

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 SUMMARY¹

XL092

An oral tyrosine kinase inhibitor

Nivolumab

An anti PD-1 monoclonal antibody²

~291 patients

(papillary, unclassified, and translocation-associated nccRCC)

Primary objective

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

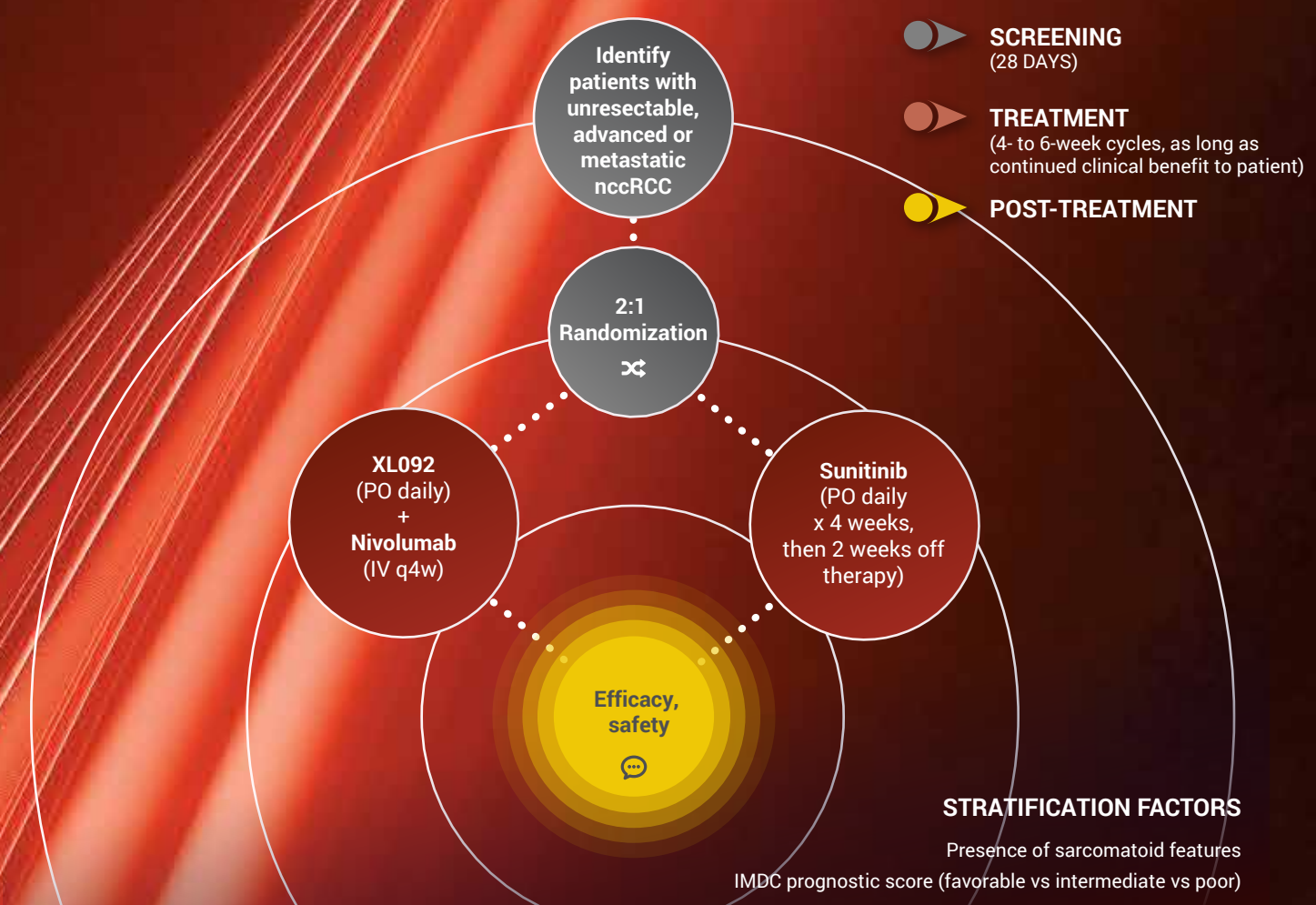
170 sites globally

(North America, South America, Europe, Asia Pacific)

Primary endpoints

PFS and ORR by BICR

TRIAL AT-A-GLANCE¹



KEY ELIGIBILITY CRITERIA¹

- ▶ 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

i 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.