# Proposed biosimilar drug shows potential as breast cancer treatment

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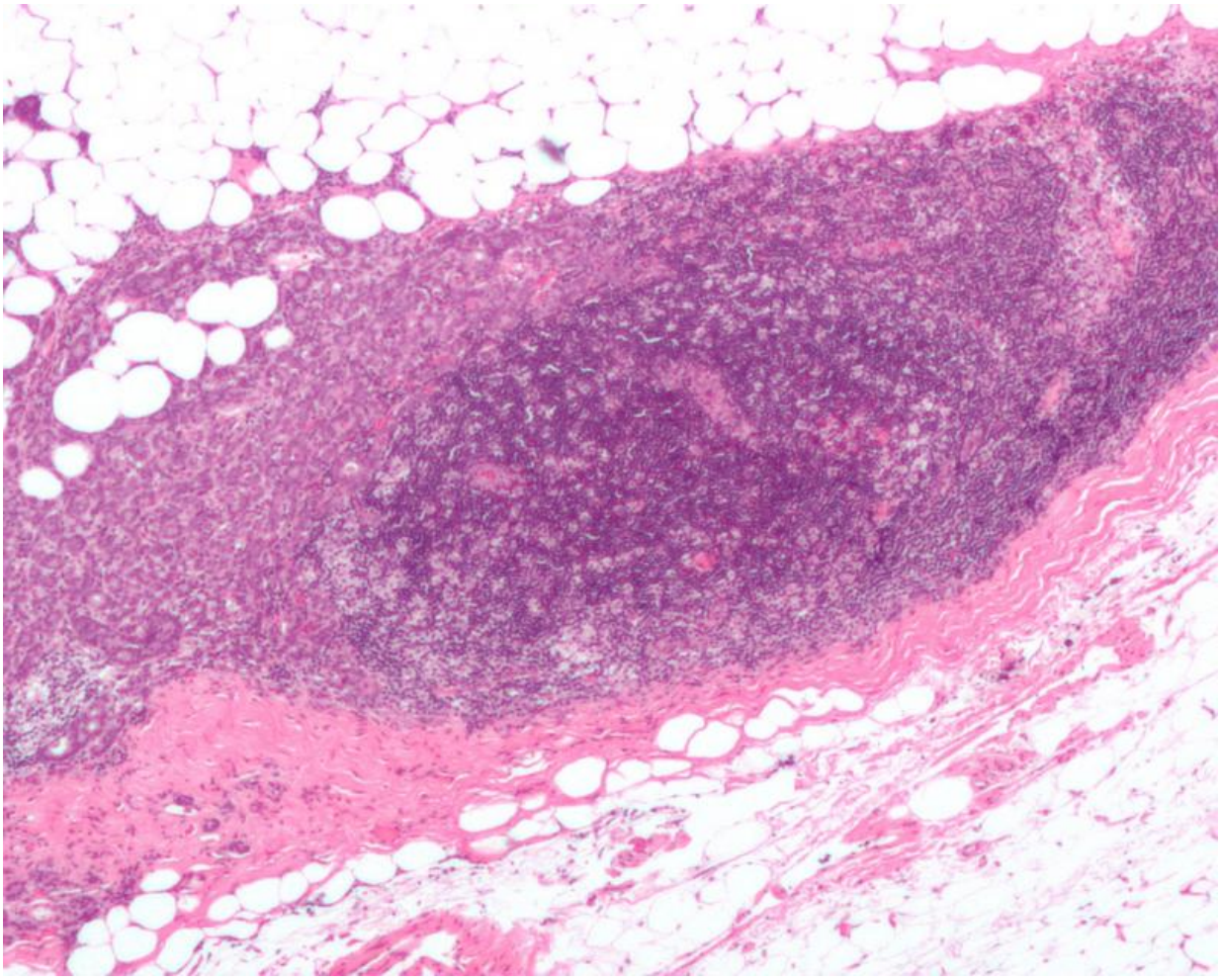

Micrograph showing a lymph node invaded by ductal breast carcinoma, with extension of the tumour beyond the lymph node. Credit: Nephron/Wikipedia

Among women with metastatic breast cancer, treatment with a drug that is biosimilar to the breast cancer drug trastuzumab resulted in an equivalent overall response rate at 24 weeks compared with trastuzumab, according to a study published online by *JAMA*.

Biological agents, including monoclonal antibodies, have increased the treatment options and greatly improved outcomes for a number of cancers. However, patient access to these biologics is limited in many countries. With impending patent expiration of some biological agents, development of biosimilars has become a high priority for drug developers and health authorities throughout the world to provide access to high-quality alternatives. A biosimilar drug is a biological product that is highly similar to a licensed biological product, with no clinically meaningful differences in terms of safety or potency.

Treatment with the anti-ERBB2 humanized monoclonal antibody trastuzumab and chemotherapy significantly improves progression-free and overall survival in patients with ERBB2 (HER2)-positive metastatic breast cancer. In this multicenter, phase 3 study, Hope S. Rugo, M.D., of the University of California San Francisco Helen Diller Family Comprehensive Cancer Center, and colleagues randomly assigned patients with ERBB2-positive metastatic breast cancer to receive a proposed trastuzumab biosimilar (MYL-14010) (n = 230) or trastuzumab (n = 228) with a taxane (a chemotherapy agent) to compare the overall response rate and safety after 24 weeks. Chemotherapy was administered for at least 24 weeks followed by antibody alone until unacceptable toxic effects or disease progression occurred. Tumor was assessed every 6 weeks. The primary outcome was week 24 overall response rate defined as complete or partial response.

The overall response rate was 70 percent for the proposed biosimilar vs 64 percent for trastuzumab. At week 48, there was no statistically significant difference with the proposed biosimilar vs trastuzumab for

time to tumor progression (41 percent vs 43 percent), progression-free survival (44 percent vs 45 percent), or overall survival (89 percent vs 85 percent). In the proposed biosimilar and trastuzumab groups, 99 percent and 95 percent of patients had at least 1 adverse event.

"Trastuzumab is not widely available around the world," the authors write. "A biosimilar treatment option may increase global access to biologic cancer therapies, provided, among other issues, that the price of the biosimilar is sufficiently inexpensive to enable women in non-high-income countries to access this therapy."

The researchers note that further study is needed to assess safety as well as long-term clinical outcome.

In an accompanying editorial, Howard Bauchner, M.D., Editor in Chief, *JAMA*, Chicago, and colleagues write that one of the sponsors of this study, Mylan, "has recently attracted attention because of the pricing, promotion, and involvement in the health policies of schools regarding one of its products, injectable epinephrine (EpiPen). There has been substantial criticism of the company by patients, physicians, and politicians about the recent price increase and the subsequent introduction of a generic epinephrine product by the same company."

"The proposed trastuzumab biosimilar will need to be priced at a level at which patients who otherwise would not have access to expensive therapies such as trastuzumab could receive needed therapy. In announcing their FDA submission for the proposed trastuzumab biosimilar, the sponsors of the trial by Rugo et al have expressed their 'shared commitment to increasing access to these critical medicines worldwide' and indicated that 'this advancement in the U.S. will enable us to enhance access to this affordable therapy to larger patient pools.' Ultimately, to fulfill these pledges the manufacturers must ensure that the pricing of this biosimilar product is responsible and fair and provides

access to this important therapy at an affordable price."

"The greatest potential value of the proposed trastuzumab biosimilar would be facilitating access to treatment for patients with ERBB2-positive breast cancer and gastric cancer around the world who now are untreated because of prohibitive costs," write Harold J. Burstein, M.D., Ph.D., and Deborah Schrag, M.D., M.P.H., of Harvard Medical School, Boston, and Associate Editor, *JAMA* (Dr. Schrag) in an accompanying editorial. "Unless the price of the trastuzumab biosimilar is set considerably lower than the 25 percent to 30 percent discounts typically seen during the last decade for biosimilars entering European markets, treatment will remain inaccessible for far too many patients."

This study "opens the pathway to therapeutic biosimilars in oncology and should facilitate market forces that lead to lower drug prices. Hopefully, this competition will be sufficient to make trastuzumab and other biologics more affordable and thereby make cancer care both more effective and more equitable around the world."

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