BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Abbvies' brain tumour drug gets orphan drug status

August 7, 2014 | Regulatory | By BioSpectrum Bureau



Singapore: The drug maker Abbvie, has stated that both the US Food and Drug Administration (USFDA) and European Medicines Agency (EMA) have approved ABT-414, an anti-epidermal growth factor receptor antibody drug conjugate, as a treatment for patients with glioblastoma multiforme.

Every year in the US and Europe, two to three out of every 100,000 people are diagnosed with glioblastoma multiforme, the most common and most aggressive type of malignant primary brain tumour. The tumor has a five-year survival rate of just four percent and the treatment options are limited.

Early clinical data for ABT-414 looks promising. In a Phase I trial presented at ASCO's annual meet earlier this year, preliminary responses were noted in three out of nine patients administered the drug. The results included two partial and one complete response. Phase II studies are currently being planned.