SINGAPORE, 26 February 2009

HSA UPDATES

"HSA UPDATES" addresses topics of current public interest, and is subject to change as more information becomes available.

HSA UPDATES NO 1/2009

HSA REQUESTS MERCK TO SUSPEND THE SALES OF EFALIZUMAB (RAPTIVA®)

The Health Sciences Authority (HSA) has requested Merck Pte Ltd to suspend the sales of efalizumab Raptiva® in Singapore with effect from 26 February 2009 owing to concerns of new safety issues associated with the product.

2 Raptiva® is available locally as a prescription medicine. It contains the active ingredient, efalizumab, a biological product, used for the treatment of adult patients with moderate to severe chronic plaque psoriasis. Plaque psoriasis is a disease causing red, scaly patches on the skin.

RECENT SAFETY FINDINGS

3 Based on the assessment of data available to-date, HSA and its Pharmacovigilance Advisory Committee have concluded that the risks of Raptiva® outweigh its benefits in the treatment of plague psoriasis. Raptiva® is reported to be associated with rare but serious adverse effects such as Progressive Multifocal Leukoencephalopathy (PML) and other serious adverse effects relating to infections and disorders that damage the nerves and the brain. PML is a rare disease affecting the muscles and nerves caused by opportunistic infections that usually lead to severe disability or death. To-date, there have been four worldwide reports of PML (three confirmed and one suspected) associated with the product in patients who had been continuously treated with Raptiva® for three or more years. Two of the three confirmed cases resulted in the patients' death.

4 In its assessment, HSA has also considered the fact that plague psoriasis is a potentially serious but rarely life-threatening medical condition, and that there are many alternatives available for the treatment of plague psoriasis. The risk of potentially fatal adverse effects reported with Raptiva® is hence unacceptable in view of Raptiva®'s modest benefits.

5 The sale of Raptiva® has also been recently suspended in Europe and Canada by the European Medicines Agency (EMEA) and Health Canada

respectively. Both agencies have also considered the risk-benefit profile of Raptiva® to be unfavourable.

6 To-date, HSA has not received any local adverse drug reaction reports associated with Raptiva®.

HSA'S ADVISORY

7 Patients who are taking this medicine should consult their doctors as soon as possible to assess the most appropriate treatment alternative based on their individual medical situation and needs. They should not change or stop their treatment without first consulting their doctor as abrupt discontinuation of Raptiva® without alternative treatment may lead to a return of psoriasis or onset of new psoriasis.

8 Healthcare professionals are advised not to start new patients on Raptiva®. For those patients currently taking the drug should, however, not have their therapy discontinued abruptly. Instead, healthcare professionals are advised to review the treatment of patients currently taking this drug to assess the most appropriate alternatives as soon as possible. They should monitor their patients who have been treated with Raptiva® closely for neurological symptoms and symptoms of infection.

9 For further clarifications, members of the public may contact the Merck Pte Ltd's hotline at 6890 6701.

HEALTH SCIENCES AUTHORITY
26 February 2009

- **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation's blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit www.hsa.gov.sg

- **About the Health Products Regulation Group (HPRG)**

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards.

- **About HSA Updates**

The "HSA Updates" seeks to provide current information, in a consistent and accurate manner, on topics of public interest. For all issues of HSA Updates, please visit www.hsa.gov.sg, click "News & Events", and select "HSA Updates".

Media representatives are welcome to send any queries to the Corporate Communications Department @ HSA.