

# News Release

Takeda Pharmaceutical Company Limited  
AstraZeneca K.K.  
Mitsubishi Pharma Corporation  
Eisai Co., Ltd.

## **Approval of an additional dosage and administration for secondary eradication of *Helicobacter pylori* for proton pump inhibitors in Japan**

**Osaka and Tokyo, Japan, August 24, 2007** --- It is announced today that an additional dosage and administration for secondary eradication of *Helicobacter pylori* (“*H. pylori*”) for proton pump inhibitors (“PPI”) currently marketed in Japan<sup>(\*)</sup> was approved on August 24, by the Japanese Ministry of Health, Labour and Welfare. The Secondary eradication regimen consists of a PPI, amoxicillin and metronidazole, which is applicable following the failure of eradication with the already approved triple therapy, a PPI, amoxicillin and clarithromycin.

<sup>(\*)</sup> Lansoprazole (tradename: Takepron®, marketed by Takeda Pharmaceutical Company Limited)  
Omeprazole (tradenames: Omepral® and Omeprazon®, marketed by AstraZeneca K.K. and Mitsubishi Pharma Corporation, respectively)  
Rabeprazole sodium (tradename: Pariet®, marketed by Eisai Co., Ltd.)

*H. pylori* is one of the bacteria commonly existing in the human stomach and is known to have the pivotal role in the onset of peptic ulcers. The eradication of *H. pylori* is therefore an effective treatment for the prevention of recurrence of peptic ulcers, remarkably lowering the recurrence rate for patients with a history of peptic ulcers.

Currently in Japan, triple therapy with a PPI, amoxicillin and clarithromycin is being prescribed, however, *H. pylori* is still not eradicated in 10 to 20% of patients. Additionally, it is difficult to eradicate *H. pylori* with this triple therapy even if it is repeated in this resistant patient population. The newly approved triple therapy regimen, replacing clarithromycin with metronidazole, has proven to be effective in the eradication of *H. pylori* in a variety of clinical studies conducted both in Japan and overseas.

It is expected that the approval of the secondary eradication of *H. pylori* will highly contribute to improvement in the Quality of Life of the patients with peptic ulcers by lowering the recurrence rate.

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**<Approved administration and dosage >**

Lansoprazole:

lansoprazole 30mg, amoxicillin 750mg (potency) and metronidazole 250mg, b.i.d.,  
for seven days

Omeprazole:

omeprazole 20mg, amoxicillin 750mg (potency) and metronidazole 250mg, b.i.d.,  
for seven days

Rabeprazole sodium:

rabeprazole sodium 10mg, amoxicillin (potency) 750mg and metronidazole 250mg, b.i.d.,  
for seven days

**<Processes of approval of this dosage and administration>**

In July 2005, The Japanese Society for *Helicobacter* Research submitted a request to the Japanese Ministry of Health, Labour and Welfare, for the reimbursement of this secondary eradication regimen under the National Health Insurance. All the companies which are marketing PPI and also some of those which are marketing amoxicillin or metronidazole submitted a joint application in August 2006 without conducting clinical studies, and it was approved based on the scientific evidence of clinical findings both in Japan and overseas and also on the approval of this dosage and administration already granted in overseas countries. The proposed administration and dosage was recognized to offer medical/pharmacological benefits, thus, was approved.

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