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Roche subcutaneous Herceptin gets EU nod

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Singapore: The European Commission has granted Roche European Union (EU) marketing authorization for the use of a time-saving subcutaneous (SC) formulation of Herceptin (trastuzumab) for the treatment of HER2-positive breast cancer.

The formulation utilizes Halozyme's recombinant human hyaluronidase (rHuPH20) and is administered in two-to-five minutes, rather than 30-to-90 minutes with the standard intravenous form.

The European Commission's approval was based on data from the HannaH study which showed that the subcutaneous formulation of Herceptin was associated with comparable efficacy (pathological complete response, pCR) to Herceptin administered intravenously in women with HER2-positive early breast cancer and resulted in non-inferior trastuzumab plasma levels.

Overall, the safety profile in both arms of the HannaH study was consistent with that expected from standard treatment with Herceptin and chemotherapy in this setting. No new safety signals were identified.

Dr Gregory I Frost, president and chief executive officer, Halozyme, said that, "This approval is great news for the more than 80,000 patients who receive treatment with Herceptin each year in the EU. The reduced administration time and enhanced convenience may enable patients in the EU to spend less time in the hospital while also increasing efficiency for physicians and other health care providers. We're excited that patients will soon benefit from this application of Halozyme's technology."