

## **Datamonitor: Roche - novel Herceptin formulation promises greater convenience on reports-research.com**

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Press release from: [dynamic technologies GmbH, Köln, Germany](#)



Having stepped up lifecycle management for its leading breast cancer monoclonal antibody, Herceptin, Roche hopes to encourage uptake of a more convenient formulation of the drug. This strategy could help to conserve its share of an increasingly competitive market, but may be challenging to implement due to concerns over compliance and financial incentives to prescribe intravenous cancer drugs.

Roche has invested roughly CHF190m (\$183m) at two production sites to manufacture devices that will allow patients to self-administer a subcutaneous formulation of Herceptin (trastuzumab; Roche/Genentech/Chugai).

One site will supply the devices for a Phase III study which could support approval of the subcutaneous formulation. In this study, 552 patients with stage I-IIIc breast cancer will receive chemotherapy in combination with either subcutaneous or intravenous Herceptin before surgery, followed by 10 three-weekly infusions of subcutaneous or intravenous Herceptin.

Herceptin is a monoclonal antibody directed towards the human epidermal growth factor receptor-2 (HER-2), which is over-expressed in approximately 25% of the breast cancer population. In its intravenous formulation, Herceptin has established itself as a leading treatment for HER-2-positive breast cancer, both for patients with early-stage (stage I-III) and metastatic (stage IV) forms of the disease. In 2008, global sales of the drug totaled \$4.7 billion.

Herceptin's current intravenous formulation requires patients to receive the drug in hospital via a one-hour infusion. The subcutaneous formulation (developed in partnership with Halozyme Therapeutics) would increase convenience, allowing patients to self-administer the drug at home via a five-minute infusion. This is important given that Herceptin is administered for up to a year in early-stage breast cancer. Additionally, this would help to reduce costs associated with patient hospitalization and could improve the drug's side-effect profile by reducing infusion reactions.

Roche will hope that these factors increase brand loyalty and protect Herceptin's market share against potentially fierce competition from GlaxoSmithKline's oral HER-2 inhibitor, Tykerb (lapatinib), which is approved for metastatic breast cancer and is currently in Phase III trials for early-stage HER-2-positive breast cancer. Furthermore, switching patients to a subcutaneous formulation could help insulate against potential competition from biosimilar versions of intravenous Herceptin. As the lucrative monoclonal antibody market approaches maturity, such lifecycle management activities are likely to become increasingly common.

However, Roche could find it challenging to encourage uptake of subcutaneous Herceptin because it will make it more difficult for physicians to ensure patient compliance. Indeed, patient compliance can be a problem for some orally administered anticancer drugs. In the US, financial incentives for oncologists to prescribe intravenous drugs could further restrict uptake of the subcutaneous formulation. The ongoing Phase III study may therefore have to show that the more convenient subcutaneous formulation also has superior efficacy in order to drive appreciable uptake.

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