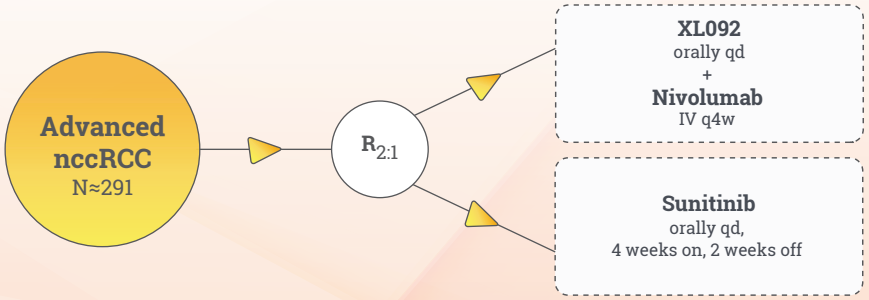
STELLAR 304

PHASE • 3

Phase 3 Study of XL092 With Nivolumab vs Sunitinib in Advanced or Metastatic Non–Clear Cell Renal Cell Carcinoma

THE COMBINATION OF XL092 AND NIVOLUMAB 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 + Nivolumab vs Sunitinib in Subjects With Advanced or Metastatic Non–Clear Cell Renal Cell Carcinoma



Study Overview

Approximately 291 eligible patients with advanced or metastatic nccRCC will be randomly assigned in a 2:1 ratio to XL092 in combination with nivolumab or to sunitinib to evaluate the effect of the combination therapy on PFS and ORR vs sunitinib.

Investigational Treatment

Eligible patients will be randomly assigned in a 2:1 ratio to the following treatment arms:

- **Experimental arm:** oral XL092 qd + nivolumab infusion q4w
- **Control arm:** oral sunitinib qd, 4 weeks on, 2 weeks off

Stratification Factors

- Histology (papillary w/o sarcomatoid features vs other subtypes w/o sarcomatoid features vs any histology with sarcomatoid features)
- IMDC prognostic score (favorable vs intermediate vs poor)

Key Eligibility Criteria

- Unresectable, advanced, or metastatic nccRCC (papillary, unclassified, and translocation subtypes); sarcomatoid features allowed
- Measurable disease
- No prior systemic anticancer therapy for unresectable locally advanced or metastatic nccRCC
  - One prior systemic adjuvant therapy, excluding sunitinib, allowed if recurrence ≥6 months after last dose

Key Endpoints

Multiple Primary Endpoints

- PFS by BIRC
- ORR by BIRC

Secondary Endpoint

- OS

Additional Endpoints

- DOR by BIRC
- PFS, ORR, and DOR by investigator
- PROs accessed by FKSI-19 and EQ-5D-5L

Participating Regions

Approximately 170 sites globally in

- North America
- South America
- Europe
- Asia Pacific

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To learn more about this trial, visit clinicaltrials.gov and search for **NCT05678673** or contact Exelixis Medical Information at **1-888-EXELIXIS** (1-888-393-5494) or **druginfo@exelixis.com**.

BIRC, Blinded Independent Radiology Committee; **DOR,** duration of response; **EQ-5D-5L**, EuroQol health questionnaire instrument; **FKSI,** Functional Assessment of Cancer Therapy-Kidney Symptom Index; **IMDC,** International Metastatic RCC Database Consortium; **IV,** intravenous; **nccRCC,** non–clear cell renal cell carcinoma; **ORR,** objective response rate; **OS,** overall survival; **PFS,** progression-free survival; **PRO,** patient-reported outcomes; **q4w,** once every 4 weeks; **qd,** once daily; **R**, randomization; **vs,** versus; **w/o,** without.

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