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Roche / Genentech's "Magic Bullet" in HER2+ Breast Cancer

3 Jun 2012, by Gordon Gochenauer

HER2-targeted therapy was the star of the show at today's plenary session at the 2012 ASCO meeting. T-DM1 (trastuzumab emtansine) is Genentech / Roche's antibody-drug conjugate, consisting of a potent microtubule polymerization inhibitor conjugated to the trastuzumab monoclonal antibody via a highly stable linker. T-DM1 is designed to take advantage of the targeted nature of the antibody to selectively deliver the cytotoxic agent to HER2+ breast cancer cells. Roche is hoping that T-DM1 will further expand their franchise in HER2+ breast cancer. Roche's other product, Herceptin (trastuzumab), currently dominates the HER2+ market, with about 70% utilization in front-line HER2+ metastatic breast cancer patients.† Although Tykerb® (lapatinib, GlaxoSmithKline) is approved in the second-line in combination with Xeloda® (capecitabine, Roche), about half of U.S. physicians choose to rechallenge with Herceptin plus chemotherapy, leaving Tykerb for later-lines of therapy.†

In today's presentation (LBA1), Roche / Genentech wowed the audience with the impressive results from the EMILIA study, which evaluated TDM-1 monotherapy versus Xeloda plus Tykerb (XT) in relapsed HER2+ metastatic breast cancer patients. TDM-1 showed a progression-free survival (PFS) benefit of 9.6 months versus 6.4 months with XT (HR=0.650, $p<0.0001$) and improved overall survival - although the median was not yet reached in the TDM-1 arm, the OS was 23.3 months in the XT-arm (HR=0.621, $p=0.0005$). Adding to the excitement was the improved toxicity profile of TDM-1, showing lower rates of Grade 3 Adverse Events (41% versus 57%), very little gastrointestinal toxicity, and only liver toxicity was increased compared to XT. It would appear that the XT-arm underperformed in EMILIA compared to the Phase III registration-enabling trial for Tykerb, in which XT showed a 8.4 month PFS. Hopefully more detailed future analyses will shed some light on reasons for the apparent discrepancy in XT performance. A cursory analysis of the presented patient demographics does not afford an explanation as the demographics were comparable and discontinuation rates were similar between the two studies.

Based on this impressive data, it will be interesting to see exactly where TDM-1 fits into the treatment paradigm once it is approved. With the success of the CLEOPATRA trial and Perjeta's (pertuzumab, Roche / Genentech) impending approval in combination with first-line Herceptin, this raises the question of whether TDM-1 will occupy the second-line after Herceptin/pertuzumab, or will Herceptin "rechallenge" remain the second-line treatment of choice, followed by third-line TDM-1? Where will Tykerb fit in? The treatment paradigm in first-line may change again soon, as Roche is studying TDM-1 with or without Perjeta and compared to Herceptin plus Perjeta and taxane in the MARIANNE study. Whichever scenario comes to fruition, it is evident that Roche / Genentech have been successful in muscling out most competitors in this tumor subtype, and TDM-1 gives the company some protection from potential future biosimilar competition that they face for Herceptin.

† Utilization data from the 2011 Kantar Health CancerMPact® U.S. Treatment Architecture.

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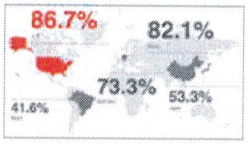

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