

Update on Overall Survival in COLUMBUS: A Randomized Phase 3 Trial of Encorafenib (ENCO) Plus Binimetinib (BINI) vs Vemurafenib (VEM) or ENCO in Patients With BRAF V600-Mutant Melanoma


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Background

In Part 1 of the COLUMBUS trial, 577 patients with advanced/metastatic BRAF V600-mutant melanoma were randomized to receive ENCO 300 mg QD or 450 mg QD or BINI 45 mg QD, or VEM 960 mg BID. Median overall survival (OS) in Part 1 of COLUMBUS was 16.3 months for ENCO, 17.5 months for BINI, and 11.0 months for VEM. Discontinuations due to adverse events occurred in 10% of patients in the ENCO arm, in 49% for BINI, and in 44% for VEM.

Methods

This Phase 3 extension trial, COLUMBUS, enrolled an additional 300 patients with advanced/metastatic melanoma from 162 sites in 28 countries. The primary end point was OS in all patients. Secondary end points were progression-free survival (PFS), objective response rate (ORR), and tolerability. This analysis included 360 patients evaluable for OS and PFS who had received ENCO 450 mg QD (141), ENCO 300 mg QD (102), or VEM 960 mg BID (117) on a continual basis.