BioSpectrum the business of Bio & Health Sciences

Halozyme gets FDA approval for Herceptin Hylecta™

04 March 2019 | News

Herceptin Hylecta™ is approved for the treatment of certain people with HER2-positive early breast cancer

Halozyme Therapeutics, a biotechnology company developing novel oncology and drug-delivery therapies, has announced that Genentech, a member of the Roche Group, has received approval from the U.S. Food and Drug Administration (FDA) for Herceptin Hylecta™, a subcutaneous fixed-dose combination of trastuzumab and hyaluronidase-oysk.

Herceptin Hylecta™ is approved for the treatment of certain people with HER2-positive early breast cancer (node-positive, or node-negative and ER/PR-negative or with one high-risk feature) in combination with chemotherapy and HER2-positive metastatic breast cancer in combination with paclitaxel or alone in people who have received one or more chemotherapy regimens for metastatic disease.

Herceptin Hylecta™ is a co-formulation of trastuzumab with Halozyme's proprietary recombinant human hyaluronidase enzyme (ENHANZE® technology). Herceptin Hylecta™ is a ready-to-use formulation that can be administered in two to five minutes, compared to 30 to 90 minutes for intravenous trastuzumab.

Halozyme's proprietary ENHANZE® drug-delivery technology is based on its patented recombinant human hyaluronidase enzyme (rHuPH20). rHuPH20 has been shown to remove traditional limitations on the volume of biologics that can be delivered subcutaneously (just under the skin). By using rHuPH20, some biologics and compounds that are administered intravenously may instead be delivered subcutaneously. ENHANZE® may also benefit subcutaneous biologics by reducing the need for multiple injections. This delivery has been shown in studies to reduce health care practitioner time required for administration and shorten time for drug administration.