FDA Approves New Formulation of Herceptin for Subcutaneous Use

HannaH trial demonstrated that Herceptin Hylecta was comparable to intravenous trastuzumab.

February 28, 2019 By Food and Drug Administration (FDA)

On February 28, 2019, the Food and Drug Administration approved trastuzumab and hyaluronidase-oysk injection,for subcutaneous use (Herceptin Hylecta, Genentech Inc.). Herceptin Hylecta is a combination of trastuzumab, a HER2/neu receptor antagonist, and hyaluronidase, an endoglycosidase, for the treatment of HER2-overexpressing breast cancer.

Approval was based on two randomized trials, HannaH (NCT00950300) and SafeHER (NCT01566721). In HannaH, 596 patients with HER2-positive operable or locally advanced breast cancer, including inflammatory breast cancer, were randomized to receive 8 cycles of either Herceptin Hylecta or intravenous trastuzumab concurrently with chemotherapy, followed by surgery and continued therapy with either Herceptin Hylecta or intravenous trastuzumab, for an additional 10 cycles.

HannaH demonstrated comparability between Herceptin Hylecta and intravenous trastuzumab based on co-primary endpoints of pathologic complete response and pharmacokinetics. Pathological complete response (pCR) was observed in 118 patients (45.4%) on the Herceptin Hylecta arm and in 107 patients (40.7%) receiving intravenous trastuzumab (95% CI for difference in pCR: -4.0; 13.4).

SafeHER was a prospective, two-cohort, non-randomized, multinational, open-label trial assessing the overall safety and tolerability of Herceptin Hylecta with chemotherapy in 1,864 patients with HER2-positive breast cancer. Patients received a fixed dose of 600 mg Herceptin Hylecta every 3 weeks for 18 cycles. Herceptin Hylecta was initiated either sequentially with chemotherapy, concurrently with chemotherapy, or without adjuvant chemotherapy, or in combination with neoadjuvant chemotherapy followed by trastuzumab.

The most common adverse reactions of Herceptin Hylecta observed in at least 10% of patients were fatigue, arthralgia, diarrhea, injection site reaction, upper respiratory tract infection, rash, myalgia, nausea, headache, edema, flushing, pyrexia, cough, and pain in extremity.

The recommended Herceptin Hylecta dose is 600 mg/10,000 units (600 mg trastuzumab and 10,000 units hyaluronidase) administered subcutaneously over approximately 2-5 minutes once every three weeks.

View full prescribing information for Herceptin Hylecta.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

Follow the Oncology Center of Excellence on Twitter @FDAOncology.

This announcement was originally posted on the Food and Drug Administration website.

© 2026 Smart + Strong All Rights Reserved.

http://beta.docker.cancerhealth.com/blog/fda-approves-new-formulation-herceptin-subcutaneous-use