

Takeda resubmits NDA to the US FDA for alogliptin

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Singapore: Takeda Global Research & Development Center resubmitted New Drug Applications (NDAs) to the US FDA for alogliptin and fixed-dose combination (FDC) alogliptin and pioglitazone. Takeda anticipates that these applications will be reviewed within the next six months. These NDAs were resubmitted in response to the complete response letter Takeda received from the FDA, dated April 25, 2012.

Dr David Recker, senior VP, clinical science, Takeda Global Research & Development Center, said that, "Takeda was able to respond to the FDA promptly with significant new data from our ongoing clinical trial program and updated postmarketing data from outside the US."

"Based on our meeting with the FDA in late June, Takeda believes the information included in the NDA resubmissions for alogliptin and the fixed-dose combination alogliptin and pioglitazone will address the Agency's request for additional data, and these investigational therapies remain a top priority for the company," Dr Recker said.

This 2012 resubmission includes additional data from three phase III clinical trials involving more than 3,275 patients conducted at 1,384 centers worldwide. When combined with previously submitted phase III clinical data, which included more than 8,000 patients conducted in more than 1,000 centers worldwide, nearly 10,000 patients have been treated with alogliptin in the clinical development programs to date.

The most common adverse events (greater than or equal to five percent and greater than placebo) reported in the alogliptin

phase III program include headache, urinary tract infection, nasopharyngitis, and upper respiratory tract infection. With regard to the co-administration of alogliptin and pioglitazone, common adverse events (greater than or equal to five percent) reported include nasopharyngitis, back pain, urinary tract infection, and influenza.