

Establish Olanzapine as THE Standard of Care

Through global and country-specific clinical trials, demonstrate olanzapine's combined safety and efficacy profile and differentiate it from the competition. Market opportunity is for a "safer clozapine." However, the major competitor at launch is likely to be risperidone.

- Design clinical trials to demonstrate the following:
 - efficacy in positive and negative symptoms
 - low/absent tardive dyskinesia and EPS
 - no significant monitoring required, low/absent elevation of prolactin
 - superior safety relative to clozapine and typical antipsychotics
 - improvement in cognition, QOL, and resource utilization
- Demonstrate similar efficacy to clozapine in treatment-resistant patients
- Demonstrate safety similar to risperidone
- Demonstrate long term safety
- Clinical trials planned or underway include:
 - pivotal efficacy (HGAD, E003, HGAP) and safety (HGAJ)
 - clozapine treatment-resistant paradigm, risperidone comparator, negative symptom study, geriatric study.
- Conduct country-specific template studies and Plan D trials to address country-specific issues, broaden product use and sustain market share
- Investigate developing a Patient Registry system to collect longitudinal data

Obtain broad package labelling to expand use and address global differences in diagnosis

- Understand geographic and cultural differences in psychoses disease management
- Determine desired labelling in major markets
- Conduct appropriate country-specific trials to maximize use opportunities in key markets

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Develop health economics (HE) and quality of life (QOL) data

- Form a global health economics strategy team
- Consult with HE experts in designing assessments and outcome measures
- Incorporate HE and QOL measurements in clinical trials to gain “core data package”
- Conduct additional country-specific HE, QOL, and outcome studies or analysis as needed to supplement core data package
- Use HE and QOL data to obtain optimal pricing/reimbursement, formulary access; and to demonstrate optimal outcomes
- Incorporate HE measures in comparator trials
- Build HE and pricing models
- Develop an Econometric model for schizophrenia
- Conduct cost of illness studies
- Collect outcomes data (incorporating clinical HE, and QOL measures) with key customers

Position olanzapine as an integral component of a menu of patient intervention (disease management) programs that focus on achieving optimal clinical and economic outcomes

- Disease Management offerings may be designed to fit any one of three categories:
 1. Pharmaceutical Care - Lilly products and Interventions/Services that pull Lilly product
 2. Managed Pharmaceutical Care - Core services, connectivity, and intervention/services and management for total pharmaceutical care
 3. Medical Management - Delivery of interventions/services and management for the clinical delivery of care to provide specific outcomes
- A flexible service offerings model will be employed.
 - standard offerings are services uniformly valued by all customers in a given segment

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- optional offerings are particular services valued by individual customers within the segment
- services will focus on helping strategic customers to improve their medical services and financial performance. Even optimal offerings will be designed to provide value exceeding cost.
- Tentative standard flexible service offerings include:
 - Disease/illness education modules
 - Medication management modules
 - Medical information/customer service
 - Reimbursement information hotline
 - Patient assistance program
 - Advocacy group information
 - Basic compliance and relapse prevention materials
- Tentative optional flexible service offerings may include:
 - Hastings Therapeutic Advantage Patient-Centered Management Model to prevent relapse and increase compliance.
 - Access to a Community Rehabilitation Program for patients with Schizophrenia
 - Links with PCS offerings (Quantum Alert, other DUR programs, Rx Alert, Rx Compliance and clinical programs)
 - Econometric models and Pricing models
 - Links with Integrated Disease Management (IDM) programs and expertise
 - Money Back Guarantee program, capitation, or other risk sharing arrangements

Implement a plan to “redefine” optimal standard of care

- Define elements of dissatisfaction with current treatments
- Conduct gap analysis

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- Develop programs and services aimed at correcting treatment deficiencies
- Position olanzapine (along with programs and services) versus the competition, as meeting more of our customers unmet needs
- Use outcomes data to achieve a “most valued pharmaceutical partner” status with our customers and to demonstrate that better outcomes are possible
- Raise customers’ expectations of “acceptable” or desirable outcome. Focus on rehabilitation and community living “reintegration”
- Incorporate messages of “optimal care standard” in sales/marketing, corporate communications, and public relations activities
- Tie activities in with Corporate and CNS image campaigns

Develop an effective communications and Public Relations plan

- Identify key audiences that influence disease treatment and product success (internal, consumer, media, general public, legal, advocacy groups, policy-makers, health care providers/payors).
- Develop key messages using data from market, product and health economics research to effectively communicate with each audience
- Develop effective means and materials to communicate to each audience and assign responsibility for implementation
- Coordinate with broader efforts to position Lilly as CNS leader - CNS Image Campaign
- Provide core package of communication tools for affiliates to use and tailor to specific country communications needs
- Build capacity to respond to medical information requests in a timely and appropriate manner
- Conduct stigma and educational awareness campaigns
- Develop a global public relations program with Weber and Associates that focuses on decreasing stigma, establishing media contacts, and managing issues

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Create barriers to competitive entry

- Be next to market. Launch olanzapine in US, Canada, and EU markets before the launch of Seroquel, ziprasidone, and sertindole
- Competitively price olanzapine to drive market share and prevent coattail competitors from entering the market with a “lower price” strategy
- Obtain adequate funding - GBU, Heavyweight team, and global affiliate budgets to launch olanzapine into a rapidly maturing market and against a well-funded and entrenched market leader
- Demonstrate product differentiation with broad utility
 - HE, QOL, cognition, positive and negative symptom efficacy, treatment resistant efficacy, and less side effects
 - superior product profile
 - broadly worded package labelling
 - comparative studies, templates, plan D studies
- Launch multiple formulations with planned line extensions for depot, short acting IM, Zydys tablet, patch, and higher dose tablets (15 & 20 mg tablets)
- Conduct a comprehensive patent examination and filing program to provide the widest protection possible worldwide
- Leverage expertise and programs/services that are available in other Lilly subsidiaries (PCS, IDM)
- Position olanzapine as the “best” pharmacologic agent and an integral component of a menu of patient intervention and management programs designed to deliver an “optimal standard at care”
- Disease Management: Flexible service offerings model
 - Wrap standard services uniformly valued by all customers in a given segment with options (particular services valued by individual customers within the segment)
 - Focus services on helping strategic customers to improve their medical services and financial performance
 - Conduct cost-in-use studies to document incremental cost savings

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- Adding new services to standard offerings may create a barrier for competition
- Offering services as options gives management a wider choice of pricing tactics

Market Penetration Strategy

Develop a country-specific marketing strategy based on country and cultural differences in the diagnosis and treatment of schizophrenia and related psychoses.

- Clearly identify the key customers in each market and frame critical questions concerning their needs, wants and concerns in the treatment of schizophrenia and related psychosis
- Conduct market research at both corporate and affiliate level
- Utilize information available from the psychosis segmenter
- Develop customer and country-specific marketing strategies
 - Target primary customers, i.e. patients and caregivers, providers, and payors as identified by market research.
 - Target secondary customers, i.e. government, managed care, advocacy groups, etc.

Develop and implement a global branding strategy

- Select a single global trademark
- Contract with a professional branding company (i.e. Lewis and Gace)
- Brand olanzapine with an outcome that is in concert with plans to brand Lilly as a CNS leader
- Develop a “crystallized product promise” (CPP) in association with our disease state management strategy
- Consistently use the trademark and key branding elements worldwide

Undertake aggressive pre-launch marketing activities

- Monitor competitors SWOT (strengths, weakness', opportunities, threats)
- Position Olanzapine as a safe Clozapine-like atypical which provides optimal clinical and economic outcomes using:

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- Publications plan (country / market specific)
- Advocacy group collaborations for each country
- Identification of and share data/information with key opinion leaders in each country
- Utilization of input from US and international advisory boards
- Participation in key meetings (symposia, posters, presentations, abstracts)
- Demonstration of positive health economics and QOL data at launch
- Hold periodic olanzapine planners meetings
- Fill affiliate product manager positions at least 18 months prior to launch
- Develop treatment algorithms and use guidelines
- Affiliates must budget for and obtain adequate resources to implement pre-marketing strategies and programs (LifePlan)
- Affiliate delegate programs (GMC's)

Differentiate the Product

- Develop unique "crystallized product promise" and global branding elements
- Safe as first-line agent with no monitoring required
- Comparative data vs. typicals, risperidone, clozapine
- Demonstrate improves cognition, QOL, resource utilization
- Little or no EPS/tardive dyskinesia
- Switching guidelines

Implement post-launch marketing strategy to gain broad market access

- Utilize a portfolio of products / services (standard and optional flexible service and disease management offerings) approach where appropriate
- Build "aligned promotion" strategies if necessary, with major customers

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- Design and implement standard educational and service program offerings
- Adopt competitive pricing policy to maximize market share
- Evaluate strategic alliances, co-marketing, and other business development opportunities
- Evaluate opportunities for new indications
- Introduce line extensions in a planned manner to maximize uptake and create competitive barriers
- Develop publication and meeting / symposia plans for the product life-cycle
- Evaluate capitation and risk sharing type patient management programs with key local providers / payors
- Tie in the product with disease management and flexible service offerings where appropriate to “pull” more product

Identify channels of distribution

- Conduct market research on patient service segments and corresponding distribution
- Develop plans to facilitate customer access to product
- Understand and integrate distribution plan with corporate strategy
- Special packaging needs

Evaluate new indications and off-label indications

- Refractory bipolar disorder
- Psychotic depression
- Personality disorder with psychotic features
- Non-drug induced organic mental disorders
- Mania, bipolar disorder

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- Drug-induced mental disorders
- Attention deficit disorder
- Dementia with psychosis
- Children/Adolescent use

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