

5th August 2009

Dr. Almath Spooner  
Pharmacovigilance Unit  
Irish Medicines Board  
Earlsfort Terrace  
Dublin 2

### **Important Safety Information about EFIENT® (prasugrel)**

Dear Dr. Spooner,

Daiichi-Sankyo and Lilly wish to inform you about important prescribing information about EFIENT® (prasugrel).

#### **Indication**

Efient, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in patients with acute coronary syndrome (i.e. unstable angina, non-ST segment elevation myocardial infarction [UA/NSTEMI] or ST segment elevation myocardial infarction [STEMI]) undergoing primary or delayed percutaneous coronary intervention (PCI).<sup>(1)</sup>

#### **Results of the pivotal registration study TRITON-TIMI 38**

The TRITON-TIMI 38 study included 13,608 patients with ACS (UA/NSTEMI and STEMI) undergoing PCI comparing prasugrel with clopidogrel to assess efficacy and safety by measuring the incidence of a composite endpoint (cardiovascular death, nonfatal MI, or nonfatal stroke). In the study, EFIENT® (prasugrel) significantly reduced the incidence of the primary endpoint by 2.2% (absolute risk reduction).<sup>(2)</sup>

#### **Important Safety Information**

Prasugrel's superior efficacy compared to Clopidogrel was accompanied by a significant increase in the incidence of severe (including fatal) haemorrhagic events by 0.6% (absolute risk increase). Analysis of the data highlighted two patient subgroups at increased risk; elderly patients,  $\geq 75$  years of age and patients with a low body weight ( $< 60$  kg).


As a consequence, the following **maintenance** doses are recommended:

- Efient 10mg is recommended for patients  $< 75$  years of age. Alternative therapies should be considered for patients  $\geq 75$  years of age. If, after a careful individual benefit/risk evaluation by the prescribing physician, treatment is deemed necessary in patients  $\geq 75$  years of age, a reduced maintenance dose of 5mg should be prescribed.
- A reduced dose of Efient 5mg is recommended for patients  $< 60$  kgs. The evidence for a 5mg dose is based on PK/PD analysis and no clinical data currently exist on the safety of this dose in the at risk sub groups.
- Efient 60mg is the recommended **loading** dose for all patients commenced on Efient.

Please find attached the Summary of Product Characteristics.

If you have any further questions, please do not hesitate to contact Lilly at 01 5245108.

Kind Regards,



Dr. Harald Vangerow,  
Clinical Research Physician, Lilly Cardiovascular UK & Republic of Ireland

#### References

- <sup>1)</sup> Summary of Product Characteristics
- <sup>2)</sup> Wiviott et al. *NEJM* 2007; 357(20):2001-2015 - Please note that the licenced loading dose of clopidogrel is 300mg.