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FDA approves Roche's BLA for combination treatment of breast cancer

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Fixed-dose combination administered under the skin in just minutes, compared to hours with intravenous administration, significantly reducing time spent receiving treatment US Food Drug and Administration is expected to decide on approval by 18 October 202

Roche has announced that the US Food and Drug Administration (FDA) has accepted the company's Biologics License Application (BLA) for the fixed-dose combination (FDC) of Perjeta® (pertuzumab) and Herceptin® (trastuzumab) with hyaluronidase, administered by subcutaneous (SC) injection in combination with intravenous (IV) chemotherapy, for the treatment of eligible patients with HER2-positive breast cancer. The BLA for the FDC is based on results from the phase III FeDeriCa study, which demonstrated non-inferior levels of Perjeta in the blood (pharmacokinetics) and comparable efficacy and safety to standard IV infusions of Perjeta plus Herceptin and chemotherapy.

"For more than two decades, our medicines have redefined the standard of care for people with HER2-positive breast cancer," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Today's acceptance builds upon our commitment by potentially offering patients a faster way to administer Perjeta and Herceptin. We're working with the FDA to bring this treatment option to patients as quickly as possible."

SC administration of the FDC takes approximately eight minutes for the initial loading dose and approximately five minutes for each subsequent maintenance dose.[1] This is compared to approximately 150 minutes for infusion of a loading dose of Perjeta and Herceptin using the standard IV formulations, and between 60-150 minutes for subsequent maintenance infusions of the two medicines.[2,3,4]

The FeDeriCa study met its primary endpoint, with SC administration of the FDC showing non-inferior levels of Perjeta in the blood during a given dosing interval (Ctrough) when compared to IV administration of Perjeta. A secondary endpoint of non-inferior Ctrough of Herceptin was also met. A non-inferiority endpoint was chosen for the study to ensure that people were receiving sufficient dosing with Perjeta and Herceptin as compared to the established IV doses at the same treatment intervals. In addition, rates of total pathological complete response (pCR), another secondary endpoint, were comparable between the treatment arms. The safety profile of the FDC in combination with chemotherapy was comparable to that of IV administration of Perjeta plus Herceptin and chemotherapy and no new safety signals were identified, including no

meaningful difference in cardiac toxicity. The most common adverse events in both arms were alopecia, nausea, diarrhoea and anaemia.[1]

In previous studies of other SC formulations, SC administration has been shown to be strongly preferred by the majority of patients compared to IV administration of the same medicine, with the most common reason being that administration required less time in the clinic.[5,6] In the PHranceSCa study, Roche is currently investigating patient preference for SC administration of the FDC compared to standard IV administration of Perjeta and Herceptin in people with HER2-positive early breast cancer (eBC).[7] Interim results of this phase II study will be presented at a future medical meeting.