BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

# EC approves Roche's Perjeta for HER2-positive early breast cancer

June 3, 2018 | News

**HER2-positive breast cancer affects almost 100,000 women in Europe each year**




Global drug giant, Roche recently announced that the European Commission has approved Perjeta (pertuzumab) in combination with Herceptin (trastuzumab) and chemotherapy (the Perjeta-based regimen) for post-surgery (adjuvant) treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence.

High risk of recurrence is defined as lymph node-positive or hormone receptor-negative disease. The Perjeta-based regimen should be administered for a total of one year (up to 18 cycles) as part of a complete regimen for eBC and regardless of the timing of surgery.

HER2-positive breast cancer affects almost 100,000 women in Europe each year. The majority of these cases are diagnosed at an early stage, when the aim of treatment is cure. While significant advances have been made in treating HER2-positive eBC, around one in four patients treated with Herceptin and chemotherapy will eventually see their disease return in the long-term. It is estimated that two out of three cases of HER2-positive advanced breast cancer (aBC) are a result of recurrence, as opposed to aBC being the initial diagnosis. There is no cure for breast cancer that recurs and reaches an advanced stage; in these cases, treatment is aimed at prolonging life for as long as possible.

“Despite advances in the treatment of HER2-positive early breast cancer, many people still have a recurrence and progress to an incurable stage. In the early breast cancer setting, where the ultimate goal is cure, it is critical that we continue building on existing therapies,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “Today’s approval is great news, as we believe the Perjeta-based regimen has the potential to make a significant impact on

the lives of people with HER2-positive early breast cancer who are at high risk of recurrence.”

The EC approval is based on results from a large phase III study (APHINITY), involving over 4,800 people with HER2-positive eBC, which showed that the Perjeta-based regimen significantly reduced the risk of invasive breast cancer recurrence or death as compared to Herceptin and chemotherapy alone in the overall study population.

The Perjeta-based regimen is already approved in the US and several other countries for adjuvant treatment of HER2-positive eBC at high risk of recurrence. The combination has also been previously approved for the treatment of people with advanced HER2-positive breast cancer, where it has been shown to significantly extend survival compared to Herceptin and chemotherapy alone.