

# Seroxat/Paxil fact file

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## Section 1

### Towards the second billion — all SSRIs are not the same

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## Section 1

### Towards the second billion — all SSRIs are not the same

Worldwide internal flash sales of Seroxat/Paxil in 1997 were in excess of £1 billion and it is on track to be SB's biggest selling product. Growth will continue as the older, traditional agents are eroded and new indications are approved. Key to the success of Seroxat/Paxil is its positioning as an effective agent in lifting depression and lowering the associated symptoms of anxiety. The launch of Seroxat/Paxil as the first SSRI for the treatment of panic disorder further reinforced this positioning and has been instrumental in differentiating it from the other SSRIs, particularly fluoxetine. The SSRI market is, however, becoming increasingly competitive, as new and current competitors fight for market share and pursue additional indications to improve their position.

### Seroxat/Paxil — performance to date

The opportunity for agents which are effective in the treatment of depression and anxiety disorders is enormous, — around 90 million adults in North America and Europe are affected at any one time. Efforts on the part of the pharmaceutical industry, researchers and patient organizations have resulted in much greater awareness of psychiatric illness and the availability of safe and effective treatments. In addition, there is growing acceptance of the significant level of comorbidity in depression and anxiety disorders.

#### [SLIDE 1]

In 1997 the market was valued at close to £4 billion, with an annual growth rate of 24%. The global market for the treatment of depression and anxiety disorders has shown extensive growth in the last 5 years and is expected to continue into the next decade, with sales estimated to exceed £5 billion by 2002. This growth has been driven by increased use of SSRIs, currently worth £3 billion. Of this, the US accounted for 78% of sales.

In volume terms, Seroxat/Paxil is already the second biggest antidepressant worldwide, having overtaken sertraline in 1996. In several markets — Canada, Belgium, Spain, Austria, Holland, Greece, Ireland, Israel, Portugal, South Korea, South Africa, Brazil and Peru — it is the leading antidepressant as of March 1998. The impetus for this success came from the launch of Seroxat/Paxil for panic disorder which:

- provided categorical evidence of its efficacy in anxiety disorders
- underpinned the core positioning of 'first-choice antidepressant for depression, and depression with anxiety'
- provided a key point of differentiation from both fluoxetine and sertraline. [SLIDE 2]

## Seroxat/Paxil(strategy)

The overall strategy for Seroxat/Paxil is to differentiate the product from competitors and claim ownership of the expanding depression and anxiety market as follows.

- Develop the market for depression with anxiety and establish customer needs for a broad spectrum antidepressant to treat this population.
- Add new anxiety disorders (e.g. social anxiety disorder/social phobia, GAD, PTSD) to the label which reinforce the positioning as first choice antidepressant for depression and depression with anxiety.
- Continue to meet customer needs in depression by improving speed of onset of action and demonstrating efficacy in all types of depression including severe depression, adolescent depression and depression comorbid with physical illness.

## Strategic objectives

To achieve global market leadership in the plan period by focusing on the following objectives.

### Qualitative:

- to grow the value of Seroxat/Paxil business from depression with anxiety
- to own the depression and anxiety market segment by leading other SSRIs in showing efficacy in anxiety disorders, either by being first to market and/or by having superior data
- to strengthen the profile of Seroxat/Paxil in the core indication of depression by continuing to differentiate from TCAs, fluoxetine (including generic fluoxetine), sertraline, citalopram and venlafaxine
- to successfully manage the life cycle through development of new indications, alternative formulations, and exploring the possibility of 'over the counter' indications.

### Quantitative:

- to achieve worldwide sales of £2 billion by 2001 (flash sales)
- to achieve worldwide sales of £1.9 billion by 2001 (IMS).

## New indications

Approvals for OCD and panic disorder have been granted in the majority of European markets, the US and Canada. Efforts are now concentrated on being the first SSRI approved for social phobia/social anxiety disorder, an anxiety disorder with enormous potential. [TABLE]

## All SSRIs are not the same

The continued success of Seroxat/Paxil at the expense of both fluoxetine and sertraline has clearly demonstrated that doctors do indeed make a distinction when choosing an antidepressant. Key to Seroxat/Paxil's success has been its positioning as an agent which can lift depression and lower associated symptoms of anxiety. Its launch as the first new agent for panic disorder in almost a decade further reinforced this positioning and has been instrumental in differentiating it from other SSRIs, particularly fluoxetine.

The objective for the future is to continue to capitalize on the fact that Seroxat/Paxil is seen to be different, a fact which will be underlined as more indications are approved. However, even today, it is appropriate to say that Seroxat/Paxil offers the most robust data for the widest range of conditions of any antidepressant:

- all types of depression including severe and resistant
- long-term treatment of depression, including relapse prevention
- depression and anxiety indication (some markets)
- OCD — acute treatment
- OCD — long-term, including relapse prevention
- panic disorder — acute treatment
- panic disorder — long-term, including relapse prevention.

The inclusion of both short- and long-term data and relapse prevention in the labelling plays a critical part in further distinguishing Seroxat/Paxil from the other SSRIs, and reinforces its positioning as the first-choice antidepressant for patients with depression and depression and anxiety.

In addition to the indications already available, Seroxat/Paxil has demonstrated efficacy and safety in:

- depression accompanying medical illness (e.g. cancer, rheumatoid arthritis, patients with cardiovascular disease)
- social phobia/social anxiety disorder (open and double-blind data published<sup>1</sup>).

Filing for approvals for social phobia/social anxiety disorder will commence Q2 1998.

### Seroxat/Paxil — efficacy across the depression—anxiety spectrum

It is well accepted that psychiatric patients do not present with neat clusters of symptoms. Rather the clinician often has to play 'detective' in eliciting which symptoms predominate and thereby understand what the primary diagnosis might be. The efficacy of Seroxat/Paxil across a wide range of symptoms and often overlapping diagnoses helps substantially in removing the potential for confusion and inappropriate management. This positioning has been very successful in many markets.

### Reference

- 1 Stein MB, Chartier MJ, Hazen AL *et al.* Paroxetine in the treatment of generalized social phobia: open-label treatment and double-blind placebo-controlled discontinuation. *J Clin Psychopharmacol* 1996; **16**: 218—22.