

World Congress on **Breast Cancer**

August 03-05, 2015 Birmingham, UK

Neoadjuvant therapy for early stage breast cancer: A new pathway to registration?

Graham Ross

Roche Products Limited, UK

One of the paradoxes in oncology research is that the more successful we are, the longer it takes to prove the clinical value of new treatments. Breast cancer is a very good example: from the time docetaxel was registered as a treatment for metastatic breast cancer, it took five years to define its role in the adjuvant treatment of early stage breast cancer; from the time trastuzumab was registered as a treatment for metastatic HER2 positive breast cancer it took eight years to establish its role in adjuvant therapy. It is imperative that we come up with strategies to accelerate the development process and to make new active therapies available to patients, especially in the era of molecular sub-typing and targeted therapies. Both the FDA and the EMA issued draft guidelines in 2014 on the potential for accelerated approval or approval with agreed conditions, respectively, based on the use of pathological Complete Response (pCR) following neoadjuvant therapy, provided that certain criteria are met (for example the population treated needs to be at high risk of relapse, there has to be a convincing increase in the rate of pCR preferably by “adding on” to standard therapy in randomized studies, the mode of action has to be well characterized, the additional toxicity must be “minor” and a suitable confirmatory study needs to be well underway). HER2 positive breast cancer is a good model for testing this potential new pathway, and the positive lessons as well as caveats and disappointments will be discussed.

Biography

Graham Ross was trained in Durban, South Africa in the Department of Radiotherapy and Oncology. For 20 years he has worked in medicines development in the pharmaceutical industry, the last nine years as the Global Clinical Science Leader for the development of pertuzumab. He has worked on the development of several compounds in various indications including small cell lung cancer, ovarian cancer, breast cancer and the management of emesis. He is a Fellow of the Faculty of Pharmaceutical Medicine.

Notes: