STELLAR 305

An International, Randomized, Double-Blind Phase 2/3 Study of Zanzalintinib (XL092) + Pembrolizumab vs Pembrolizumab as First-Line Treatment in PD-L1–Positive Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma

STELLAR 305 SUMMARY[1]

Zanzalintinib
An oral tyrosine kinase inhibitor

Pembrolizumab
An anti–PD-1 monoclonal antibody[2]

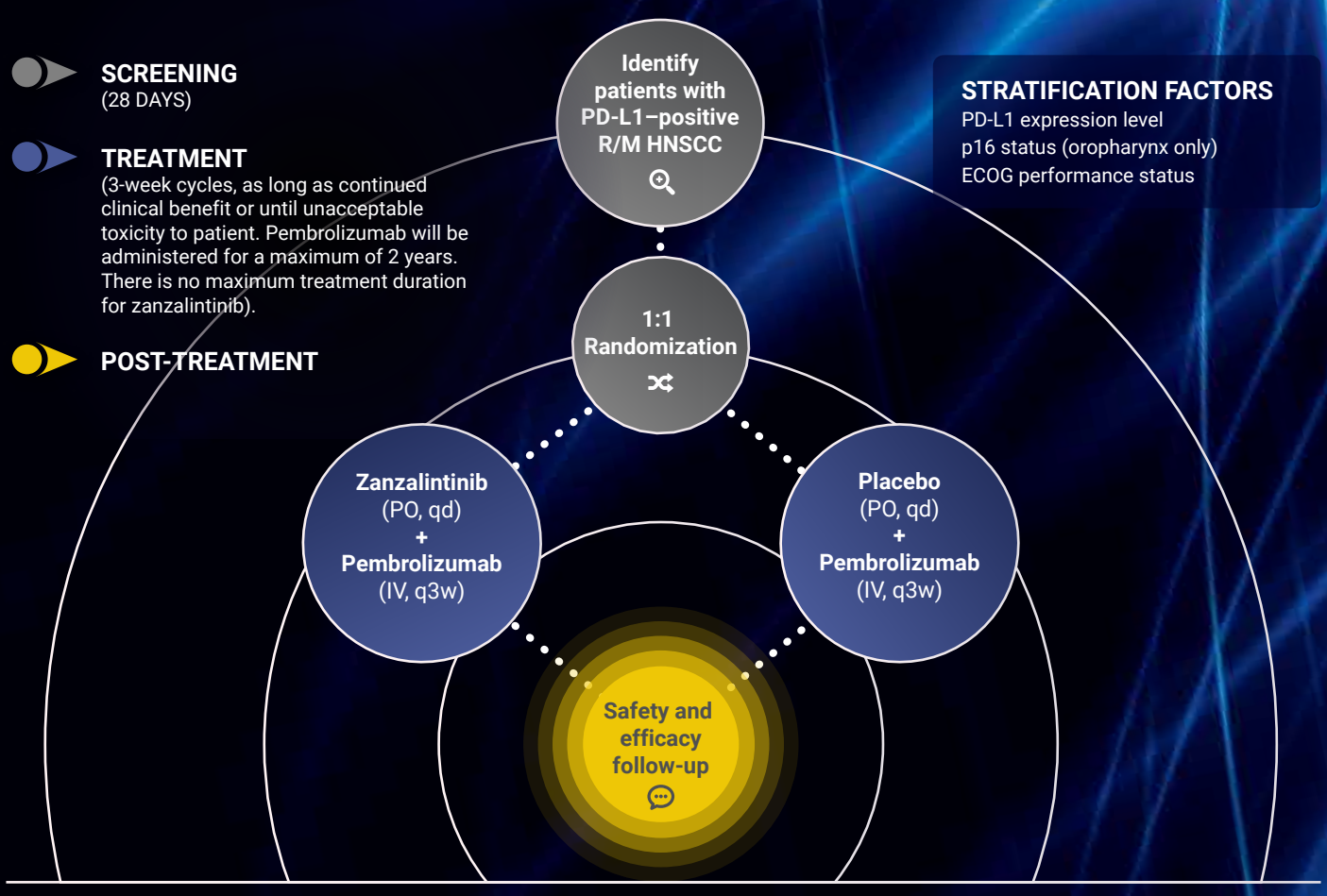
~500 patients
PD-L1–positive R/M HNSCC
~250 patients in Phase 2
~250 patients in Phase 3

~200 sites globally
(North America, South America, Europe, Asia Pacific)

Multiple primary endpoints
PFS by BICR
OS

Primary objective
Assess the efficacy of zanzalintinib + pembrolizumab vs pembrolizumab + placebo in patients with PD-L1–positive R/M HNSCC

TRIAL AT-A-GLANCE[1]



KEY ELIGIBILITY CRITERIA[1]

- R/M HNSCC of the oropharynx, oral cavity, hypopharynx, and larynx incurable by local therapy; nasopharynx not allowed
- Measurable disease according to RECIST 1.1
- No prior systemic therapy for R/M HNSCC
  - Systemic therapy given as part of multimodal treatment for locally advanced disease allowed if completed >6 months prior to randomization
- PD-L1 CPS ≥1
- No prior therapy with any anti–PD-1/PD-L1/PD-L2 agent, or an agent directed to another stimulatory or co-inhibitory T-cell receptor
- No prior treatment with zanzalintinib

For more information about this trial, go to clinicaltrials.gov and search for NCT06082167, or contact Exelixis Medical Information at medinfo@exelixis.com.

References:

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

Abbreviations: BICR, blinded independent central review; CPS, combined positive score; ECOG, Eastern Cooperative Oncology Group; HNSCC, head and neck squamous cell carcinoma; IV, intravenous; OS, overall survival; PD-1, programmed cell death protein-1; PD-L1, programmed cell death protein ligand-1; PD-L2, programmed cell death protein ligand-2; PFS, progression-free survival; PO, oral; q3w, once every 3 weeks; qd, once daily; RECIST 1.1, Response Evaluation Criteria in Solid Tumors version 1.1; R/M, recurrent or metastatic

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

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