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ASIA EDITION

Study shows Lipitor well-tolerated among Asians

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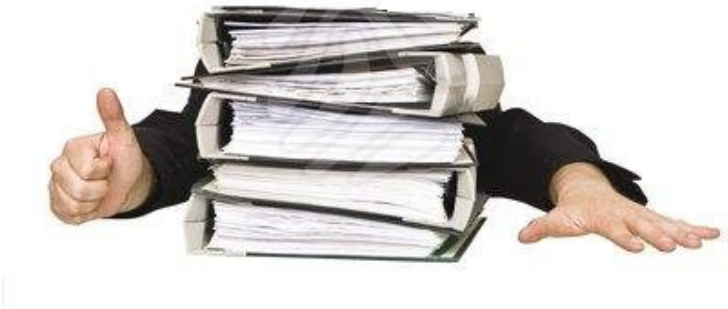

Singapore: A large-scale retrospective database analysis on atorvastatin (Lipitor) by Astellas Pharma and Pfizer Japan has demonstrated that atorvastatin is as well tolerated by the Asian population as it is by the overall study population at all approved doses. The data were released at the 23rd Great Wall International Congress of Cardiology in Beijing.

Asia is facing a heart-health crisis, with heart disease, heart attack and stroke being major causes of death. In Southeast Asia, for example, an estimated 3.6 million deaths are due to cardiovascular diseases. In fact, people in the region die from cardiovascular diseases at relatively young ages, with 27 percent of all deaths due to cardiovascular diseases occurring before the age of 60 years,compared to 16 percent in the rest of the world.

In a region where changing demographics and lifestyle drive an increasing incidence of cardiovascular diseases, concerns about tolerability may mean that treatment is not optimized to achieve the goals set out by international guidelines, leaving many Asians at unnecessary risk of cardiovascular events. Even though the benefit and safety profile of atorvastatin were established through many international clinical trials and clinical experience over 20 years, the safety data on Asian people (compared to those on non-Asians) was so far limited in scope.

This analysis was the first large-scale database analysis performed to investigate the tolerability of atorvastatin at all approved doses in the overall subject population and in Asians in particular.

In this retrospective analysis, 77,949 patients (including 3,191 Asian patients) in 58 atorvastatin clinical trials were included. Of these, 2,519 Asian patients received atorvastatin treatment. Out of the 58 clinical trials, the outcomes of the six long-term trials (median duration from 3.1 to 4.9 years) were analyzed individually and the 52 short-term trials (median duration from 4 to 72 weeks) that had included atorvastatin at doses ranging from 10 mg to 80 mg were pooled and analyzed by category.

Asians, Orientals, South Asians, Indians and Pacific Islanders were included in the study. Japanese people were not part of this analysis.

A separate analysis was performed on five trials that had been carried out in several countries and a region in Asia (China, South Korea, Taiwan, Thailand and the Philippines) that had enrolled Asian subjects only. The analysis did not find any evidence indicating increased rates of adverse events in the Asian population compared with rates in the overall patient population. The rates of adverse events, serious adverse events, and discontinuations due to adverse events were similar for the Asian
population and the overall patient population. Also, a dose-response relationship in adverse events was not found for the Asian population.

The most frequently reported adverse event in the Asian population and the non-Asian population was gastrointestinal dysfunction. Among patients treated with atorvastatin, the incidence of adverse effects in the muscular system was lower in the Asian population than in the overall patient population, the incidence of myalgia being 8 percent among non-Asian patients and 6.7 percent among Asian patients.

Among Asian patients, treatment-related serious adverse events were extremely rare, and no occurrence of rhabdomyolysis was found. For patients treated with atorvastatin, rates of elevations in liver enzymes for Asian patients were similar for the Asian population and the overall patient population.