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GlaxoSmithKline and Dainippon Sumitomo Pharma commence the co-promotion of anti-depressant *Paxil*[®] *CR Tablets*

GlaxoSmithKline K.K.

Dainippon Sumitomo Pharma Co, Ltd.

GlaxoSmithKline K.K. (President: Philippe Fauchet, Head Office: Shibuya-ku, Tokyo, hereinafter referred to as GSK) and Dainippon Sumitomo Pharma Co, Ltd. (President: Masayo Tada, Head Office: Chuo-ku, Osaka, hereinafter referred to as DSP) announce that the companies will commence the co-promotion of GSK's anti-depressant *Paxil*[®] *CR Tablets 12.5mg* and *Paxil*[®] *CR Tablets 25mg* (paroxetine hydrochloride hydrate, hereinafter referred to as *Paxil*[®] *CR*) in Japan from April 1, 2012.

As announced on January 19, 2012, the two companies have already signed a "basic agreement". This time the two companies signed a "Co-promotion agreement". Under this agreement, effective April 1, 2012, GSK and DSP will co-promote *Paxil*[®] *CR Tablets* to medical institutions. GSK will deal with distribution and sales.

Paxil[®] *CR* 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. *Paxil*[®] *CR* will be launched soon after insurance price has been decided. 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.

Commenting on the co-promotion Philippe Fauchet, president of GSK, said, "GSK obtained marketing approval on *Paxil*[®] *CR* from the MHLW in addition to the existing *Paxil*[®] *IR*. 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, which has expertise and extensive experience in the psychiatry area, GSK hopes to contribute to the treatment of depression by further enhancing medical information provision to medical institutions regarding the drug's safety and efficacy."

Masayo Tada, President and Chief Executive Officer, Dainippon Sumitomo Pharma Co., Ltd. commented, "We are working on the CNS area as one of our focus marketing areas and have developed promotional activities in this area including antipsychotic drugs. With this agreement, by adding *Paxil*[®] *CR Tablets* to our product line, we believe our activities can be expanded in the area of anti-depressants and we can further enhance our presence in the CNS area. We hope to contribute further to the treatment of depression by providing proper information to medical institutions in collaboration with GSK."

(Reference)

Profile of Paxil® CR

Product name	<i>Paxil® CR Tablets 12.5mg, Paxil® CR Tablets 25mg</i>
Generic name	paroxetine hydrochloride hydrate
Date of approval	18 January 2012
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.

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 as change in blood concentration during repeated administration is small, it is expected to reduce the risk of adverse events.
- Overseas clinical trial³、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.

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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