STELLAR 304

An International, Randomized Phase 3 Study of XL092 + Nivolumab vs Sunitinib in Advanced or Metastatic Non-Clear Cell Renal Cell Carcinoma

STELLAR 304 SUMMARY[1]

XL092
An oral tyrosine kinase inhibitor

Nivolumab
An anti PD-1 monoclonal antibody[2]

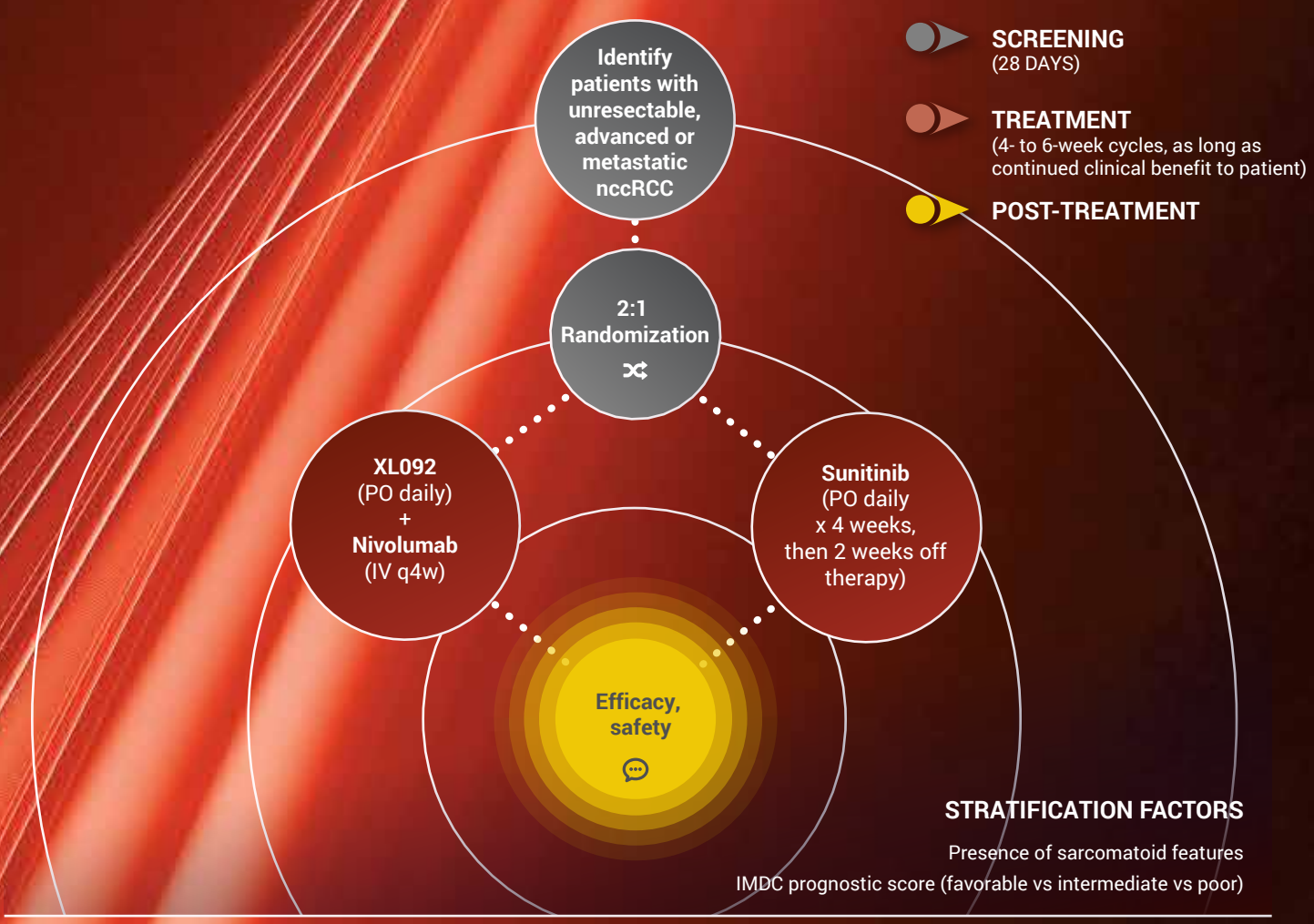
~291 patients
(papillary, unclassified, and translocation-associated nccRCC)

170 sites globally
(North America, South America, Europe, Asia Pacific)

Primary endpoints
PFS and ORR by BICR

Primary objective
Determine the efficacy of XL092 plus nivolumab vs sunitinib monotherapy in patients with unresectable, locally advanced, or metastatic nccRCC

TRIAL AT-A-GLANCE[1]



KEY ELIGIBILITY CRITERIA[1]

- Histologically confirmed nccRCC (including papillary, unclassified, and translocation-associated subtypes) that is unresectable, locally advanced, or metastatic. Among the eligible histologic subtypes, sarcomatoid features are allowed.
- Measurable disease according to RECIST 1.1
- No prior systemic anticancer therapy for unresectable, locally advanced, or metastatic nccRCC
  - One prior systemic adjuvant therapy (excluding sunitinib) allowed for completely resected RCC and if recurrence occurred ≥6 months after the last dose of adjuvant therapy

For more information about this trial, go to clinicaltrials.gov and search for NCT05678673, or contact Exelixis Medical Information at medinfo@exelixis.com.

References:

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

Abbreviations: BICR, blinded independent central review; IMDC, International Metastatic RCC Database Consortium; IV, intravenous; nccRCC, non-clear cell renal cell carcinoma; ORR, objective response rate; PD-1, programmed cell death protein-1; PD-L1, programmed cell death protein ligand-1 PFS, progression-free survival; PO, oral; q4w, once every 4 weeks; RECIST 1.1, Response Evaluation Criteria in Solid Tumors version 1.1

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