-line therapy. Many of our patients do not qualify for this study because their tumors are close to blood vessels or because of other complications. I believe that this is an important question to ask, but I doubt that such studies will be positive unless we can find a biomarker to identify patients who are likely to respond to this class of drugs. Nonetheless, this study is open at our center and we have enrolled patients on the trial.

DR SOCINSKI

Ramucirumab is a monoclonal antibody to the VEGF-2 receptor and has a different mechanism of action than bevacizumab, which binds VEGF ligands. Bevacizumab demonstrated improved survival with chemotherapy in the first-line setting but not in the second line in the BeTa trial of erlotinib with or without bevacizumab. As much as I would like to see this trial of docetaxel with or without ramucirumab produce positive results, I am less optimistic, but I would have no reservation about enrolling a patient.