# The High Unmet Need of Patients with Early Relapse After the KEYNOTE-522 Regimen - Evidence from the Neo-Real/GBECAM-0123 Study

*Bonadio RC[1], Lapuchesky L[2], Tavares MC[3], Nunes NC[4], Testa L[1], Salas I[2], Winocur M[2], Balint FC[3], de Sousa IM[3], Andrade MO[5], Gouveia MC[6], Madasi F[7], Bines J[7], Ferreira RP[8], Rosa DD[8], Santos CL[9], Monteiro MR[10], de Souza ZS[11], Assad-Suzuki D[11], dos Anjos CH[12], Gagliato DM[13], Gomes AU[13], Zucchetti BM[6], Ferrari A[14], de Brito ML[15], Monteiro MF[16], Signorini PA[17], Gomes NJ[18], Abuin GG[2], Sanches S[3], Tavares M[19], Hoff PM[1], Estevez-Diz MP[20], Barroso-Sousa R[5]*

1. Instituto D'Or de Pesquisa e Ensino (IDOR), São Paulo, Brazil. 2. SUMA (Grupo Cooperativa Argentino para el estudio y la investigación del Cáncer de Mama), Buenos Aires, Argentina. 3. A.C.Camargo Cancer Center, São Paulo, Brazil. 4. Grupo Américas, Rio de Janeiro, Brazil. 5. Brasilia Hospital, Grupo Américas, Brasília, Brazil. 6. Hospital 9 de Julho,Grupo Américas, São Paulo, Brazil. 7. Instituto D'Or de Pesquisa e Ensino, Rio de Janeiro, Brazil. 8. Hospital Moinhos de Vento, Porto Alegre, Brazil. 9. Instituto D'Or de Pesquisa e Ensino, Recife, Brazil. 10. Hospital Samaritano, Grupo Americas, São Paulo, Brazil. 11. Hospital Sírio-Libanês, Brasília, Brazil. 12. Hospital Sírio-Libanês, São Paulo, Brazil. 13. Hospital Beneficência Portuguesa, São Paulo, Brazil. 14. Hospital Santa Paula, Grupo Américas, São Paulo, Brazil. 15. Clínica AMO, Salvador, Brazil. 16. Instituto do Câncer do Ceará, Fortaleza, Brazil. 17. Centro Integrado de Pesquisa da Amazônia (CINPAM), Manaus, Brazil. 18. Hospital São Domingos, DASA Oncologia, São Luiz, Brazil. 19. Instituto D'Or de Pesquisa e Ensino, Salvador, Brazil. 20. Instituto do Câncer do Estado de São Paulo, Faculdade de Medicina da Universidade de São Paulo, São Paulo, Brazil.

## Introduction

Triple-negative breast cancer (TNBC) is an aggressive subtype of tumor characterized by early disease recurrence, with most events occurring within the first two years after definitive treatment. With the adoption of the KEYNOTE-522 regimen—pembrolizumab (P) added to neoadjuvant chemotherapy (CT)—we aimed to describe the patters and rates of early recurrence events in a real-world population treated with this regimen.

## Methods

The Neo-Real/GBECAM-0123 study is a real-world data analysis of patients with TNBC treated with P+NAC at sites in Brazil and Argentina since July 2020. The current analysis evaluated recurrence patterns following P+NAC:

- **Early recurrence:** recurrence occurring during or within six months after completion of neoadjuvant/adjuvant therapy. Disease progression during NAC that precluded surgery was also classified as early recurrence.
- **Late recurrence**: Recurrence occurring more than six months after therapy completion was considered.

Overall survival (OS) was calculated from: 1) the date of diagnosis to the date of death from any cause; 2) the date of progression precluding surgery/ recurrence until the date of death.

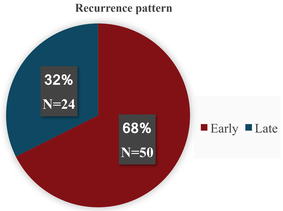
## Results

A total of 726 patients were evaluated. After a median follow-up of 22 months, 70 patients (9.6%) experienced disease recurrence, 4 (0.55%) disease progression precluding surgery, and 8 patients (1.1%) died without recurrence.

**Table 1. Patients' characteristics, N (%)**

| | Early recurrence (N=50) | Late recurrence (N=24) |
|---|---|---|
| Age, median (range) | 45 (26 – 80) | 46 (22 – 76) |
| Histology | | |
| Ductal | 38 (76%) | 23 (95.8%) |
| Special type | 9 (18%) | 1 (4.2%) |
| Premenopausal | 22 (44%) | 12 (50%) |
| Ki67 index ≥ 50 | 33 (66%) | 16 (66.7%) |
| Grade | | |
| 1-2 | 16 (32%) | 6 (25%) |
| 3 | 32 (64%) | 15 (62.5%) |
| Clinical T status | | |
| T1 | 3 (6%) | 0 (0%) |
| T2 | 15 (30%) | 17 (70.8%) |
| T3 | 13 (26%) | 4 (16.7%) |
| T4 | 17 (34%) | 2 (8.3%) |
| Clinical Nodal status, | | |
| N0 | 11 (22%) | 10 (41.7%) |
| N1 | 11 (22%) | 7 (29.2%) |
| N2-N3 | 27 (54%) | 7 (29.1%) |
| Stage | | |
| II | 14 (28%) | 16 (66.7%) |
| III | 34 (68%) | 7 (29.2%) |
| BRCA | | |
| Mutated | 6 (12%) | 1 (4.2%) |
| Wild-type/Unknown | 44 (88%) | 23 (95.8%) |
| AC schedule | | |
| Every 3 weeks | 21 (42%) | 8 (33.3%) |
| Dose-dense | 24 (48%) | 16 (66.7%) |

**Figure 1.** Recurrence patterns after neoadjuvant CT+P.




Most patients with early recurrence have received adjuvant therapy. In patients with pathologic complete response (pCR), 8 out of 9 (88.9%) received adjuvant P. Among patients with residual disease, 32 out of 37 (86.5%) received adjuvant treatment, including P plus capecitabine in 19 (51.3%), P alone in 6 (16.2%), capecitabine alone in 6 (16.2%), P plus Olaparib in 1 (2.7%). Five patients (13.5%) received no adjuvant therapy, mainly due to early relapse.

**Figure 2.** Recurrence patterns and sites of recurrence according to pathologic response group.

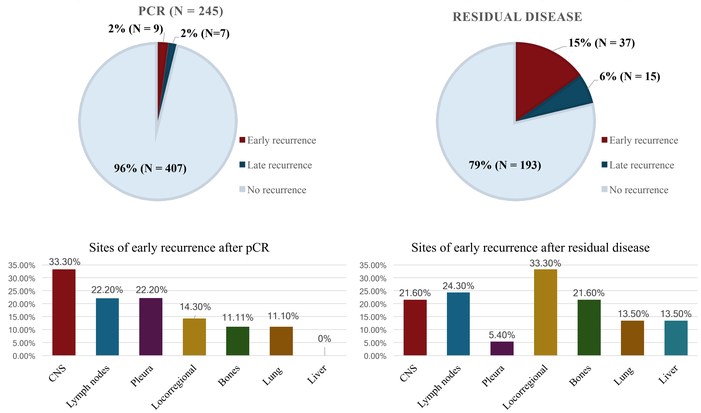
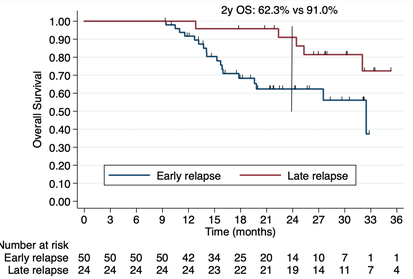



**Figure 3.** Overall survival from the date of initial diagnosis to death from any cause, according to pattern of recurrence (early vs late).




From the date of progression precluding surgery/ recurrence, the 6-month OS rate was: **77.7%** for early recurrence and **87.9%** for late recurrence.

## CONCLUSIONS

The majority of recurrences after the KEYNOTE-522 regimen occurred early. These patients are resistant to four chemotherapeutic agents and an immune checkpoint inhibitor (ICI) and face markedly poor survival outcomes. Our findings underscore a critical unmet need for effective therapeutic options in this population, which is often excluded or underrepresented in clinical trials investigating first-line regimens, including studies of antibody-drug conjugates combined with ICI.

**References**

1. Schmid P, et al. Overall Survival with Pembrolizumab in Early-Stage Triple-Negative Breast Cancer. NEJM 2024.
2. Cortes J, et al. Primary results from ASCENT-03: a randomized phase 3 study of sacituzumab govitecan (SG) vs chemotherapy (chemo) in patients (pts) with previously untreated metastatic triple-negative breast cancer (mTNBC) who are not candidates for PD-(L)1 inhibitors. ESMO 2025.
3. Dent R, et al. First-line (1L) datopotamab deruxtecan (Dato-DXd) vs chemotherapy in patients with locally recurrent inoperable or metastatic triple-negative breast cancer (mTNBC) for whom immunotherapy was not an option: Primary results from the randomised, phase 3 TROPION-Breast02 trial. ESMO 2025

Copies of this poster obtained through Quick Response (QR) Code are for personal use only and may not be reproduced without permission from SABCS® and the author of this poster. This presentation is the intellectual property of the author/presenter. Contact them at rrccbonadio@gmail.com for permission to reprint and/or distribute.