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Resultsof a phase III, randomized, double-blind, placebo-controlledtrialofpegfilgrastim (PEG) inpatients (pts) receivingfirst-line FOLFOX or FOLFIRI andbevacizumab (B) forcolorectalcancer (CRC).

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AbstractDisclosures

Abstract

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Background: Theliteraturereportsthataddingbiologicstochemotherapy (ctx) mayincreasetheincidenceofclinicallysignificantneutropenia. histrialwasconductedtoevaluatetheefficacyof PEG inreducingtheincidenceoffebrileneutropenia (FN) inptswithlocally-advanced (LA) ormetastatic (m)CRC receivingfirst-linetreatmentwitheither FOLFOX/B or FOLFIRI/B. **Methods:** Keyeligibility: ≥ 18 yearsold; measurable, nonresectable CRC per RECIST 1.1. Ptswererandomlyassigned 1:1 toeitherplaceboor 6 mg PEG ~24 h afterctx/B. Thestudytreatmentperiodincludedfour Q2W cycles, butptscouldcontinuetheirassignedregimenuntilprogression. Ptswerestratifiedbyregion (NorthAmericavsrestofworld), stage (LA vsmCRC), andctx (FOLFOX vs FOLFIRI). Estimatedsamplesize (N = 800) wasbasedontheexpectedincidenceofgrade 3/4 FN (primaryendpoint) acrossthefirst 4 cyclesofctx/B, poweredfor PEG superiorityoverplacebo. Otherendpointsincludedoverallresponserate (ORR), progression-freesurvival (PFS), andoverallsurvival (OS). **Results:** 845 ptswererandomized (Nov 2009 toJan 2012) andreceivedstudytreatment; 783 ptscompleted 4 cyclesofctx/B. Medianagewas 61 years; 512 (61%) ptsweremale; 819 (97%) hadmCRC; 414 (49%) received FOLFOX, and 431 (51%) received FOLFIRI. Grade 3/4 FN (first 4 cycles) forplacebovs PEG was 5.7% vs 2.4%; OR 0.41; p = 0.014. A similarincidenceofother ≥ grade 3 adverseeventswasseeninbotharms (28% placebo; 27% PEG). Seetableforadditionalresults. **Conclusions:**PEGsignificantlyreducedtheincidenceofgrade 3/4 FN inthisptpopulationreceivingstandardctx/B for CRC. Follow-upisongoing. Clinicaltrialinformation: NCT00911170.

	Placebo (n=423)	PEG (n=422)	Placebovs PEG
Grade 3/4 FN (95% CI)	5.7% (3.7, 8.3)	2.4% (1.1, 4.3)	Diff = -3.3% (-6.6, 0.0) OR=0.41 (0.19, 0.86) p=0.014
ORR* (95% CI)	238/420†; 56.7% (51.8, 61.5)	244/420†; 58.1% (53.2, 62.0)	Diff = 1.4% (-6.5, 9.3) OR = 1.06 (0.81, 1.39) p=0.683
Median PFS* (95% CI), mo	10.1 (9.3, 11.1)	9.7 (9.2, 10.8)	HR = 1.05 (0.88, 1.26) p=0.552
Median OS* (95% CI), mo	24.6 (21.3, NR)	21.8 (18.5, 25.6)	HR = 1.05 (0.81, 1.36) p=0.704

*Immaturedata. †Measurabledisease.