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Singapore:Ã?Â Pharma giant Pfizer has received a complete response letter from the US Food and Drug Administration (FDA) on its New Drug Application (NDA) for tafamidis meglumine. The agency is requesting the completion of a second efficacy study to establish substantial evidence of effectiveness prior to an approval. The agency has also asked for additional information on the data within the current tafamidis NDA. Pfizer will work with the FDA to address the content of the letter. Tafamidis is a novel, investigational medication for the treatment of Transthyretin Familial Amyloid Polyneuropathy (TTR-FAP) in adult patients with symptomatic polyneuropathy to delay neurologic impairment.

The European Commission (EC) approved VYNDAQEL (tafamidis) for the treatment of TTR-FAP in adult patients with stage 1 symptomatic polyneuropathy on November 16, 2011. In the US, there is no FDA-approved treatment for TTR-FAP.

"TTR-FAP is a relentless and debilitating disease. We understand the urgent need within the patient community and stand firmly behind this innovative medicine," said Dr. Yvonne Greenstreet, senior vice president and head of Medicines Development Group for Pfizer's Specialty Care Business Unit. "It is our intention to request a meeting as soon as possible with the Agency in order to discuss a potential path forward."

TTR-FAP is a rare, progressive and fatal neurodegenerative disease that affects approximately 8,000 patients worldwide. Because it is a hereditary disease, family members may also be at risk for developing the disease.