

June 22, 2012

Anti-depressant *Paxil*[®] CR Tablets newly launched

GlaxoSmithKline K.K.

Dainippon Sumitomo Pharma Co., Ltd.

GlaxoSmithKline K.K. (President: Philippe Fauchet, Head Office: Shibuya-ku, Tokyo, hereinafter referred to as GSK) announces that it has launched its anti-depressant *Paxil*[®] CR Tablets 12.5mg and *Paxil*[®] CR Tablets 25mg (paroxetine hydrochloride hydrate, hereinafter referred to as *Paxil*[®] CR Tablets, CR stands for Controlled Release) in Japan on June 22, following its NHI price listing on the same day.

GSK and Dainippon Sumitomo Pharma Co., Ltd. (President: Masayo Tada, Head Office: Chuo-ku, Osaka, hereinafter referred to as DSP) have started co-promoting *Paxil*[®] CR Tablets from April 1, 2012.

Paxil[®] CR tablets is the controlled-release¹ formulation of *Paxil*[®] tablets, an SSRI (selective serotonin reuptake inhibitor) anti-depressant. It received regulatory approval in Japan from MHLW on 18 January 2012 for the indication of depression and depressive state. Overseas, development of anti-depressants using new formulation technology are being conducted actively and with the approval of *Paxil*[®] CR Tablets, Japan too has entered the era of controlled-release formulations. *Paxil*[®] CR Tablets was approved in the US in 1999 and as of June 2011, has been approved and widely used in over 40 countries worldwide.

About *Paxil*[®] CR Tablets

- First controlled-release anti-depressant in Japan, which has a slow pharmacokinetic profile by using formulation technology.
- Using an enteric coating and two layer controlled-release technology², it is designed so that the drug is released gradually and continuously after it has left the stomach.
- Compared to *Paxil*[®] IR Tablets, blood concentration increases gradually during single dose administration and change in blood concentration during repeated administration is small. According to overseas clinical trials³, it has been shown to decrease nausea.
- Overseas clinical trial^{3,4} results have shown that treatment dropout due to adverse events do not differ greatly to placebo making it easy to take and it is expected to contribute to improving the continuity of long-term treatment.

Commenting on the launch Philippe Fauchet, president of GSK, said, "GSK has just launched *Paxil*[®] *CR tablets* which is the first controlled-release anti-depressant in Japan. By adopting new formulation technology *Paxil*[®] *CR Tablets* is expected to alleviate gastrointestinal symptoms in the early stages of administration of anti-depressants and contribute to improving the continuity of long-term treatment. Through the partnership with DSP, GSK continues to be committed to focusing our efforts in contributing to the treatment of patients who suffer from depression by further enhancing medical information provision to medical institutions regarding the drug's safety and efficacy."

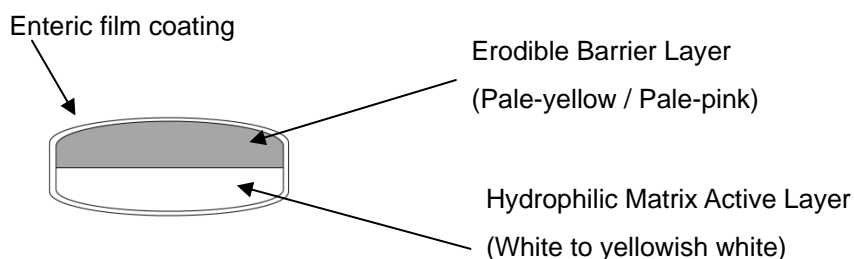
Masayo Tada, President and Chief Executive Officer, DSP commented, "DSP aims to contribute further to the treatment of depression by providing proper information on *Paxil*[®] *CR Tablets* to medical institutions in collaboration with GSK."

(Reference)

Profile of Paxil CR[®]

Product name	<i>Paxil</i> [®] <i>CR Tablets 12.5mg</i> , <i>Paxil</i> [®] <i>CR Tablets 25mg</i>
Generic name	paroxetine hydrochloride hydrate
Date of approval	18 January 2012
Launch Date	22 June 2012 : <i>Paxil</i> [®] <i>CR Tablets 12.5mg, 25mg</i> 140 tablets (14 tablets × 10), 29 June 2012 : <i>Paxil</i> [®] <i>CR Tablets 12.5mg, 25mg</i> 500 tablets (bottle)
NHI price	One 12.5mg tablet: 105.60 yen, one 25mg tablet: 184.70 yen
Indications	Depression and depressive state
Dosage and Administration	Usually for adults, paroxetine is administered orally at 12.5 mg as the initial dose once daily after evening meal, and the dose is subsequently increased to 25 mg a day taking a week or longer. Dosage should be adjusted according to symptoms and age in the dosing range not exceeding 50 mg a day and either of the above dose will be administered once daily after evening meal. When the dose is increased, it should be increased by 12.5 mg as a daily dose at intervals of a week or longer.

Cross-sectional view of Paxil[®] CR Tablets



Barrier Layer: To limit drug release from the Active Layer

Active Layer: Controlled Release Layer containing Paroxetine

- 1) Controlled-release formulation: Formulation using CR technology that controls drug release for continuous and gradual release
- 2) Two layer controlled-release technology. Paxil[®] CR Tablets is made up of 2 layers – an affinity matrix layer that includes active ingredients in the plain tablet (inner core) and an erodent barrier layer that does not include active ingredients, thereby controlling the rate of drug release.
- 3) Golden RN et al :J Clin Psychiatry,2002; 63 (7) : 577-584
- 4) Eaddy M, et al: Manage Care Interface,2003; 16(12): 22-7

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