

## TaiMed Biologics taps on humanized mAb for HIV therapy

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Publicly-held biotech company TaiMed Biologics was set up in 2007 with the mission to discover, develop and deliver innovative medicines that help patients prevail over serious infectious diseases, by acquiring the patent of TMB 355 drug from Genentech.

TMB-355 (Ibalizumab), a humanized monoclonal antibody (mAb) and a member of an emerging class of HIV therapies known as viral-entry inhibitors, has passed through the hands of three companies (Biogen, Tanox and Genentech) before being bought by TaiMed Biologics. This drug candidate is distinct from other entry inhibitors as it binds to the CD4 molecule, the primary receptor for HIV infection, thereby interfering with the penetration of the virus into the cell. It is the first entry-blocking humanized mAb to treat HIV/AIDS.

TaiMed Biologics has won the BioSpectrum Asia Pacific Bioscience Industry Emerging Company of the Year Award for 2012.

TMB-355 caught the attention of the scientific community in February 2003, when results from the phase I single-dose clinical trial showed a transient but clinically significant reduction in the patients' viral load. Moreover, it was well tolerated with no evidence of adverse effects on CD4 T-cells of treated subjects unlike the majority of approved drugs for HIV.

TaiMed Biologics has made much progress in its short existence, under the guidance of its scientific founder and chief

scientific officer Dr David Da-i Ho, an AIDS researcher. "It is because of the outstanding management team with industry experience in both Taiwan and the US that TaiMed could complete the TMB 355 phase IIa and IIb studies for treating patients with AIDS. In addition, in collaboration with the Aaron Diamond AIDS Research Center, the development of Ibalizumab for prevention of HIV infection was explored in a phase I trial in the second half of 2010. This project has received grant funding from the Bill and Melinda Gates Foundation," says Dr James Chang, president and CEO, TaiMed Biologics.

On the current status of TMB-355, Dr James Chang says, "A 113-patient phase IIb clinical trial of patients with multiple drug resistant HIV-1 infections was completed in January 2011. The primary efficacy endpoint is the proportion of patients achieving undetectable viral loads at week 24. Secondary objectives include evaluation of changes in viral load, CD4+ cell counts, TOLVR, PK sensitivity, susceptibility and safety."

TaiMed Biologics intends to seek a partner for phase III development which is expected to begin by 2012 using multinational clinical sites including Taiwan. The company plans to file biologics license application for Ibalizumab to the US FDA and to launch the commercial product by the end of 2013. In addition to TMB-355, TaiMed has been working on TMB- 607/TMB - 657 and TMB-571.

During the first half of 2011, TaiMed Biologics signed a definitive agreement with a Canadian publicly-held biotechnology company, Ambrilia Biopharma, under which TaiMed Biologics will acquire exclusive worldwide rights to manufacture, develop and commercialize both protease inhibitor (PI) and integrase inhibitor programs for HIV. The PI program includes PPL-100, which has been shown to possess advantageous properties, such as a high genetic barrier, low cross-resistance profile and no requirement for ritonavir, boosting phase I trials.

(inputs from Vipul Murarka)