Results

• Anlotinib, a novel multi-target tyrosine kinase inhibitor that effectively inhibits VEGFR, PDGFR, FGFR, c-KIT, c-MET, and RET, monotherapy has been proven effective in HER-2 negative metastatic breast cancer, but its efficacy in early-stage triple-negative breast cancer (TNBC) is unknown.

• This phase 2 study (ChiCTR200010043027) aims to evaluate the efficacy and safety of adding anlotinib to neoadjuvant chemotherapy in patients (pts) with primary TNBC.

Methods

• Eligible pts were women aged 18-70 years with histologically confirmed primary stage II-III TNBC; previously untreated; an ECOG PS of 0-1; and adequate organ function.

• Eligible pts were treated with 5 cycles of anlotinib (12mg, d1-d14, q3w) plus 6 cycles of taxanes (docetaxel 75 mg/m², d1 or nab-paclitaxel 125 mg/m², d1 and d8, q3w) and lobaplatin (30 mg/m², d1, q3w), followed by surgery.

• The primary endpoint was the pathologic complete response (pCR) rate confirmed by Chia Tai Central Medical Center, Chia Tai Pharmaceutical Group Co., Ltd. Nanjing, China.

• Histologic type 9 (20%)

• Based on the FUSCC IHC-based subtypes, the tpCR rates were 68.8% (11/16) for IM subtype, 58.3% (7/12) for BLIS subtype, and 33.3% (4/12) for LAR subtype, respectively. Next-generation sequencing revealed that the tpCR were 76.9% (9/12) for BLIS subtype, 75.0% (11/14) for IM subtype, 58.3% (7/12) for BLIS subtype, and 33.3% (4/12) for LAR subtype, respectively.

• The addition of anlotinib to NCT showed manageable toxicity and promising antitumor activity for pts with early-stage TNBC.

• There was no conflict of interest in any author to declare. This research was sponsored by Chia Tai Tianqing Pharmaceutical Group Co., Ltd.

Background

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