

'Seroquel' Strategy Summary

Compound Description

'Seroquel' - an oral atypical antipsychotic (dibenzothiazepine derivative) indicated for schizophrenia with a superior tolerability profile and at least as effective as the major competition.

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Launch dates

- 1st launch: UK - Sept 1997
- US - Oct 1997, Canada - Jan 1998
- EU: Germany - February 2000, Italy - May 2000, Spain - Sept 2000
- Japan - February 2001

Positioning

Brand Essence: *Improvement without impairment*

Positioning Statement: 'Seroquel', the first line, first choice atypical antipsychotic

Key Claims

| Current Claims |
|---|
| At least as efficacious as other first line atypicals (olanzapine/isiperidone) |
| More effective than haloperidol and chlorpromazine (typical antipsychotics) |
| Effective at controlling depressive symptoms and improving cognition |
| Superior tolerability to typicals and first line atypicals |
| Weight neutral, placebo-level EPS and prolactin levels, and no clinically significant QT prolongation |

| LCM claims | Timing |
|--|--------|
| Effective in the treatment of acute mania as monotherapy / adjunct to mood stabiliser. (Likelihood of achieving claim: High) | 2002 |
| Does not induce depressive symptoms in patients with manic episodes. (Likelihood of achieving claim: High) | 2004 |
| Significant anxiolytic/calming effect. (Likelihood of achieving claim: High) | 2004 |
| Efficacy in controlling manic episode demonstrated within 4 days ((Likelihood of achieving claim: Medium) | 2004 |
| Placebo-level EPS, prolactin, weight in patients with acute mania. (Likelihood of achieving claim: High) | 2004 |
| Therapeutic dose achieved at day one with the SR formulation. (Likelihood of achieving claim: High) | 2003 |
| Once daily dosing suitable for all patient groups. (Likelihood of achieving claim: High) | 2003 |
| Superior risk/benefit profile compared with olanzapine. (Likelihood of achieving claim: Medium) | 2003 |
| Granules will offer better compliance and more flexible dosing (25mg, 50mg, 100mg, 150mg) than risperidone liquid | 2002 |

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Situation Analysis:

Unmet Medical Needs:

Approximately 1% of the global population suffers from schizophrenia and 1.5% from Bipolar Disorder. Older typical antipsychotics are not well tolerated resulting in a low rate of compliance. The medical need for an effective, well tolerated antipsychotic was high. Whilst the atypical antipsychotics achieve this to a greater or lesser extent, the typicals are still the most widely prescribed antipsychotics globally.

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debilitating side effects of EPS, extreme weight gain and increased prolactin are also important to the psychiatrist and patient - and are a major cause of non-compliance and hence relapse. Seroquel is the only first line antipsychotic which is weight neutral in the long-term and has an EPS and prolactin profile which does not exceed placebo. This is the major differentiator for Seroquel - 'Improvement without impairment'; the only first line antipsychotic which offers efficacy without associated EPS, weight and prolactin-related side effects EVEN at the highest dose. This translates into unsurpassed clinical effectiveness. This profile is highly suited to Bipolar patients.

Key success factors

| | Key Success Factor | Required Actions | Risk/Urgency | Responsible |
|---|--|---|--------------|-------------------|
| 1 | Maintain competitive SoV | Increased \$ and CNS experienced manpower, both globally and MCs | M/H | SET MCP GPT |
| 2 | Delivery of compelling data into marketplace | Publication/communication of data to support stronger efficacy message and to differentiate on superior tolerability via: Data mining, clinical trials, comparative data, HTs | L/H | GPT |
| 3 | Broaden Seroquel use on and off label | Utilise whole selling team. Educational programmes to share off label data. | L/H | MC |
| 4 | Maintain competitive label | Successfully deliver LCM programme: Granules 2002 Sustained Release 2003 Bipolar Disorder 2003/4 Remove eye monitoring from US label. Defend against potential FDA label threats: QTc, diabetes | M/H | GPT |
| 5 | Communicate efficacy at the right dose | Communicate clear dosing guidelines and data. Promote starter pack. SR formulation. | L/H | GPT MC |

PRODUCT STRATEGY - Grower Megabrand Brand Strategy - Win Competitors Customers

AZ aims to optimise Seroquel's market penetration, in order to maintain a position of at least third (in value terms) in the antipsychotic class. The objective for Seroquel is to grow sales faster than the market and maintain its lead over the expected new market entries. This will be achieved in an increasingly intense competitive environment as Pfizer (ziprasidone) and BMS (aripiprazole), amongst others, enter the marketplace. The long term aspirational target for Seroquel is to overtake the sales of risperidone. The incidence (per year) of schizophrenia is low, so a switch strategy is key to achieving this target.

| Strategic objective | Implementation | Responsible |
|---|--|-------------|
| Launch (0-2 years) | Win competitors customers i.e. switches from: <ul style="list-style-type: none"> • typicals (first line switch) • atypicals Establish Seroquel as atypical of choice in the first episode schizophrenia patients - this has a halo effect as these patients are particularly sensitive to EPS and weight gain. Secure launch take off above risperidone. | MC |
| "Penetrate the rapidly growing atypical market" | | |

Differential Analysis

The perceived efficacy of an antipsychotic is the most important attribute to psychiatrists when treating patients. In schizophrenia efficacy is viewed in terms of a spectrum of domains; positive, negative and affective symptoms, cognition and hostility. Unlike the typical antipsychotics Seroquel is highly effective in treating all these domains. The main atypical competition, risperidone and olanzapine, have a similar efficacy profile to Seroquel. The

