PharmaPoint: HER2-Positive Breast Cancer - Global Drug Forecast and Market Analysis to 2023

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Summary

HER2-positive breast cancer is the second most common cancer in the world and the most common cancer in women worldwide. This report focuses on the current treatment landscape, unmet needs, current pipeline, and commercial opportunities in the HER2-positive breast cancer market, with coverage of multiple settings of the disease including neoadjuvant, adjuvant, first-, second-, third-, and fourth-line metastatic.

Since its introduction in 1998, Roche's gold standard therapy, Herceptin (trastuzumab), a monoclonal antibody, revolutionized the treatment of the disease. The realization that targeting the HER2 receptor could significantly improve disease-free survival (DFS) has created a large market for HER2-directed therapies. In 2013, Roche dominated the HER2-positive market, with a share of 95%. With Herceptin's patent expiry looming in Europe Roche launched Perjeta and Kadcyla in 2012 and 2013 to maintain its leadership. The publisher forecasts that the two monoclonal antibodies that also target the HER2 receptor will ensure Roche still occupies over 95% of the market in 2023.

The challenge for new entrants into the HER2-positive market is to find patient populations that are currently underserved, and can work cooperatively with Roche's targeted therapies. The HER2-positive pipeline is weak, and there are still unmet needs that have yet to be suitably addressed. The publisher expects that the HER2-positive market will grow due to the premium pricing of new agents, and an increasing aging population in the US, 5EU, Japan, and China.

Highlights

Key Questions Answered
- What are the R&D strategies being used by drug makers?
- How is the disease management evolving? What impact for drug manufacturers?
- What opportunities remain for future players?
- How large are the neoadjuvant, adjuvant, and metastatic markets for HER2 targeting agents, and which one is growing the fastest?
- What exciting, innovative approaches are being investigated in HER2-positive breast cancer?
- What to KOLs think about the latest therapies and drug development strategies?

Key Findings
- The HER2-positive breast cancer market will increase by 2.5-fold, reaching $12.63bn by 2023, at a CAGR of 9.82%, driven by the rapid uptake of the latest premium-priced biologics. Approval of these agents in the early (non-metastatic) stages will have the greatest impact on the market, along with combinations of branded therapies.
- By 2023, the largest market segment will be the adjuvant setting, with rapid growth at a CAGR of 12.3%, and representing 63% of the total HER2-positive market. Herceptin will no longer be the market leader, with new agents Perjeta and Kadcyla taking 37% and 39% market share respectively.
- The patent expiry of Herceptin in the 5EU in 2014, and in the US in 2019, will significantly reduce Herceptin sales, however, its introduction of a more convenient subcutaneous reformulation of Herceptin will limit this impact.
- Development of new HER2-targeting therapies is slow, with only one agent, Puma Biotechnology's neratinib, in Phase III, following the failure of BI's gilotrif. The recent failure of GSK's Tykerb in the adjuvant setting shows that TKIs are best suited to later stages of metastatic disease.
- Entry into the Roche-dominated HER2-positive market is challenging, with new players needing to find alternative MOAs in underserved patient populations. KOLs identified areas of important unmet need that can still provide opportunities in the HER2-positive space.
- Future drug development will begin to merge the HER2-positive and HER2-negative populations, as new
targets and MOAs are developed, providing exciting opportunities.

Scope

- Overview of HER2-positive breast cancer, including epidemiology, etiology, pathophysiology, symptoms, diagnosis, and disease management.
- Annualized HER2-positive breast cancer therapeutics market revenue, annual cost of therapy, and treatment usage patterns in six patient segments (including neoadjuvant and adjuvant), forecast from 2013 to 2023.
- Key topics covered include strategic competitor assessment, market characterization, unmet needs, R&D strategies, and clinical trial design for the HER2-positive breast cancer therapeutics market.
- Pipeline analysis: comprehensive data assessing emerging trends and mechanisms of action under development for different lines of therapy. The most promising candidate in Phase III development is profiled.
- Analysis of the current and future market competition in the global HER2-positive breast cancer therapeutics market. Insightful review of the key industry drivers, restraints and challenges. Each trend is independently researched to provide qualitative analysis of its implications.

Reasons to buy

- Develop and design your in-licensing and out-licensing strategies through a review of pipeline products and technologies, and by identifying the companies with the most robust pipeline.
- Develop business strategies by understanding the trends shaping and driving the global HER2-positive breast cancer therapeutics market.
- Drive revenues by understanding the key trends, innovative products and technologies, market segments, and companies likely to impact the global HER2-positive breast cancer therapeutics market in the future.
- Formulate effective sales and marketing strategies by understanding the competitive landscape and by analysing the performance of various competitors.
- Identify emerging players with potentially strong product portfolios and create effective counter-strategies to gain a competitive advantage.
- Organize your sales and marketing efforts by identifying the market categories and segments that present maximum opportunities for consolidations, investments and strategic partnerships.

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