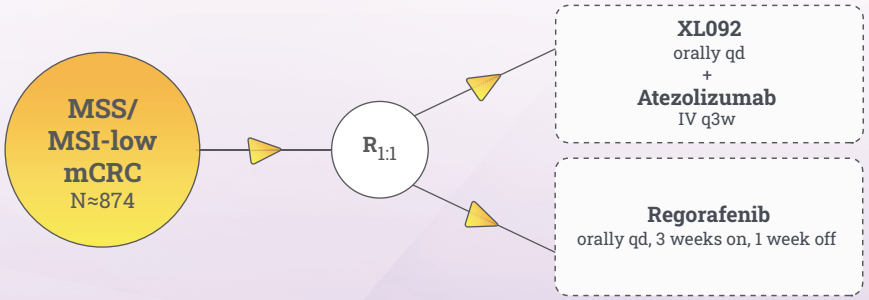
STELLAR 303

PHASE • 3

Phase 3 Study of XL092 With Atezolizumab vs Regorafenib in Metastatic CRC

THE COMBINATION OF XL092 AND ATEZOLIZUMAB
IS NOT APPROVED FOR THE USE UNDER INVESTIGATION IN THIS TRIAL.
SAFETY AND EFFICACY HAVE NOT BEEN ESTABLISHED.

A Randomized Open-Label Phase 3 Study of XL092 + Atezolizumab vs Regorafenib in Subjects With Metastatic Colorectal Cancer



Study Overview

Approximately 874 eligible patients with MSS/MSI-low mCRC who have progressed during or after, or are intolerant to, SOC therapy will be randomly assigned to XL092 in combination with atezolizumab or regorafenib monotherapy to evaluate the activity of the combination therapy on duration of OS vs regorafenib monotherapy. Primary analysis is non-liver metastases (NLM) patients. Approximately 350 NLM patients will be enrolled, while enrollment of patients with liver metastases will be capped at approximately 524.

Investigational Treatment

Eligible patients will be randomly assigned in a 1:1 ratio to the following treatment arms:

- **Experimental arm:** oral XL092 qd + atezolizumab infusion q3w
- **Control arm:** oral regorafenib qd, 3 weeks on, 1 week off

Key Eligibility Criteria

- MSS/MSI-low metastatic colorectal adenocarcinoma with measurable disease
- Known RAS status
- Progressed, refractory, or intolerant to all of the following SOC regimens for mCRC:
  - Fluoropyrimidine, irinotecan, and oxaliplatin, ± anti-VEGF mAb
  - Anti-EGFR mAb for RAS^{WT}
  - BRAF inhibitor for known BRAF V600E mutations
- Progression ≤4 months following the last dose of SOC regimen
- No prior treatment with XL092, regorafenib, trifluridine/tipiracil, or PD-L1/PD-1–targeting ICIs

Key Endpoints

Primary Endpoint

- OS in NLM patients

Secondary Endpoints

- OS in all patients
- PFS by investigator
- ORR by investigator
- DOR by investigator

Exploratory Endpoint

- HRQoL by EORTC QLQ-C30/ QLQ-CR29 and EQ-5D-5L

Participating Regions

Approximately 140 sites globally in

- North America
- Europe
- Asia Pacific

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To learn more about this trial, visit clinicaltrials.gov and search for **NCT05425940** or contact Exelixis Medical Information at **1-888-EXELIXIS** (1-888-393-5494), 1-303-389-1847, or **medinfo@exelixis.com**.

CRC, colorectal cancer; **DOR,** duration of response; **EGFR,** epidermal growth factor receptor; **EORTC QLQ-C30/QLQ-CR29,** European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30/Colorectal 29; **EQ-5D-5L,** EuroQoL health questionnaire instrument; **HRQoL,** health-related quality of life; **ICI,** immune checkpoint inhibitor; **IV,** intravenous; **mAb,** monoclonal antibody; **mCRC,** metastatic colorectal cancer; **MSI-low,** microsatellite instability–low; **MSS,** microsatellite stable; **ORR,** objective response rate; **OS,** overall survival; **PD-1,** programmed death receptor-1; **PD-L1,** programmed death receptor-1 ligand; **PFS,** progression-free survival; **q3w,** once every 3 weeks; **qd,** once daily; **SOC,** standard of care; **VEGF,** vascular endothelial growth factor; **WT,** wild-type.

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