Finalresultsfromstudy 181: Randomizedphase III studyof FOLFIRI withorwithoutpanitumumab (pmab) forthetreatmentofsecond-linemetastaticcolorectalcancer (mCRC).

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AbstractDisclosures

Abstract

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Background: Intheprimaryanalysisofstudy 181, pmab+FOLFIRIsignificantlyimprovedprogression-freesurvival (PFS) vs FOLFIRI assecond-linetherapyinpatients (pts) withwild-type (WT) *KRAS* mCRC. Here, wereporttheresultsof a prespecifiedfinaldescriptiveanalysisplannedfor 30 months (mos) afterthelastptwasenrolled.

Methods: Ptswererandomised 1:1 topmab 6.0 mg/kg Q2W+FOLFIRI (Arm 1) vs FOLFIRI alone (Arm 2). Ptshadonepriorfluoropyrimidine-basedchemotherapyregimenformCRCand ECOG 0-2. Theco-primaryendpointswere PFS (centralassessment) and OS, andwereindependentlytested. Secondaryendpointsincludedobjectiveresponserate (ORR), andsafety. *KRAS* statuswasdeterminedby a blindedcentrallab.

Results: 1,186 ptswererandomisedandreceivedtreatment (tx): 591 inArm 1, 595 InArm 2. 1,083/1,186 pts (91%) had *KRAS* results. Adverseeventrateswereconsistentwiththeprimaryanalysis. Resultsareshowninthetable.

Conclusions: InArm 1, PFS (standardandon-treatmentdefinition) and ORR wereimproved, andtherewas a trendtowardimproved OS inptswith WT *KRAS* mCRC. Thelargeproportionofptsreceivingpost-progressionanti-EGFR therapymayhaveaffectedtheabilitytoobserve a differencein OS betweenthetxarms. Inptswith
MT *KRAS* therewasnodifferenceinefficacy. *KRAS* testingiscriticaltoselectappropriateptsfortxwithpmab.

WT *KRAS* mCRC (n = 597)	Arm 1 (n = 303)	Arm 2 (n = 294)	HR (95%CI)	p value[a]
Median PFS - mos (95% CI)	6.7 (5.8-7.4)	4.9 (3.8-5.5)	0.82 (0.69-0.97)	0.023
			0.73* (0.60-0.88)	0.001*
Median OS - mos (95% CI)	14.5 (13.0-16.1)	12.5 (11.2-14.2)	0.92 (0.78-1.10)	0.366
ORR[b] - % (95%CI)	36 (31-42)	10 (7-14)		

Oddsratio (95%CI)	5.50 (3.32-8.87)			< 0.0001
MT *KRAS* mCRC (n = 486)	Arm 1 (n = 238)	Arm 2 (n = 248)		
Median PFS - mos (95% CI)	5.3 (4.2-5.7)	5.4 (4.0-5.6)	0.95 (0.78-1.14)	0.561
Median OS - mos (95% CI)	11.8 (10.4-13.3)	11.1 (10.3-12.4)	0.93 (0.77-1.13)	0.482
ORR[b] - % (95% CI)	13 (9-18)	15 (11-20)		
Oddsratio (95% CI)	0.93 (0.53-1.63)			0.885
Ptsreceivingpost-studyanti-EGFR tx – n (%)	Arm 1	Arm 2		
WT *KRAS*	38 (12.5)	101 (34.4)		
MT *KRAS*	21 (8.8)	79 (31.9)		

* Ontreatment; [a]Descriptive; [b]Ptswithbaselinemeasurablediseasepermodified RECIST.