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ABSTRACTS

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Randomized Phase 3 Study of Panitumumab With FOLFOX4 Compared to FOLFOX4 Alone as 1st-line Treatment (tx) for Metastatic Colorectal Cancer (mCRC): The PRIME Trial

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Background: Panitumumab (pmab) is a fully human anti-epidermal growth factor receptor monoclonal antibody approved as monotherapy for patients (pts) with mCRC. The PRIME trial was designed to evaluate the efficacy and safety of pmab with FOLFOX4 vs. FOLFOX4 alone as first-line treatment for mCRC according to tumor *KRAS* mutational status.

Methods: This was a randomized, multicenter, phase 3 study. Pts were randomized 1:1 to receive pmab 6.0 mg/kg Q2W+FOLFOX (Arm 1) vs. FOLFOX alone (Arm 2). Pts had metastatic adenocarcinoma of the colon or rectum; no previous chemotherapy for mCRC; no previous oxaliplatin therapy; ECOG 0-2; and available tumor tissue for biomarker testing. Randomization was stratified by ECOG 0-1 vs. 2 and region (Western EU, Canada, and Australia vs. rest of world). The primary end point was progression-free survival (PFS). Originally designed to compare the tx effect in the all-randomized population, the study was formally amended to focus on hypothesis testing in the wild-type (WT) *KRAS* subset. *KRAS* status was determined by a blinded central laboratory using allele-specific PCR after the completion of accrual, but prior to the primary analysis.

Results: From August 2006 to February 2008, a total of 1,183 pts were randomized, signed informed consent, and received tx: 593 Arm 1, 590 Arm 2. Overall demographics included 63% men, median age 62 years (range: 24-85); 55% ECOG 0; 40% ECOG 1; 5% ECOG 2. 1096/1183 pts (93%) had available

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tumor sample results for *KRAS*: 656 (60%) WT, 440 (40%) mutant. Preliminarily, across both arms, the most common grade 3 or 4 adverse events were: neutropenia (40%), diarrhea (14%), rash (8%), paresthesia (7%), and hypokalemia (7%).

Conclusions: Efficacy and safety data will be presented by *KRAS* status and treatment arm.