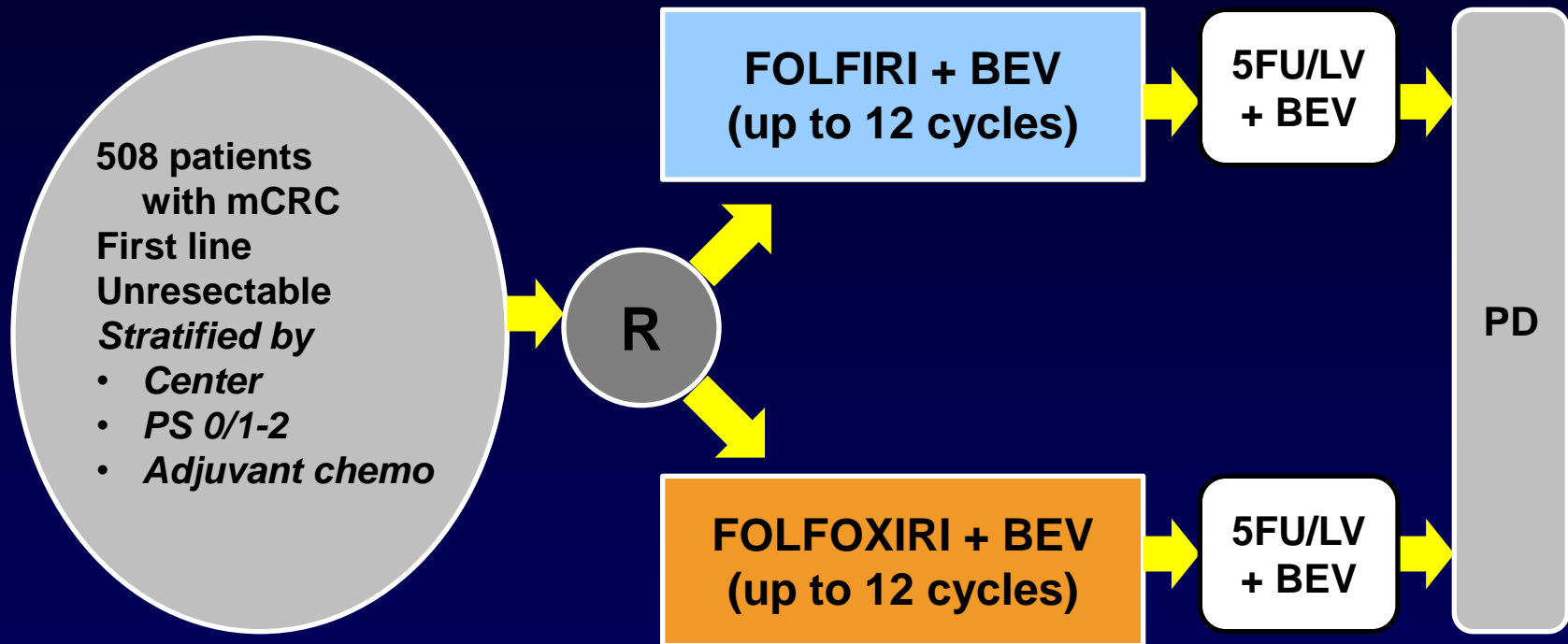


# **FOLFOXIRI Plus Bevacizumab (BEV) Versus FOLFIRI Plus BEV as First-Line Treatment of mCRC: Updated Survival Results of the Phase III TRIBE Trial by the GONO Group**

## **Abstract 657**

**Cremolini C, Loupakis F, Masi G, Zagonel V, Bergamo F, Salvatore L, Cortesi E, Tomasello G, Ronzoni M, Pinta F, Zaniboni A, Tonini G, Buonadonna A, Amoroso D, Sonaglio C, De Stefano A, Boni C, Allegrini G, Boni L, Falcone A**

# TRIBE Study Design



**Primary endpoint: Progression-free survival (PFS)**

**Participating centers: 34 Italian oncology units**

**First patient in: July 2008**

**Last patient in: May 2011**

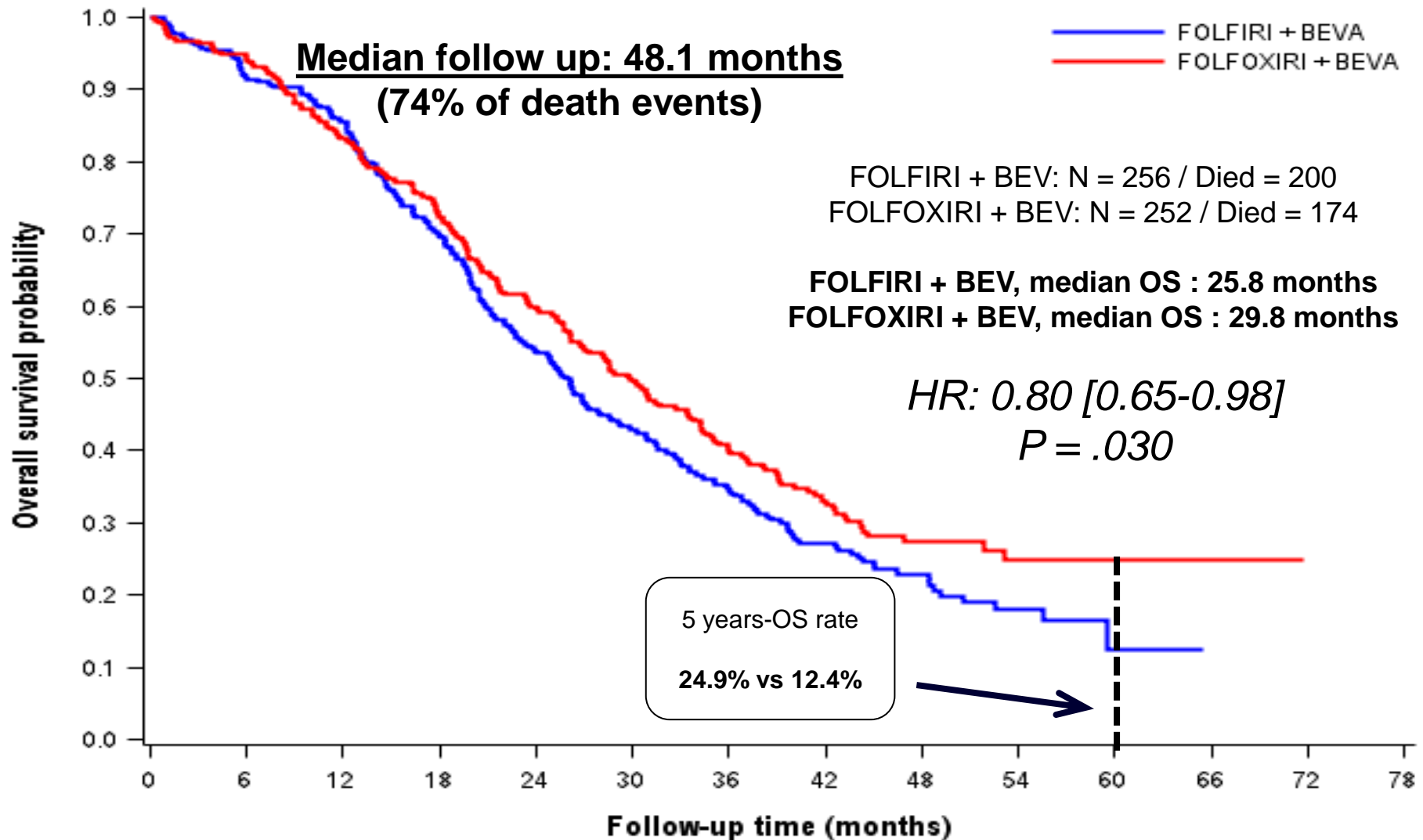
5FU/LV, fluorouracil/leucovorin; PD, progressive disease

# Background

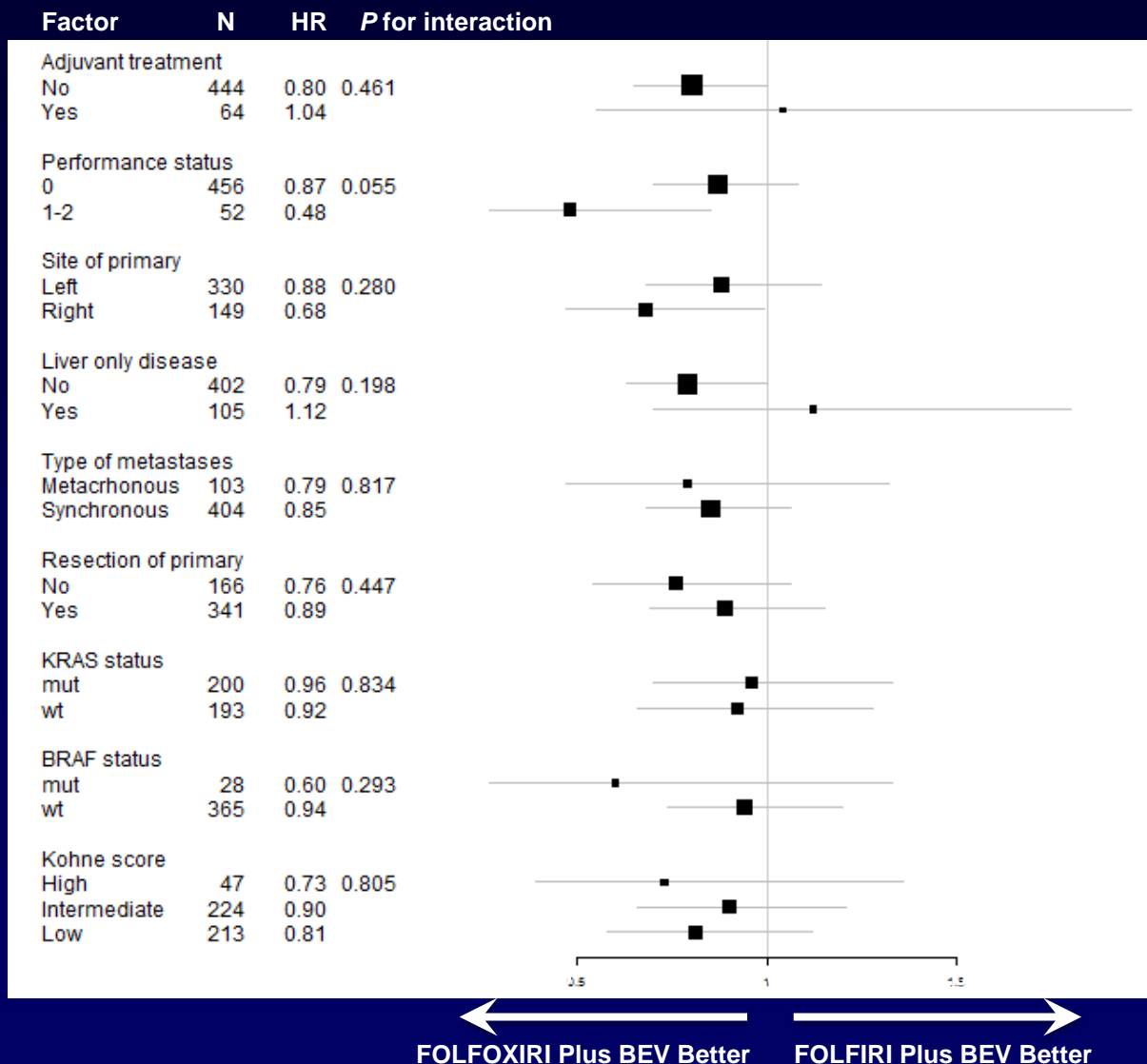
**Phase III TRIBE trial met its primary endpoint PFS. FOLFOXIRI plus bev, as compared to FOLFIRI plus bev**

- **Improved Progression Free Survival (HR: 0.75,  $P = .003$ )**
- **Increased the RECIST Response Rate (65% vs 53%,  $P = .006$ )**
- **Increased the incidence of specific G3/4 adverse events (diarrhea, mucositis, neuropathy, neutropenia), but not of febrile neutropenia, serious adverse events and treatment-related deaths**
- **At the preliminary OS analysis (56% of death events), prolonged Overall Survival with a trend toward significance (HR: 0.79,  $P = .054$ ) becoming significant at the adjusted analysis (HR: 0.72,  $P = .010$ )**

# Updated Overall Survival (OS) Results



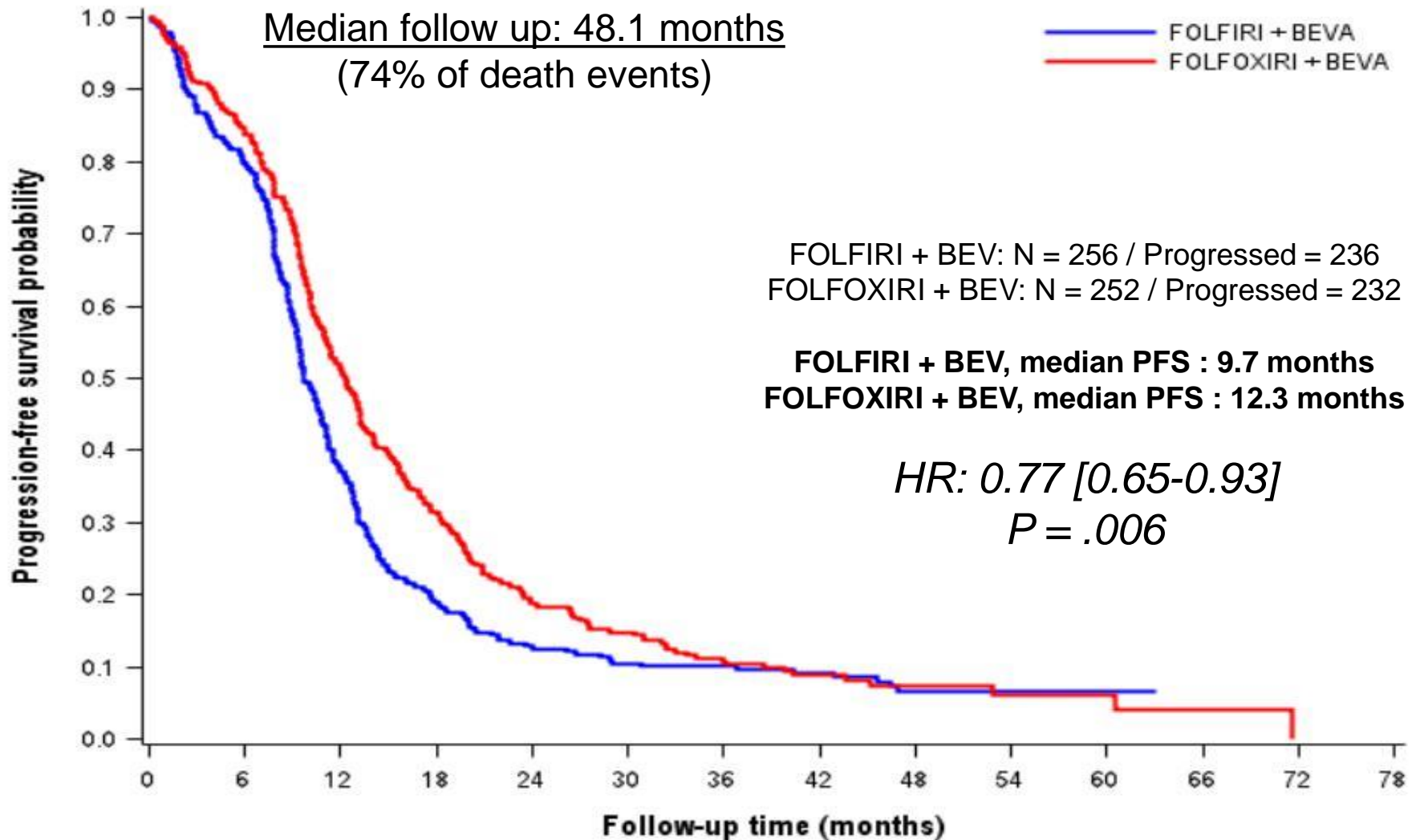
# Subgroup Analyses: OS



# Second-Line Treatments

	FOLFIRI + BEV Arm A	FOLFOXIRI + BEV Arm B
Potential candidates to second line	88.7% (227/256)	86.9% (219/252)
Any second-line therapy	79.3% (180/227)	80.4% (176/219)
Second-line agents	N = 180	N = 176
Fluoropyrimidine, %	93%	81%
Oxaliplatin, %	63%	26%
Irinotecan, %	32%	63%
Bevacizumab, %	31%	32%
Anti-EGFR mAB, %	15%	29%
Third-line anti-EGFR mAB, %	21%	13%

# Updated PFS Results



# Conclusions

- ✓ Updated results of the TRIBE study demonstrate that first-line induction FOLFOXIRI plus BEV as compared to FOLFIRI plus BEV significantly improves OS of molecularly unselected mCRC patients (median OS 29.8 vs 25.8 months, HR: 0.80,  $P = .030$ )
- ✓ The advantage in survival increases over time with an estimated 5-year OS rate of 24.9% vs 12.5%
- ✓ The significant effect on PFS is confirmed (HR: 0.77,  $P = .006$ ) with a median PFS of 12.3 vs 9.7 months

**Based on these results FOLFOXIRI plus BEV represents a new valuable option for the upfront treatment of unresectable mCRC patients.**