２００４年１１月２９日

薬害オンブズパーソン会議
代表　鈴木利廣　殿

グラクソ・スミスクライン株式会社
広報部　部長　小松義明

抗うつ剤 SSRI のデータ等の公開を求める要望書について

２００４年１０月２７日付けで貴会議より弊社社長宛にご要望頂きました標記要望書につきまして、以下の通り回答申し上げます。

グラクソ・スミスクライン（以下 GSK）はホームページを通じ、GSK が実施した全ての市販医薬品の全ての臨床試験のプロトコールと結果、すでに公表されている研究論文に関してはその出典を公表すべく、本年９月１日より GSK クリニカル・トライアル・レジスター（以下 CTR）を創設致しました。CTR は GSK のホームページから医療関係者の方をはじめ、どなたにも御利用頂けます。

CTR では第一段としてロシグリダゾン、第二段としてプロピオン酸フルチカゾンとキシナホ酸サルメテロールの配合剤のデータを公開しております。また、これに先立ちまして本年６月には塩酸パロキセチンの１８歳未満の患者さんに関するデータをホームページに掲載致しました。

今回ご要望のありました塩酸パロキセチンの成人患者さんに関するデータにつきましても CTR にてデータを公表すべく準備を進めております。順次データ公開を行い、最終的には全ての製品のデータを掲載する予定です。現時点ではパロキセチンのデータをいつまでに掲載するとお伝えできる段階にございません。

＜参考資料＞

報道資料　10/06/2004 GlaxoSmithKline clarifies availability of clinical trial data on paroxetine in adolescent and paediatric patients.

報道資料　18/06/2004 GlaxoSmithKline announces major advance in on-line Access to Clinical Trial Information.

報道資料　01/09/2004 GlaxoSmithKline posts data on Clinical Trial Register

以　上

Press Release

GlaxoSmithKline

Issued – Friday 18 June 2004, London

GLAXOSMITHKLINE ANNOUNCES MAJOR ADVANCE IN ON-LINE ACCESS TO CLINICAL TRIAL INFORMATION

GlaxoSmithKline (GSK) announced today that it will create an electronic database to enable dissemination over the Internet of information about GSK-sponsored clinical trials.

The database, to be called the GSK Clinical Trial Register, will provide summaries of trial protocols and corresponding results for GSK-sponsored trials of marketed medicines. In addition, the register will provide references to publications that have appeared in the medical literature. The register will be accessible to physicians and the public.

"The GSK Clinical Trial Register will be a major advance in providing on-line access to information to support patient care, facilitating access to study summaries by putting them on a single Internet site," said Dr. Tadataka Yamada, chairman, Research & Development, GSK. "It is important to emphasize, however, that prescribing information approved by regulatory agencies must continue to guide appropriate use of our medicines."

GSK will continue to communicate clinical data in journals, at scientific meetings, and in letters to healthcare professionals.

The register has been under consideration and development for several months; its availability will be announced when it first appears on the GSK corporate Web site.

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies. For more information on GlaxoSmithKline visit www.gsk.com.

Registered in England & Wales
No. 3888792

Registered Office
980 Great West Road
Brentford, Middlesex, TW8 9GS

Enquiries:

UK Media enquiries:	Martin Sutton	(020) 8047 5502
	David Mawdsley	(020) 8047 5502
	Chris Hunter-Ward	(020) 8047 5502
	Neil McCrae	(020) 8047 5502
US Media enquiries:	Nancy Pekarek	(215) 751 7709
	Mary Anne Rhyne	(919) 483 2839
	Patricia Seif	(215) 751 7709
European Analyst/Investor enquiries:	Duncan Learmouth	(020) 8047 5540
	Anita Kidgell	(020) 8047 5542
	Philip Thomson	(020) 8047 5543
US Analyst/ Investor enquiries:	Frank Murdolo	(215) 751 7002
	Tom Curry	(215) 751 5419

Registered in England & Wales
No. 3888792

Registered Office
980 Great West Road
Brentford, Middlesex, TW8 9GS

Press Release

GlaxoSmithKline

Issued – Thursday 10 June 2004, London UK and Philadelphia, USA

GLAXOSMITHKLINE CLARIFIES AVAILABILITY OF CLINICAL TRIAL DATA ON PAROXETINE IN ADOLESCENT AND PAEDIATRIC PATIENTS

GlaxoSmithKline's policy is to ensure transparency of the clinical data the company collects on its marketed medicines. Specifically, we endorse the PhRMA principles that call for timely publication of meaningful trial results.

With regard to clinical trial data on paroxetine, GSK has already provided data that were collected during clinical trials in adolescent and paediatric patients to the US, UK, European and other regulatory agencies.

In addition, data have previously been made available to healthcare professionals through publication in peer-reviewed journals, poster presentations at scientific meetings, and medical letters to physicians. This approach is accepted standard practice for making data available.

However, in order to clarify the nature of these data, GSK will shortly be making available full study reports of the safety and efficacy data from the clinical studies conducted with paroxetine in adolescent and paediatric patients, as well as a bibliography of public communications derived from these studies, and the US letter to physicians summarising these data. This information will be available through the media room on the company's corporate website (www.gsk.com).

Paroxetine has not been approved in Europe or North America for treatment of patients younger than 18 years of age. It is GlaxoSmithKline's policy not to promote off label use of any of our medicines.

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies. For more information on GlaxoSmithKline visit www.gsk.com.

Registered in England & Wales
No. 3888792

Registered Office
980 Great West Road
Brentford, Middlesex, TW8 9GS

Enquiries:

UK Media enquiries:	Martin Sutton	(020) 8047 5502
	David Mawdsley	(020) 8047 5502
	Chris Hunter-Ward	(020) 8047 5502
US Media enquiries:	Nancy Pekarek	(215) 751 7709
	Mary Anne Rhyne	(919) 483 2839
	Patricia Seif	(215) 751 7709
European Analyst/Investor enquiries:	Duncan Learmouth	(020) 8047 5540
	Anita Kidgell	(020) 8047 5542
	Philip Thomson	(020) 8047 5543
US Analyst/ Investor enquiries:	Frank Murdolo	(215) 751 7002
	Tom Curry	(215) 751 5419

Registered in England & Wales
No. 3888792

Registered Office
980 Great West Road
Brentford, Middlesex, TW8 9GS

Press Release

GlaxoSmithKline

GlaxoSmithKline Posts Data On Clinical Trial Register

Philadelphia, PA (September 1, 2004) – GlaxoSmithKline (NYSE: GSK) announced today that it has posted the first set of data on the GSK Clinical Trial Register, a Web site that facilitates access to information derived from GSK-sponsored clinical trials.

The Register provides summary results of GSK-sponsored trials of GSK marketed medicines. It also notes references to related publications that have appeared in the medical literature.

"The Register supplements our efforts to ease access to clinical-trial data for everyone interested in medical research and patient care," said Dr. Tadataka Yamada, chairman, Research & Development, GSK. "It is important to emphasize, however, that prescribing information approved by regulatory agencies must continue to direct the appropriate use of our medicines."

The first clinical-trial summaries to be posted on the Register concern Avandia® (rosiglitazone maleate), a medicine for type 2 diabetes. Additional information about trials of Avandia® and other GSK medicines will be posted as the data are summarized and put into the Register format. The data are presented according to criteria that apply consistently across wide-ranging studies and ensure that the summaries are scientific and non-promotional.

Access to the Register (http://ctr.gsk.co.uk) is unrestricted.

GSK will continue to communicate clinical-trial information through journals, scientific meetings, and letters to healthcare professionals.

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies. For more information on GlaxoSmithKline visit www.gsk.com.

US Media inquiries:	Nancy Pekarek	(215) 751 7709
	Mary Anne Rhyne	(919) 483 2839
	Patty Seif	(215) 751 7709
UK Media inquiries:	Martin Sutton	020 8047 5502
	Chris Hunter-Ward	020 8047 5502
	David Mawdsley	020 8047 5502
US Analyst/Investor inquiries:	Frank Murdolo	(215) 751 7002
	Tom Curry	(215) 751 5419
European Analyst/Investor inquiries:	Duncan Learmouth	020 8047 5540
	Philip Thomson	020 8047 5543
	Anita Kidgell	020 8047 5542