LXPB5268 combined with neoadjuvant chemotherapy in early-stage Triple-Negative Breast Cancer patients

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**Purpose:**

Triple-negative breast cancer (TNBC) is a highly fatal breast cancer subtype, benefits from neoadjuvant chemotherapy (NACT), known to enhance survival rates. LXPB5268, a 505(b)(2) drug, demonstrated significant tumor reduction in animal models. This study evaluates LXPB5268 combined with NACT in early-stage TNBC patients.

**Materials and Methods:**

Enrolled patients had untreated stage II-III TNBC. NACT consisted of docetaxel every 3 weeks for four cycles, followed by epirubicin and cyclophosphamide every 3 weeks for four cycles. In the LXPB5268+NACT group, patients took LXPB5268 orally once daily during NACT. After treatment, we analyzed tumor objective response rate (ORR), tumor shrinkage rate, and adverse events (AEs). Whole-exome sequencing (WES) was performed in the LXPB5268+NACT group.

**Results:**

Seven subjects were enrolled LXPB5268+NACT and compared with the NACT database at China Medical University Hospital. The LXPB5268+NACT group showed 3 pathological complete responses (pCR) and 4 pathological partial responses (pPR), while the NACT group had 6 pPR. Tumor shrinkage rates were 77.3% ± 21.8 in LXPB5268+NACT versus 43.4% ± 12.8 in NACT (p < 0.001). AEs included neutropenia (85.7%), constipation (66.7%), and insomnia (66.7%), resolving within two weeks post-treatment cessation. Higher tumor shrinkage rates correlated with XIRP2 gene mutations in the LXPB5268+NACT group.

**Conclusions:**

Combining LXPB5268 with NACT was more effective than NACT alone in early-stage TNBC, with no increase in AEs. These findings underscore the potential of LXPB5268 in TNBC therapy, particularly among patients with XIRP2 mutations. Future trials are warranted to further validate its efficacy in clinical settings.