Announcement of basic agreement concerning co-promotion of anti-depressant *Paxil® CR Tablets*

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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 Sumitimo Pharma Co, Ltd. (President: Masayo Tada, Head Office: Chuo-ku, Osaka, hereinafter referred to as DSP) announce that the companies have reached a basic agreement to co-promote 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 1st.

Paxil® CR is the controlled-release[1] 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.
Paxil® CR, the controlled-release[1] formulation of *Paxil®* tablets, is the first controlled-release formulation of a SSRI (selective serotonin reuptake inhibitor) anti-depressant developed in Japan to receive 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.

GSK is one of the leading companies in the CNS therapeutic area through supply of medicines for MDD (major depressive disorder), bipolar disorder, migraine, Parkinson's disease and epilepsy.
On the other hand, DSP with its 230 CNS specialized MRs, supplies medication for schizophrenia, Parkinson's disease and epilepsy, and tackles the CNS therapeutic area as one of its main target areas.
Both companies, through the present collaboration, aim to contribute to the measures against psychological disorders of Japan and maximize the proper use and distribution of *Paxil® CR Tablets* by providing proper information to medical institutions.

Profile of *Paxil® CR*

Product name	*Paxil® CR Tablets 12.5mg*, *Paxil® CR Tablets 25mg*
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 technology [2], 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 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.

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