

Hormone Receptor (HR)-positive/ Human Epidermal Receptor 2 (HER2)-negative Breast Cancer- Market Insights, Epidemiology and Market Forecast–2028

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Abstracts

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DelveInsight's 'Hormone Receptor (HR)-positive/Human Epidermal Receptor 2 (HER2)-negative Breast Cancer- Market Insights, Epidemiology and Market Forecast–2028 report delivers an in-depth understanding of the disease, historical, and forecasted epidemiology as well as the market trends of Hormone Receptor (HR)-positive/Human Epidermal Receptor 2 (HER2)-negative Breast Cancer in the United States, EU5 (Germany, France, Italy, Spain, and the United Kingdom), and Japan.

The report provides the current treatment practices, emerging drugs, market share of the individual therapies, the current and forecasted market size of HR-positive/HER2-negative breast cancer from 2017 to 2028 segmented by the seven major markets.

HR-positive/HER2-negative breast cancer is the most common form of breast cancer. This type accounts for a higher percentage of all breast cancers. Hormone receptors are proteins that receive hormone signals and tell the cancer cells to grow. If breast cancer cells get signals from the hormone estrogen that could promote tumor growth, it is known as estrogen receptor-positive (ER+) breast cancer. If cancerous cells get signals from the hormone progesterone that could promote growth, it is known as progesterone receptor-positive (PR+) breast cancer. Breast cancer that is ER-positive or PR-positive falls under the category of hormone receptor-positive (HR+) breast cancer. Addition to this, there is another factor which is also responsible for breast cancer which is known as human epidermal growth factor receptor 2 (HER2). Human

epidermal growth factor receptor-2 is a gene that helps control how cells grow, divide, and repair themselves. There are more number of cases for breast cancer in women observed in comparison to the men.

Geography Covered

The United States

EU5 (Germany, France, Italy, Spain, and the United Kingdom)

Japan

Study Period: 2017–2028

Hormone Receptor (HR)-positive/Human Epidermal Receptor 2 (HER2)-negative Breast Cancer– Disease Understanding and Treatment Algorithm

HR-positive cancer is usually treated with Endocrine therapies or a combination of hormone therapy with targeted therapy to help stop tumor growth first. However, sometimes cancer outsmarts the treatment and becomes resistant to hormonal therapy and stops working. Most endocrine therapies for breast cancer inhibit tumor growth by depriving the cell of estrogen or by blocking its receptor. However, some drugs, such as tamoxifen, can bind to the estrogen receptor (ER) and have both estrogenic and antiestrogenic effects depending on the tissue, cell or promoter.

Currently there are number of classes of anti-estrogenic agents available for patients with early, advanced, or metastatic breast cancer which includes selective estrogen receptor modulators (SERMs), aromatase inhibitors (AIs), and a selective estrogen receptor degrader.

ETs are a common first-line treatment in advanced or metastatic breast cancer (MBC), resistance inevitably develops. Some patients may develop resistance to ET with one agent class, a response to treatment may occur with exposure to another class. Sequential ET is preferred in postmenopausal women with HR+, HER2- MBC. Guidelines currently recommend Aromatase Inhibitors (AIs) with the CDK4/6 inhibitors, palbociclib or ribociclib, or fulvestrant as a first-line ET option. As a second-line ET option, fulvestrant in combination with palbociclib or abemaciclib is recommended for patients with prior adjuvant ET exposure or patients who received ET in the metastatic

setting. However there is one drawback of Endocrine therapies that patients become resistance to this after continues use. For this Targeted CDK4/6 Inhibitors are used as First-Line Regimens. In addition to this, First-Line Regimens, mTOR Inhibitors and Akt Inhibitors also recommended.

The DelveInsight's Hormone Receptor (HR)-positive/Human Epidermal Receptor 2 (HER2)-negative Breast Cancer market report gives a thorough understanding of the HR-positive/HER2-negative by including details such as disease definition, classification, symptoms, etiology, pathophysiology, diagnostic trends. It also provides treatment algorithms and treatment guidelines for HR-positive/HER2-negative in the US, Europe, and Japan.

Hormone Receptor (HR)-positive/Human Epidermal Receptor 2 (HER2)-negative Breast Cancer– Epidemiology

The HR-positive/HER2-negative epidemiology division provides insights about historical and current patient pool and forecasted trend for every seven major countries. It helps to recognize the causes of current and forecasted trends by exploring numerous studies and views of key opinion leaders. This part of the DelveInsight's report also provides the diagnosed patient pool and their trends along with assumptions undertaken.

The disease epidemiology covered in the report provides historical as well as forecasted epidemiology [segmented by Total Incidence of Breast Cancer in the 7MM, Incidence of Breast Cancer Cases by Menopausal Status in the 7MM, Incidence of Breast Cancer Cases by Menopausal Status in the 7MM, Stage Specific Incidence of Breast Cancer in Post-Menopausal Women in the 7MM, Stage Specific Incidence of Breast Cancer in Post-Menopausal Women in the 7MM, Diagnosed Incidence of Early Stage Breast Cancer in Post menopause by Molecular Subtype in the 7MM and Diagnosed Incidence of Locally Advanced and Metastatic Breast Cancer in Postmenopause by Molecular Subtype in the 7MM] of HR-positive/HER2-negative in the 7MM covering the United States, EU5 countries (Germany, France, Italy, Spain, and the United Kingdom) and Japan from 2017 to 2028.

According to DelveInsight's epidemiology model for HR-positive/HER2-negative Breast Cancer has assessed that total incident population of Breast Cancer in the 7MM is expected to grow at CAGR of 0.83%, during study period [2017–2028]. DelveInsight's estimate suggests the United States show higher incidence of Breast Cancer. As per the DelveInsight's estimation, in 2017, among the EU-5 countries, Spain has the least number of breast cancer incident cases. According to the DelveInsight's analyst,

among the 7MM countries, Japan accounts for the second highest breast cancer incident cases.

In addition to this according to DelveInsight's epidemiology model, based on the menopausal status of women suffering from breast cancer, in the 7MM, the higher number of cases were observed for the postmenopausal Breast cancer, accounting for 70–80% of the cases, while premenopausal women contributed a significantly lesser proportion of the patients. DelveInsight's estimates suggests that based on stage-specific incidence of breast cancer in postmenopausal women, Stage IIIb,c and IV-specific breast cancer were observed to be less in number of patients. On the other hand, Stage I-IIIa together accounted for majority of the patient pool.

Hormone Receptor (HR)-positive/Human Epidermal Receptor 2 (HER2)-negative Breast Cancer– Drug Chapters

This segment of the HR-positive/HER-Negative report encloses the detailed analysis of marketed drugs and late stage (Phase-III and Phase-II) pipeline drugs. It also helps to understand the clinical trial details, expressive pharmacological action, agreements and collaborations, approval and patent details, advantages and disadvantages of each included drug and the latest news and press releases.

For the treatment of HR-positive/HER-Negative there are many drugs are available. Ibrance (Palbociclib; Pfizer), PIQRAY (Alpelisib; BYL719; Novartis), Lynparza (olaparib; AstraZeneca Pharmaceuticals), Verzenio (Abemaciclib; Eli Lilly), Kisqali (Ribociclib; LEE011: Novartis Pharmaceuticals), Afinitor (Everolimus; Novartis), Faslodex (Fulvestrant Injection: AstraZeneca) and many more approved for the management of the HR-Positive/Her2negative breast cancer.

Ibrance is a kinase inhibitor indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. IBRANCE currently is approved in more than 90 countries.

It is used in combination with an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or fulvestrant in patients with disease progression following endocrine therapy for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

PIQRAY (BYL719; ALPESLIB) is an investigational, orally bioavailable, alpha-specific PI3K inhibitor developed by Novartis. In breast cancer cell lines harboring PIK3CA mutations, BYL719 has been shown to potentially inhibit the PI3K pathway and have antiproliferative effects. In addition, cancer cell lines with PIK3CA mutations were more sensitive to BYL719 than those without the mutation across a broad range of different cancers.

Verzenio (Abemaciclib) is indicated for the treatment of women with hormone receptor (HR)-positive in combination with fulvestrant. There are other kinase inhibitors recommended in combination to the conventional endocrine therapies. KISQALI is a kinase inhibitor used in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of pre/perimenopausal or postmenopausal women, with hormone receptor (HR)-positive breast cancer (BC). It is also used for human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy.

There are other approved drugs in the market for the management of HR-positive/Her2-negative breast cancer.

Hormone Receptor (HR)-positive/Human Epidermal Receptor 2 (HER2)-negative Breast Cancer– Market Outlook

The HR-Positive/HER2-Negative Breast cancer market outlook of the report helps to build the detailed comprehension of the historic, current and forecasted trend of the market by analyzing the impact of current therapies on the market, unmet needs, drivers and barriers and demand of better technology.

This segment gives a thorough detail of market trend of each marketed drug and late-stage pipeline therapy by evaluating their impact based on the annual cost of therapy, inclusion and exclusion criteria's, mechanism of action, compliance rate, growing need of the market, increasing patient pool, covered patient segment, expected launch year, competition with other therapies, brand value, their impact on the market, and view of the key opinion leaders. The calculated market data are presented with relevant tables and graphs to give a clear view of the market at first sight.

As per the assessment by DelveInsight's analysts, it has been observed that the market size of HR-positive/HER2-negative Breast in the 7MM countries was observed to be USD 5,237.2 million in 2017. Among the 7MM countries, the United States had the highest market size of HR-positive/HER2-negative breast cancer in 2017, of the total

market. At present, the growth of market size for HR-positive/HER2-negative breast cancer is attributed to drugs that have been approved for HR-positive breast cancer by the US FDA.

As per the DelveInsight's analyst, among the 7MM countries, Japan had the second highest market size of HR-positive/HER2-negative breast cancer in 2017. Among the EU-5 countries, Germany had the highest market size of HR-positive/HER2-negative breast cancer in 2017. At present, the growth of market size for HR-positive/HER2-negative breast cancer is attributed to drugs that have been approved for HR-positive breast cancer in EU-5 countries. The market size for HR-positive/HER2-negative breast cancer. At present, the growth of market size for HR-positive/HER2-negative breast cancer is attributed to drugs that have been approved for HR-positive breast cancer in EU-5 countries.

Advancement in development of novel drug candidate by various pharmaceutical companies the dynamics of HR-positive/HER2-Negative breast cancer market is anticipated to change in the coming years owing to the expected launch of emerging therapies during the forecasted period of 2019–2028. There are presently many drugs focused on the treatment of HR-positive/HER2-Negative breast cancer, which are expected to enter the market during the forecast period [2019–2028].

Hormone Receptor (HR)-positive/Human Epidermal Receptor 2 (HER2)-negative Breast Cancer– Drugs Uptake

This section focusses on the rate of uptake of the potential drugs recently launched in the market or will get launched in the market during the study period from 2017 to 2028. The analysis covers market uptake by drugs; patient uptake by therapies, and sales of each drug.

This helps in understanding the drugs with the most rapid uptake, reasons behind the maximal use of new drugs and allow the comparison of the drugs on the basis of market share and size which again will be useful in investigating factors important in market uptake and in making financial and regulatory decisions.

The dynamics of HR-positive/Her2-negative breast cancer market is anticipated to change in the coming years owing to the improvement in the diagnosis methodologies, raising awareness of the diseases, and advancement in the research and development of emerging therapies during the forecast period of 2019-2028. Companies across the globe are thoroughly working toward the development of new treatment therapies for

HR-positive/HER2-negative breast cancer.

More than a dozen companies have shifted their focus towards this therapeutic area. To name a few: Jiangsu HengRui Medicine Co., Odonate Therapeutics, Radius Pharmaceuticals, Immunomedics, Roche Group Syndax Pharmaceuticals, Merck Sharp & Dohme Corp, Eagle Pharmaceuticals and others.

Tesetaxel is an investigational agent developed by Odonate Therapeutics, belongs to a class of drugs known as taxanes, which are widely used in the treatment of cancer. This is an orally administered chemotherapy. Odonate is hoping to qualify as a New Chemical Entity (NCE) if and when a New Drug Application (NDA) is submitted, retains the same taxane core as the approved taxanes, but includes the addition of two novel, nitrogen-containing functional group. This new formulation does not contain solubilizing agents contained in other taxane formulations which are known to cause hypersensitivity reactions. This is currently being accessed in phase III.

Sacituzumab govitecan (IMMU-132: Immunomedics) is an advanced product candidate, which is a novel, first-in-class antibody-drug conjugate (ADC). Sacituzumab govitecan is an ADC that contains SN-38, the active metabolite of irinotecan, approved by many Health Authorities, including the US Food and Drug Administration (FDA) as a chemotherapeutic for patients with cancer. SN-38 cannot be given directly to patients because of its toxicity and poor solubility. This novel drug is currently in Phase III clinical developmental stage.

SHR6390 (Jiangsu HengRui Medicine) is Cyclin-dependent kinases 4 and 6 (CDK4/6) of cell cycle progression and are dysregulated in cancers. Inhibition of CDK4/6 induces G1 phase cell cycle arrest, therefore retards tumor growth. This inhibits retinoblastoma (Rb) protein phosphorylation early in the G1 phase, which prevents CDK-mediated G1-S phase transition and leads to cell cycle arrest. This suppresses DNA replication and decreases tumor cell proliferation. CDK4 and 6 are serine/threonine kinases that are up-regulated in many tumor cell types and play a key role in the regulation of cell cycle progression. SHR6390 has been recently accessed in phase II clinical trials.

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Key Benefits

This DelveInsight report will help to develop Business Strategies by

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understanding the trends shaping and driving the Hormone Receptor (HR)-positive/Human Epidermal Receptor 2 (HER2)-negative Breast Cancer market

Organize sales and marketing efforts by identifying the best opportunities for Hormone Receptor (HR)-positive/Human Epidermal Receptor 2 (HER2)-negative Breast Cancer market

To understand the future market competition in the Hormone Receptor (HR)-positive/Human Epidermal Receptor 2 (HER2)-negative Breast Cancer market.

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