

Glenmark's Bi-Specific Antibody - GBR 1302 to enter Phase I trials

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Glenmark Pharmaceuticals S.A. (GPSA), a wholly owned subsidiary of Glenmark Pharmaceuticals Limited India (GPL), announces the completion of Phase 1 supporting studies and the submission of a clinical trial application to the Paul-Ehrlich Institute in Germany with a novel clinical development candidate, GBR 1302. GBR 1302 is a HER2xCD3 bi-specific antibody based on Glenmark's proprietary BEAT platform. GBR 1302 is the first clinical development candidate based on the BEAT technology. Glenmark expects to obtain approval for the initiation of clinical studies with GBR1302 during this financial year.

GBR 1302 material for Phase 1 clinical trials was manufactured in Glenmark GMP production unit in Switzerland. HER2, also known as HER2/neu, or receptor tyrosine-protein kinase erbB-2, is the target of the antibody cancer drugs trastuzumab, pertuzumab and trastuzumab emtansine and is implicated in breast cancer, ovarian, gastric, and certain uterine cancers.

Commenting on this milestone, Dr Michael Buschle, chief scientific officer and president - Biologics, Glenmark Pharmaceuticals said, "We have high expectations for GBR 1302. During the preclinical characterization of the bi-specific antibody we have discovered that GBR 1302 does not only kill trastuzumab resistant cancer cells, but also very efficiently kills cancer cells with a weak expression of HER2 against which all current HER2 targeting antibodies are not effective."

GBR 1302's mode of action is different from current HER2 targeting antibodies. It redirects cytotoxic T cells through its CD3 binding arm onto HER2 expressing cancer cells and induces the killing of the cancer cells. Preclinically, the killing of cancer cells by GBR 1302 is more rapid, more complete and not expected to be subject to the same resistance escape mechanisms as therapies directed against HER2.