Neoadjuvant QL1209 (a pertuzumab biosimilar) compared with pertuzumab plus trastuzumab and docetaxel in early or locally advanced, HER2-positive, ER(-)/PR(-) breast cancer: A multicenter, randomized, double-blind, equivalence, phase III study


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Background

Dual HER2-blockade with trastuzumab (T) and pertuzumab (P) plus docetaxel as neoadjuvant therapy showed an improved pathological complete response (pCR) rate and was approved by the FDA and EMA for early HER2-positive breast cancer. QL1209 is a biosimilar of the originator P (Perjeta, Roche). Here we present the results of the phase 3 study comparing the efficacy, safety, immunogenicity of QL1209 with P in the neoadjuvant setting for early HER2-positive breast cancer.

Methods

Eligible patients (pts) had HER2-positive, early (T2–3, N0–1, M0) or locally advanced (T2–3, N2–3,M0 or T4, any N, M0), ER(-) and PR(-) breast cancer with primary tumor larger than 2cm in diameter, and had not received any previous anticancer therapy. Pts were randomly assigned (1:1, stratified by disease stage) to receive neoadjuvant treatment of QL1209 or P (loading dose 840 mg at cycle 1, followed by 420 mg from cycles 2 to 4) plus T and docetaxel once every 3 weeks for 4 cycles. The primary endpoint was tpCR by IRC. Secondary endpoints included tpCR by investigator (INV), bpCR by IRC, bpCR by INV, ORR, safety, immunogenicity etc.

Results

517 pts were enrolled (52 sites in China) and 516 pts (QL1209/P: n=257/259) received neoadjuvant treatment, of whom 482 (93.2%) underwent surgery (QL1209: 255*; P: 259). tpCR (by IRC) was observed in 109 (42.7%) pts with QL1209 and 117 (45.2%) pts with P; ratio of tpCR (QL1209:P) 0.946 (90% CI: 0.8-1.11), p=0.014. Incidences of TEAEs and Gr≥3 TEAEs: (QL1209 vs P) (94.6% vs 96.1%; Gr≥3, 31.9% vs 34.7%). TRAEs: 77.4% vs 78%. Incidences of ADA and Nab were similar between 2 groups (2.3% vs 3.1%; 0.8% vs 0.8%).Table: 245P

<table>
<thead>
<tr>
<th>Overall, n (%)</th>
<th>QL1209 (n=257)</th>
<th>P (n=259)</th>
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</thead>
<tbody>
<tr>
<td>No of pts</td>
<td>255*</td>
<td>259</td>
</tr>
<tr>
<td>tpCR by INV</td>
<td>108 (42.4)</td>
<td>120 (46.3)</td>
</tr>
<tr>
<td>bpCR by IRC</td>
<td>128/256 (50.0)</td>
<td>134 (51.7)</td>
</tr>
<tr>
<td>bpCR by INV</td>
<td>124 (48.6)</td>
<td>133 (51.4)</td>
</tr>
<tr>
<td>ORR by INV, n (%)</td>
<td>211/257 (82.1)</td>
<td>212/259 (81.9)</td>
</tr>
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* IRC didn't receive the complete specimens for 2 patients
Conclusions
QL1209 demonstrated equivalence to P in efficacy and showed comparable safety profile and immunogenicity in patients with early or locally advanced HER2-positive breast cancer.

Clinical trial identification
NCT04629846.

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Disclosure
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