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## **GSK UPDATE ON FDA REVIEW OF PROMACTA® (ELTROMBOPAG)**

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GlaxoSmithKline today announced that the United States Food and Drug Administration (FDA) continues to review the new drug application for PROMACTA® (eltrombopag) beyond the September 19, 2008 action date. GSK continues to work closely with the FDA towards the approval of PROMACTA in order to provide physicians and chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients with a novel, once-daily oral option.

"Our discussions with the agency are progressing well and we look forward to this innovative new medicine becoming available for patients with ITP in the USA," said Paul Huckle, Senior Vice President, Global Regulatory Affairs, GlaxoSmithKline.

In December 2007, GSK submitted a new drug application to the FDA for PROMACTA for the proposed indication of the short-term treatment of previously treated patients with ITP. On May 30, 2008, the Oncology Drugs Advisory Committee (ODAC) to the FDA unanimously voted, 16-0, that PROMACTA demonstrated a favorable risk-benefit profile for the short-term treatment of patients with ITP.

In the pivotal short term studies, the most common adverse reactions reported in ≥5% of patients treated with PROMACTA 50mg were headache (8%), nasopharyngitis [common cold] (6%) and nausea (6%).

### **Enquiries:**

|                                      |                 |                 |
|--------------------------------------|-----------------|-----------------|
| UK Media enquiries:                  | Philip Thomson  | (020) 8047 5502 |
|                                      | Claire Brough   | (020) 8047 5502 |
|                                      | Alice Hunt      | (020) 8047 5502 |
|                                      | Gwenan White    | (020) 8047 5502 |
| US Media enquiries:                  | Nancy Pekarek   | (919) 483 2839  |
|                                      | Mary Anne Rhyne | (919) 483 2839  |
|                                      | Sarah Alspach   | (215) 751 7709  |
| European Analyst/Investor enquiries: | David Mawdsley  | (020) 8047 5564 |
|                                      | Sally Ferguson  | (020) 8047 5543 |
|                                      | Gary Davies     | (020) 8047 5503 |
| US Analyst/ Investor enquiries:      | Tom Curry       | (215) 751 5419  |