EPH90

Estimation of HER2-negative Metastatic Breast Cancer Population Eligible for Innovative Treatments in France

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Plain language summary

Why did we perform this research?

To accurately assess the societal impact of medical innovations for metastatic breast cancer, it is essential to estimate the number of individuals who may be eligible for new treatments. To support this, we developed a comprehensive overview of the metastatic breast cancer population in France, using published sources and presenting estimates both overall and broken down by cancer subtype and treatment line.

How did we perform this research?

We conducted a targeted literature review to identify relevant French publications. These sources were used to estimate the number of individuals in France with metastatic breast cancer, grouped by phenotype according to hormone receptor (HR) and HER2 status.

What were the findings of this research?

We identified the annual number of individuals diagnosed with each subtype of metastatic breast cancer. In addition, we also estimated how many patients in the HER2-negative mBC population would progress to each line of treatment.

What are the implications of this research?

Understanding how many individuals have specific subtypes of metastatic breast cancer and how many reach each treatment line helps define the pool of candidates eligible for innovative therapies. It also highlights the importance of enabling earlier access to such treatments.

Objectives

- This study aimed to calculate the size of different human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer (mBC) subpopulations in France from published literature.
- The study also sought to evaluate the number of mBC patients who may be candidates for innovative therapies across treatment lines.

Conclusions

- Almost 17,000 people are diagnosed with mBC every year in France. Of these, around 80% have HER2-negative mBC, and of these, 82% are HR+.
- Despite a growing eligible mBC patient population, a low share of patients reach third line (3L) and fourth line (4L). This underscores the need for earlier access to innovative treatments to ultimately improve outcomes for people with mBC.

Introduction

- Reimbursement processes for innovative mBC treatments in France require an estimate of the eligible patient population and the number of candidates in each treatment line.
- Estimates are typically derived based on hormone receptor and HER2 status.
- This study quantified the eligible mBC patient population across different treatment lines.

Methods

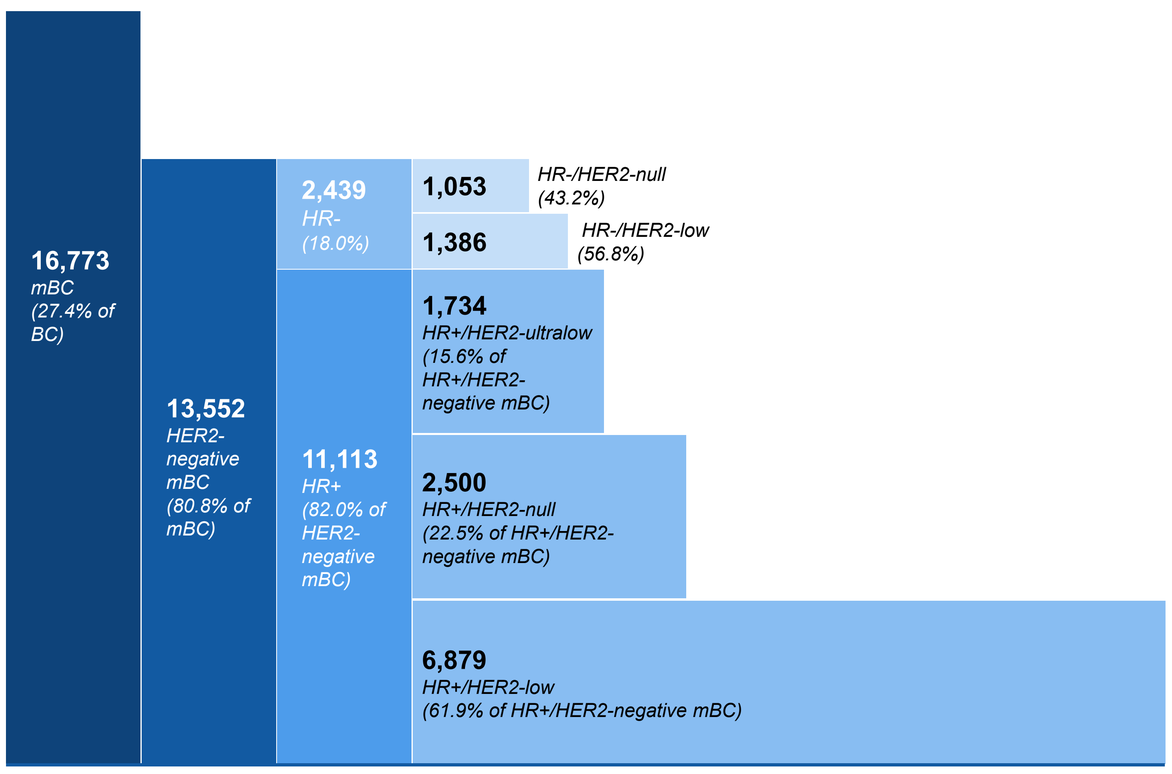
- A targeted literature review (TLR) was conducted to identify relevant scientific articles from the past 5 years estimating the number of individuals within mBC phenotypes as well as attrition rates for different treatment lines.
- Epidemiological inputs identified from six publications in the TLR were used to estimate the number of individuals in France with HER2-negative mBC, categorized as HR+/HER2-null (IHC 0 absent membrane staining), HR+/HER2-ultralow (IHC 0 with membrane staining), HR+/HER2-low (IHC 1+ and 2+/ISH-),* HR-/HER2-low and HR-/HER2-null.
- These inputs were applied proportionally to national breast cancer incidence to estimate the number of people in each subpopulation and the number of people eligible for different treatment lines.

Results

- The incidence of breast cancer in France was 61,214 in 2023[1].
- Among those, an estimated 16,773 individuals were diagnosed with mBC[2], either as de novo mBC or progressive mBC.
- Of these individuals, 80.8% (corresponding to 13,552 individuals) had HER2-negative mBC. Among the HER2-negative mBC population, 82.0% (corresponding to 11,113 individuals) were HR-positive (HR+) and 18.0% (corresponding to 2,439 individuals) were HR-negative (HR-)[3].
- Among individuals diagnosed with HR+/HER2-negative, an estimated 22.5% (2,500) were HR+/HER2-null, 15.6% (1,734) were HR+/HER2-ultralow and 61.9% (6,879) were HR+/HER2-low[4].
- An estimated 56.8% (1,386) and 43.2% (1,053) of individuals with HR- were HR-/HER2-low and HR-/HER2-null, respectively[3,5] (**Figure 1**).

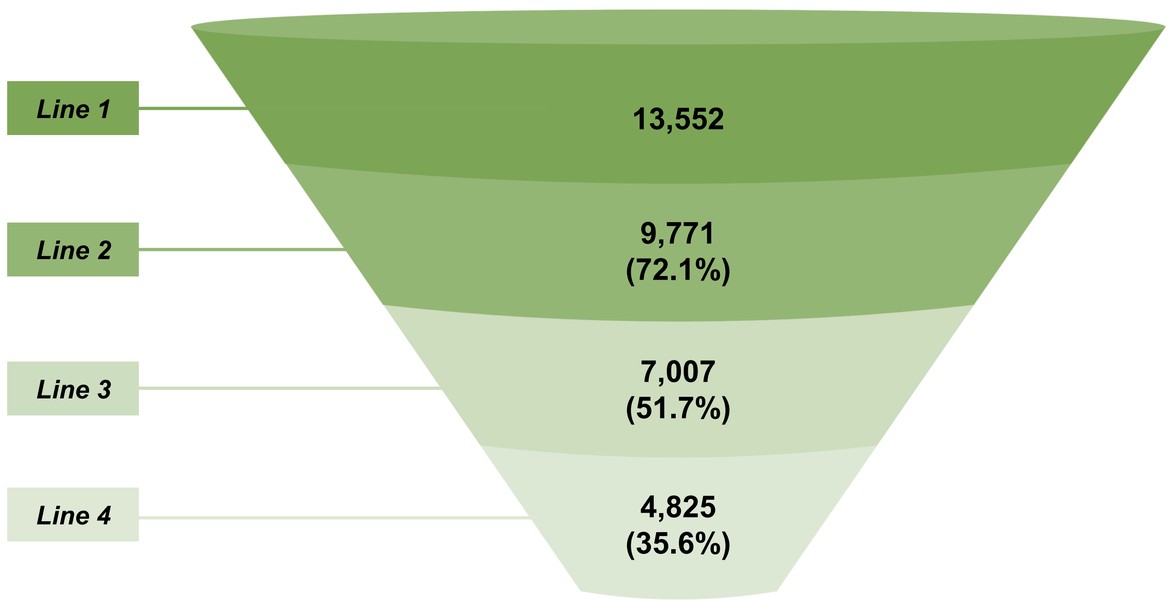
Figure 1. Overview of the metastatic breast cancer population in France

61,214 incident people with BC



Note: For each column in Figure 1, percentages were calculated using the N value in the column immediately to the left as the denominator.

Figure 2. HER2-negative mBC eligible for innovative treatment in lines 1-4



Note: Percentages in Figure 2 are calculated based on number of HER2-negative mBC (n=13,552) as denominator.

- Based on the distribution of treatment and survival patterns from the Epidemiological Strategy and Medical Economics (ESME) Database in France[6] in 2023, an estimated 9,771 people with HER2-negative mBC (72.1%) received second-line (2L) treatment, 7,007 (51.7%) received 3L treatment and 4,825 (35.6%) received 4L treatment (**Figure 2**).
- Innovative mBC treatments (excluding chemotherapy and endocrine therapy) are typically available in 2L, 3L, or 4L depending on previous treatment and mBC subtype.
- Innovative treatments have been documented to result in longer progression-free survival, demonstrating that they have the potential to increase life expectancy for thousands of individuals with mBC.

*HER2 classification has historically been binary, but HER2 expression is a continuum. Historically, HER2-low and HER2-ultralow were treated as HER2-negative but are now recognized as distinct segments.

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Disclosures

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