Article details

Title of article
Olaparib with or without bevacizumab or bevacizumab and 5-fluorouracil in advanced colorectal cancer: Phase III LYNK-003

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Trial registration number
NCT04456699

Primary objectives/rationale

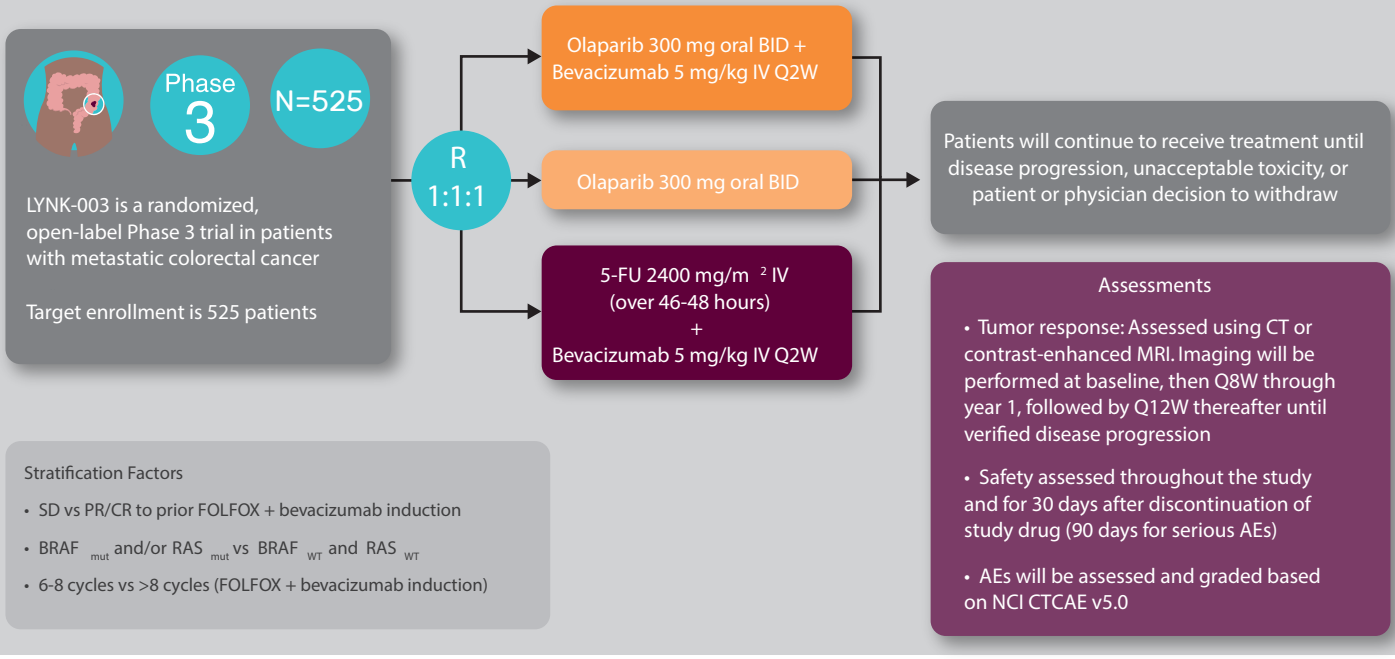
Primary objective
Compare PFS with olaparib alone or olaparib plus bevacizumab versus bevacizumab plus 5-FU in patients with unresectable or metastatic CRC that has not progressed on first-line FOLFOX plus bevacizumab. PFS will be assessed per RECIST v1.1 by BICR

Secondary objectives
- Evaluation of OS, ORR, and DOR per RECIST v1.1 by BICR
- Safety of olaparib alone and olaparib plus bevacizumab

Key eligibility criteria

- Aged 18 years
- Histologically confirmed metastatic or unresectable (stage IV) CRC
- ECOG performance status of 0 or 1
- Adequate organ function
- Patients must not have progressed after a first-line induction course of ≥6 cycles of FOLFOX (folinic acid, 5-FU, oxaliplatin) plus bevacizumab
- Patients must have experienced toxicity with oxaliplatin, which in the opinion of the treating physician warranted treatment discontinuation

Study design and treatment, including planned sample size, planned study period, and study procedures



Outcome measures/end points

Primary end points
PFS per RECIST v1.1 by BICR. The study will meet its primary objective if either olaparib alone or olaparib plus bevacizumab provides longer PFS vs bevacizumab plus 5-FU

Secondary end points
OS, ORR, and DOR per RECIST v1.1 by BICR; safety

Exploratory end points
Include PFS2 by investigator assessment; HRQoL using the EORTC QLQ-C30, EORTC QLQ-C29, and EQ-5D-5L instruments; molecular biomarkers and pharmacokinetics of olaparib alone and olaparib plus bevacizumab

Glossary
5-FU, 5-fluorouracil; AE, adverse event; BICR, blinded independent central review; BID, twice daily; CR, complete response; CRC, colorectal cancer; CT, computed tomography; CTCAE, Common Terminology Criteria for Adverse Events; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; FOLFOX, folinic acid, 5-FU, and oxaliplatin; HRQoL, health-related quality of life; IV, intravenous; MRI, magnetic resonance imaging; NCI, National Cancer Institute; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PFS2, time from randomization to second documented disease progression or death due to any cause, whichever occurs first; PO, orally; PR, partial response; Q2W, every 2 weeks; Q8W, every 8 weeks; Q12W, every 12 weeks; R, randomization; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; SD, stable disease.