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Top-line results from SUNRISE: A phase III, randomized, double-blind, placebo-controlled multicenter trial of bavituximab plus docetaxel in patients with previously treated stage IIIb/iv non-squamous non-small cell lung cancer

[D.R. Spigel](#) [I. Bondarenko](#) [G. Losonczy](#) [J. Mezger](#) [H. Kalofonos](#) [M. Reck](#) [R. Palmero](#) [T. Jang](#) [R. Natale](#) [R.E. Sanborn](#)

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Background: Exposed phosphatidylserine (PS) in the tumor microenvironment is highly immunosuppressive. Bavituximab targets PS in the presence of β 2GP1 as a high affinity complex and repolarizes myeloid derived suppressor cells and M2 macrophages to M1, resulting in production of pro-inflammatory cytokines such as IFN γ and IL-12, maturation of dendritic cells and induction of tumor specific cytotoxic T lymphocyte immunity. In a prior double-blind Phase II trial in 2nd line non-squamous NSCLC, bavituximab 3 mg/kg plus docetaxel was well-tolerated and demonstrated 60% improvement (11.7 vs 7.3 month) in median overall survival (OS) compared to control.

Methods: We accrued 597 patients with Stage IIIb/IV non-squamous NSCLC who progressed on platinum-doublet chemotherapy in a 1:1 ratio to receive up to six 21-day cycles...

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