STELLAR 303

An International, Randomized, Open-Label Phase 3 Study of XL092 + Atezolizumab vs Regorafenib in Metastatic Colorectal Cancer

STELLAR 303 SUMMARY[1]

XL092
An oral tyrosine kinase inhibitor

Atezolizumab
An anti PD-L1 monoclonal antibody[2]

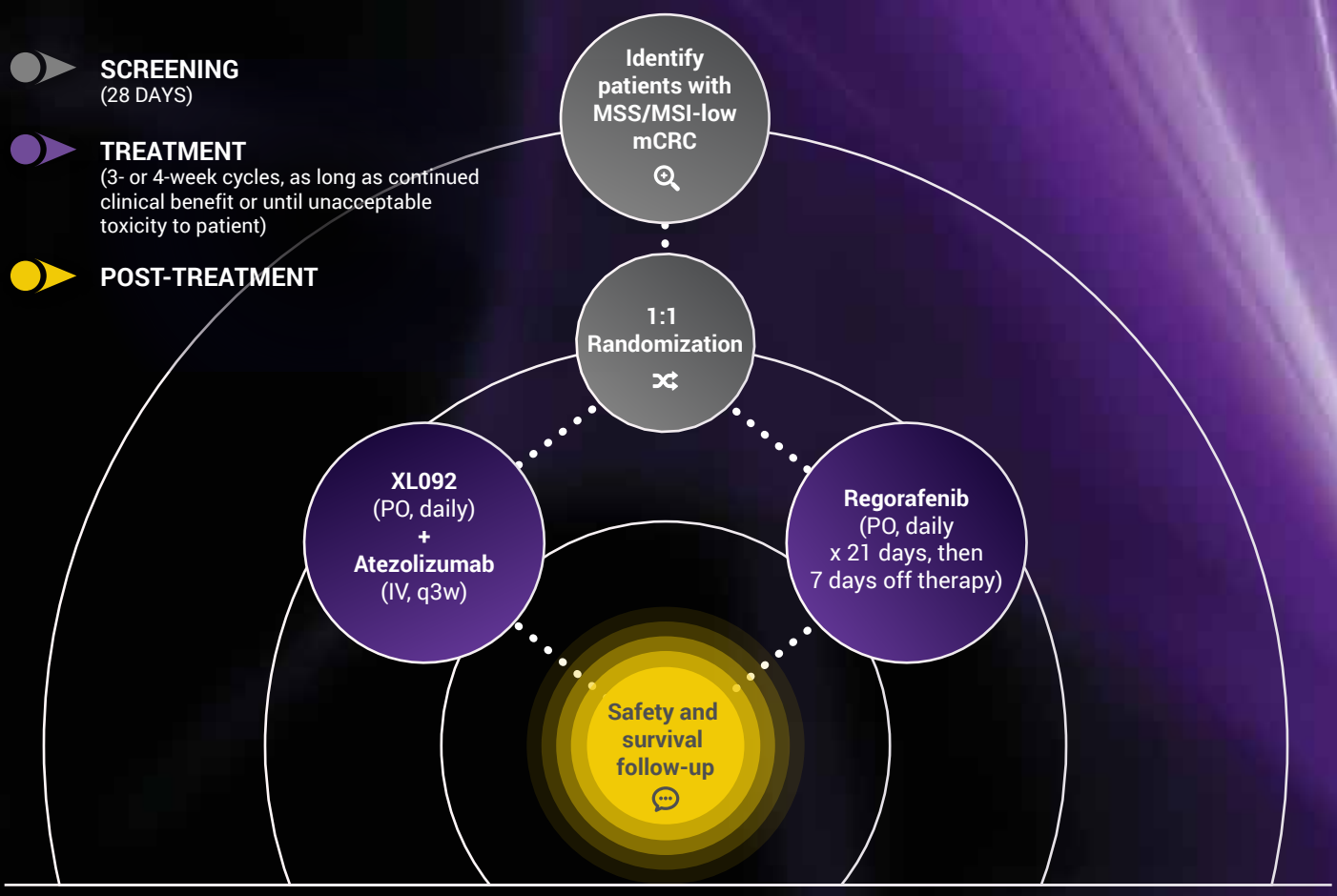
140 sites globally
(North America, Europe, Asia Pacific)

~874 patients
MSS/MSI-low
~350 patients with NLM
~524 patients with liver metastases

Primary endpoint
OS in patients with NLM

Primary objective
Evaluate the efficacy of XL092 + atezolizumab vs regorafenib in patients with MSS/MSI-low metastatic colorectal cancer, with NLM, who have progressed after or are intolerant to SOC therapy

TRIAL AT-A-GLANCE[1]



KEY ELIGIBILITY CRITERIA[1]

- MSS/MSI-low metastatic colorectal adenocarcinoma, measurable by RECIST 1.1
- Refractory, intolerant, or progressed (≤4 months after last dose) on the following SOC regimens:
  - Fluoropyrimidine, irinotecan and oxaliplatin, +/- anti-VEGF mAb
  - Anti-EGFR mAb for RAS WT
  - BRAF inhibitor for known BRAF V600E mutations
- Known RAS status (MT or WT)
- No prior treatment with XL092, regorafenib, trifluridine/tipiracil, or anti-PD-L1/PD-1 checkpoint inhibitors

For more information about this trial, go to clinicaltrials.gov and search for NCT05425940, or contact Exelixis Medical Information at medinfo@exelixis.com.

References:

1. Exelixis Inc, Data on File
2. Tecentriq Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/tecentriq-epar-product-information_en.pdf. Last accessed March 2023.

Abbreviations: EGFR, epidermal growth factor receptor; IV, intravenous; mAb, monoclonal antibody; mCRC, metastatic colorectal cancer; MSI, microsatellite instability; MSS, microsatellite stable; MT, mutant; NLM, non-liver metastases; OS, overall survival; PD-1, programmed cell death protein-1; PD-L1, programmed cell death protein ligand-1; PO, oral; RECIST 1.1, Response Evaluation Criteria in Solid Tumors version 1.1; SOC, standard of care; VEGF, vascular endothelial growth factor; WT, wildtype

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