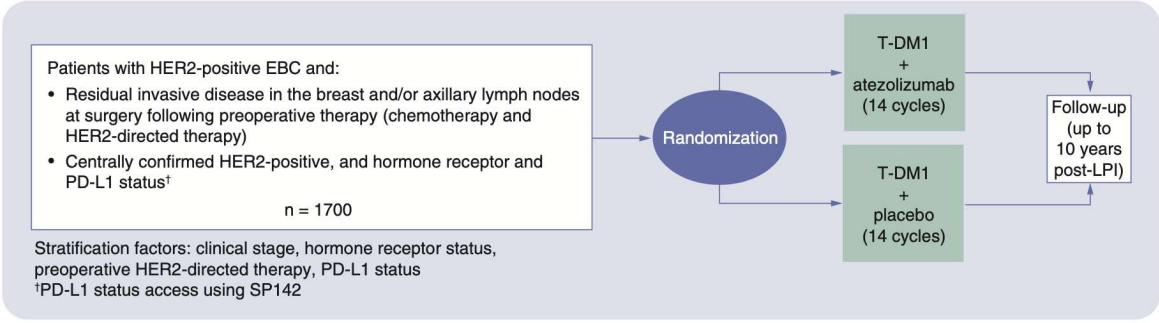


| <b>Studienname</b>                   | <b>Astefania</b><br><b>A phase III, randomized double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of adjuvant Atezolizumab or placebo and Trastuzumab Emtasine for patients with HER2 positive breast cancer and high risk of relapse following preoperative therapy</b>   |                     |                             |                                      |   |                      |   |
|--------------------------------------|---|---------------------|-----------------------------|--------------------------------------|---|----------------------|---|
| <b>Sponsor/ Studiencode</b>          | Roche<br>WO 42633   |                     |                             |                                      |   |                      |   |
| <b>Setting</b>                       | HER2 pos. eBC, postneoadjuvante Therapie, non-pCR   |                     |                             |                                      |   |                      |   |
| <b>Primäres Studienziel</b>          | Invasives DFS   |                     |                             |                                      |   |                      |   |
| <b>Studiendesign</b>                 |  <p>Hurvitz et al., Future Oncology 2022 18:32, 3563-3572</p>  |                     |                             |                                      |   |                      |   |
| <b>Einschlusskriterien (Auswahl)</b> | <ul style="list-style-type: none"> <li>○ HER2 pos. IHC score 3+ <b>OR</b> 2+ with pos. SISH</li> <li>○ Central tested HER2, ER, PR and PD-L1 Status</li> <li>○ ≥ 16 weeks neoadjuvant chemotherapy with taxan and Trastuzumab</li> <li>○ No more than 12 weeks between primary surgery and randomization</li> </ul> <table border="1" data-bbox="331 1299 1268 1467" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Initial TNM Staging</th> <th style="text-align: center;">Residual Disease at Surgery</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><i>cT1/anyN/M0 or any cT/N2-3/M0</i></td> <td style="text-align: center;"><i>Must have residual disease in either the breast or lymph nodes or both</i></td> </tr> <tr> <td style="text-align: center;"><i>cT1-3/N0-1/M0</i></td> <td style="text-align: center;"><i>Must have residual disease in lymph nodes with or without residual disease in the breast</i></td> </tr> </tbody> </table> | Initial TNM Staging | Residual Disease at Surgery | <i>cT1/anyN/M0 or any cT/N2-3/M0</i> | <i>Must have residual disease in either the breast or lymph nodes or both</i> | <i>cT1-3/N0-1/M0</i> | <i>Must have residual disease in lymph nodes with or without residual disease in the breast</i> |
| Initial TNM Staging                  | Residual Disease at Surgery   |                     |                             |                                      |   |                      |   |
| <i>cT1/anyN/M0 or any cT/N2-3/M0</i> | <i>Must have residual disease in either the breast or lymph nodes or both</i>   |                     |                             |                                      |   |                      |   |
| <i>cT1-3/N0-1/M0</i>                 | <i>Must have residual disease in lymph nodes with or without residual disease in the breast</i>   |                     |                             |                                      |   |                      |   |
| <b>Ausschlusskriterien (Auswahl)</b> | <ul style="list-style-type: none"> <li>○ Autoimmune disease</li> <li>○ Malignant history &lt; 5 years</li> <li>○ Prior treatment with atezolizumab</li> <li>○ Pulmonary complications</li> </ul>  |                     |                             |                                      |   |                      |   |
| <b>Teilnehmende Zentren</b>          | <ul style="list-style-type: none"> <li>➤ KEM</li> <li>➤ GynOnco Düsseldorf</li> </ul>   |                     |                             |                                      |   |                      |   |