

Eisai subsidiary opens antibody facility in the US

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Eisai subsidiary opens antibody production plant in the US



Singapore: Eisai's US subsidiary Morphotek has opened a new pilot manufacturing plant in Exton, Pennsylvania, for the production of antibodies to support its early-stage clinical trials. The plant gives Eisai the ability to manufacture biologics in-house, which will help shorten therapeutic antibody development time for the company and ensure early delivery of treatments.

Constructed with an investment of \$80 million on a site located next to Morphotek's current headquarters, the new 60,000-square foot facility encompasses a pilot plant designed according to current Good Manufacturing Practice (cGMP) regulations enforced by the US Food and Drug Administration (FDA), labs to support cell line optimization and product characterization, labs for quality assurance and control, and office space for support functions.

Among those present at the launch were Mr Haruo Naito, president and CEO, Eisai; Mr Christopher Molineaux, president, Pennsylvania Bio; Mr Hideki Hayashi, deputy president and chief product creation officer, Eisai; Mr Nicholas Nicolaides, president and CEO, Morphotek; Mr Philip Sass, executive vice president and COO, Morphotek; Ms Joye Bramble, vice president, pilot plant operations, Morphotek; Pennsylvania State Senator Mr Andy Dinniman; Mr Eli Avila, Pennsylvania Secretary of Health, and Mr Luigi Grasso, chief scientific officer, Morphotek.

Morphotek, which outsourced the manufacturing of antibodies to support clinical trials up until now, will undertake its antibody production in-house. The plant has been designed to enable Morphotek to undertake the manufacture multiple investigational antibodies simultaneously, thereby accelerating early-stage clinical research of novel therapeutic antibodies being undertaken by Eisai group and maximizing efficiencies in the product creation process.

The new facility is scheduled to commence production operations before the end of 2012, and following process validation, will begin to manufacture antibodies for use in clinical trials during the first half of fiscal 2013.

Morphotek specializes in the research and development of therapeutic antibodies primarily for the treatment of cancer through the use of its proprietary human antibody production technology and active engagement in partnership-based collaborative research. The company currently has a number of promising monoclonal antibodies in clinical development, including farletuzumab (MORAb-003), in phase III development for platinum-sensitive ovarian cancer and phase II development for non-small cell lung cancer, MORAb-004, in phase II development for melanoma, colorectal cancer and

sarcoma, and MORAb-009, in Phase II development for mesothelioma.