2020TIP- SOGUG-NEOWIN: A Phase 2, open-label, multi-centre, multi-national interventional trial evaluating the efficacy and safety of erdafitinib (ERDA) monotherapy and erdafitinib and cetrelimab (CET) as neoadjuvant treatment in cisplatin-ineligible patients with muscle-invasive bladder cancer (MIBC) whose tumours express FGFR gene alterations

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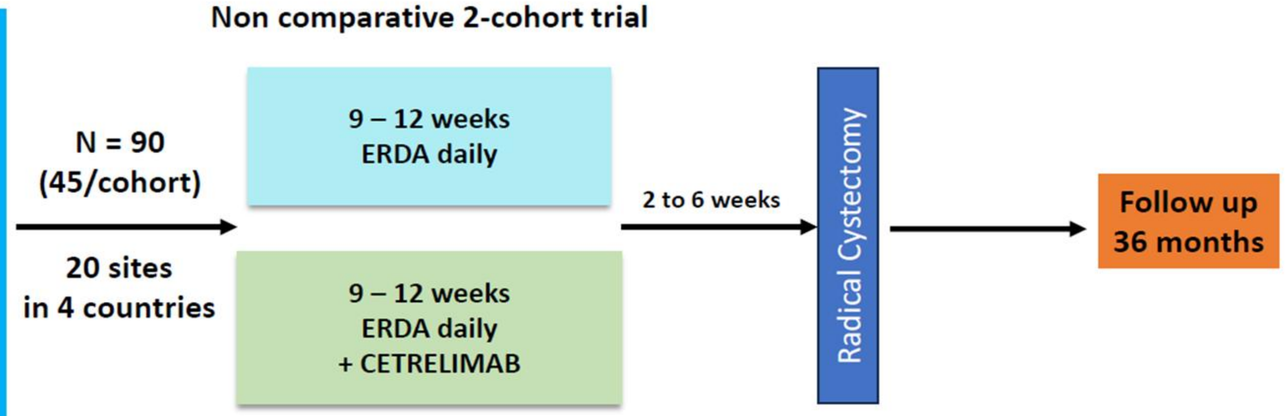
Background

- The standard treatment for nonmetastatic MIBC is neoadjuvant cisplatin-based therapy followed by radical cystectomy (RC).
- Many patients are ineligible for cisplatin.
- Immune checkpoint inhibitors (ICIs) have changed the treatment landscape for metastatic urothelial cancer (mUC), including for cisplatin-ineligible patients. Based on these results, ICIs are being explored as neoadjuvant treatment in resectable UC with preliminary data suggesting antitumor activity.
- ERDA is a Fibroblast Growth Factor Receptor (FGFR) inhibitor, which has shown efficacy in mUC with select FGFR2/3 mutations/fusions.
- ERDA plus CET demonstrated clinically meaningful activity in patients with newly diagnosed FGFR-altered mUC in the phase 2 NORSE trial.
- This study will assess whether ERDA plus CET will improve the pathological complete response (pCR) rate in patients with FGFR+ MIBC who are candidates for RC and are ineligible for or refuse neoadjuvant cisplatin-based therapy.

Study Design

Key criteria
- cT2-T4a N0/N1 M0
- FGFR + by Central Laboratory (Local reports based on validated test can be accepted)
- ECOG 0-1
- Candidate for radical cystectomy
- Ineligible/Refuse Neo-Adj Cisplatin
- No prior anti-FGFR or anti-PD(L)1 systemic therapy



Total Study Duration: 63 months from FPI to LPO
Estimated accrual: 24 months

Co-primary endpoints:
- pCR & Downstaging Rate (<ypT2)

Secondary endpoints:
- Any downstaging rate
- Event-free survival (EFS)
- Overall Survival (OS)
- Objective Response Rate (ORR) according to RECIST v1.1, after neo-adj. treatment
- Safety
- Rate of delay to surgery

Exploratory endpoint:
- Tumor response via PET-MRI
- Quality of Live (QoL)
- Biomarkers of response
- Changes in Biomarkers expression
- Genomic data in plasma, urine and feces

Key eligibility criteria

- ECOG PS 0-1
- Presence of a select FGFR alteration
- Pure or predominant UC histology
- Decline or ineligible for cisplatin-based chemotherapy as defined by one of the following criteria:
  - impaired renal function (GFR<60 mL/min),
  - ≥ grade 2 hearing loss, or
  - ≥ grade 2 peripheral neuropathy;
- Patients are considered fit for cystectomy
- No prior FGFR-targeted or anti PD-(L)1 therapy
- No prior systemic therapy, radiation or surgery (except TURBT or biopsies) for bladder cancer
- Prior BCG was allowed if completed ≥ 6 weeks prior to initiation of study treatment

The trial is approved in 4 countries (France, Italy, Spain and UK). The first patient was enrolled on 6-Jun-2024.

This trial would be the first to systematically address whether ERDA ± CET improves pCR in patients with FGFR-positive MIBC.

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