Shionogi: S-222611 (Phase I/II/HER+ Breast Cancer) a Good Candidate for Licensing; Potential to Expand Its Usage Beyond Breast Cancer

Shionogi’s R&D briefing provided updates on drug development research results and the company's pipeline. In drug development research, Shionogi is focusing on treatments for metabolic and infectious diseases, and analgesics. Groundbreaking new drugs for influenza, infections, neuralgia, and to prevent obesity are at the non-clinical trial stage. The briefing focused on the main development drugs undergoing clinical trials: naldemedine (S-297995), which eases constipation arising from the use of opioid analgesics, acute gram-negative bacterial infection remedy S-649266, and anti-cancer/reversible HER2/EGFR tyrosine kinase inhibitor S-222611.

The most promising of the three is S-222611. The drug proved to be a highly effective tumor treatment in Phase 1. Combined Phase 1/2 trials with HER2 positive breast cancer are being prepared, and we gather the drug will likely exhibit high clinical efficacy in treatment of other solid carcinomas. It is also possible that from Phase 2, Shionogi will license the drug out and embark on joint development with companies that are strong in oncology drugs in Europe and the U.S.

S-222611 for tumors with over-expression of HER2/EGFR in Phase I/II. Profile of the compound:
- Action mechanism: reversible HER2/EGFR tyrosine kinase inhibitor
- Selective and strong inhibitory effect against HER2 and EGFR (non-clinical)
- Superior anti-tumor activities with other approved drugs with the same action mechanism (non-clinical)
- Superior anti-tumor activity in intra-femur and intra-cranial implantation models in comparison to other approved drugs with the same action mechanism (nonclinical)

Phase I repeated dose study in EU: Confirmed good safety profiles in humans at doses far exceeding those at which anti-tumor activities were observed in animal models.

Phase I extension study: Observed anti-tumor activities in patients who treated with Herceptin or with Kadcyla by Roche, with Tykerb by GSK, and both with Herceptin and Tykerb.

Source: Credit Suisse/Sakai & Jefferies/Kumagai, March 19, 2014
Oncology Indication: Breast
Keyword: Clinical Trials/Pipeline