Background: Up to 36% of triple-negative breast cancer (TNBC) are androgen receptor (AR)-positive (≥10% by immuno-histochemistry, IHC). When these tumours metastasise, several clinical trials assessing antagonists of the AR or androgen synthesis suppressor showed promising clinical benefit rates (CBR). Darolutamide is a novel, effective and well tolerated AR antagonist tested in prostate cancer clinical trials. Thus we aim to assess clinical activity and safety of darolutamide in AR-positive TNBC.

Trial design: This is an open-label, multicenter, randomized, two-arm non-comparative phase II trial (NCT03383679). Women with locally recurrent (unresectable) or metastatic and centrally confirmed AR-positive TNBC are eligible. Patients should be chemotherapy naive or have received a maximum of one line of chemotherapy for advanced disease. Eligible patients are randomized (2:1) between darolutamide experimental arm (600 mg twice daily) and capecitabine control arm (according to each center policy, minimum 1000 mg/m² twice daily, 2 weeks on and 1 week off).

Randomization (minimization) is stratified by number of previous lines of chemotherapy (0 versus 1). In each arm, the primary endpoint is the clinical benefit rate (CBR) at 16 weeks, defined as complete response, partial response or stable disease as per RECIST 1.1 criteria. Tumour biopsies and sequential circulating tumour DNA are collected as part of a translational research program. A total of 90 patients will be randomized. The first patient was included in March 2018. As of May 2018, 3 patients have been screened and 1 patient has been randomized.

Clinical trial identification: NCT03383679.

Legal entity responsible for the study: UNICANCER.

Funding: Bayer.

Disclosure: All authors have declared no conflicts of interest.