FDA stalls ImmunoGen-linked breast cancer therapy approval

Mass High Tech: The Journal of New England Technology

The U.S. Food and Drug Administration has sent a Refuse to File letter to Genentech Inc., which is licensing Targeted Antibody Payload (TAP) technology from Waltham-based ImmunoGen Inc., for accelerated approval of its breast cancer treatment. The Biologic License Application is for the drug trastuzumab-DM1 (T-DM1), which is being developed by Roche Holding AG for treatment of advanced HER2+ breast cancer.

According to a press release [1] from ImmunoGen, the FDA's letter indicated that the drug did not qualify for accelerated approval since other possible treatments for metastatic breast cancer were not used in the study.

T-DM1 will continue to be tested in its current Phase 3 clinical trial, where the drug is being compared to another HER2+ breast cancer treatment – lapatinib in combination with capecitabine. The initiation of the Phase 3 trial, announced in March 2009, resulted in a $6.5 million milestone payment [2] for ImmunoGen (Nasdaq: IMGN) from Genentech and Roche.

SOURCE [3]

Links:
[1] http://phx.corporate-ir.net/phoenix.zhtml?c=97573&p=irol-newsArticle&ID=1464217&highlight=
[2] http://www.masshightech.com/stories/2009/03/02/daily10-ImmunoGen-due-for-65M-milestone-pay.html
[3] http://www.masshightech.com/stories/2010/08/23/daily40-FDA-stalls-ImmunoGen-linked-breast-cancer-therapy-approval.html