

**LTC/GERIATRICS**  
**2001 Business Plan**

**RISPERDAL - LTC/GERIATRIC  
2001 BUSINESS PLAN SUMMARY**

**I. EXECUTIVE SUMMARY:**

Atypical antipsychotics are commonly prescribed for elderly patients who exhibit psychotic symptoms (delusions, paranoia, and hallucinations) as well as disruptive behaviors that interfere with needed care. The atypicals are a more attractive option particularly in the vulnerable elderly compared to the conventionals, whose side effect profiles are very problematic. The brand's pre-launch marketing focus has been to prepare for the new indication in psychotic symptoms of Alzheimer's dementia. There are other opportunities in 2001 to effectively and appropriately expand into serious mental illnesses of the elderly, such as psychosis w/o dementia, schizophrenia, management of psychosis accompanying Parkinson's Disease and others.

There are diverse treatment settings within the geriatrics market – nursing homes, Assisted Living, Community Mental Health Centers as well as home-based care. Within each setting a different mix of prescribers and influencers are involved; including psychiatrists, primary care physicians, geriatricians, neurologists and nurse practitioners. Influencers in the market include consultant pharmacists, Directors of Nursing, nursing staff, caregivers, and regulators. The needs of all segments must be considered and will be addressed in our strategic and tactical plan for 2001.

In LTC/Geriatrics market RISPERDAL is the market leader with more than one third of all antipsychotic prescriptions written for RISPERDAL. It should be noted our competition is aggressively expanding into this market. Eli Lilly and Astra-Zeneca have had a strong presence at medical meetings and have increased their promotional activity and spend during the past year and have made market share gains. Pfizer, a recognized leader in LTC (Aricept, Zoloft) will introduce Zeldox in 1Q'01 and we will prepare for the potential impact of Zeldox despite recognized limitations due to its cardiac safety profile.

Our goals for 2001 are to increase RISPERDAL leadership in LTC/Geriatrics. The brand will achieve its goals by implementing tactics against 4 key strategies: 1) strengthen our efficacy/safety positioning and prepare for approval of our new indication; 2) expand effectively and appropriately into additional elderly markets, 3) expand reach and educate our key customer audiences, and 4) effectively position and maximize RISPERDAL **REDACTED**

The brand has several significant initiatives in its 2001 tactical plan. There will be a focus on broadening the appropriate use and benefits of RISPERDAL in serious mental illnesses that effect the elderly; implementation of appropriate non-rep mediated tactics to expand our reach to broad customer audiences as well as work with the FSF and LTC team to re-enforce messages to current called on clinicians. We will appropriately and effectively introduce RISPERDAL to new customers – such as Neurologists, Family Practice Residents, and Nurse Practitioners. We will conduct regional advisory boards to target and more effectively penetrate key markets. These are just a few of the specific programs and tactics outlined in this plan and available in more detail in our expanded tactical plan.

Several success predictors must be driven to optimized RISPERDAL LTC/Geriatrics business in 2001.

- 1) Execution of new studies & dissemination of clinical data that at a minimum match the output of our competitors;
- 2) Psychosis in Alzheimer's disease indication trials (RIS-232/INT-83) must remain on timelines;
- 3) Drive alignment and focus around our key issues, strategies and tactics among EC, CNS I-Reps, LTC, MSLs, OMP SLs, Medical Affairs, Sales Training, & JRF;

- 4) Strengthen label related to geriatrics;
- 5) Maximize FDAMA opportunity; and
- 6) Maximize RISPERDAL/REMINYL positioning & synergies.

## **II. SITUATION DIAGNOSTIC/ANALYSIS:**

There has been significant growth in the use of atypical antipsychotics in LTC/Geriatrics. Several factors are driving this growth, including:

- Demographic trends shifting toward an aging population
- Use of antipsychotics, particularly atypicals, which are increasingly recognized as the standard of care for patients struggling with behaviors and symptoms associated with psychosis
- Declining use of conventionals due to concerns about their safety, particularly EPS and TD

Use of conventional antipsychotics continues, however it is declining more rapidly in geriatrics (~25% share in elderly population) compared to the market overall.

The brand's promotional efforts have been to focus on the appropriate use of antipsychotics in the elderly for the management of psychotic symptoms and behaviors. We believe opportunities exist in 2001 to appropriately and effectively use our clinical data to continue to expand use of RISPERDAL in serious mental illnesses in the elderly, such as psychosis w/o dementia, schizophrenia, psychosis associated with Parkinson's Disease and others.

Many elderly are placed in nursing homes and other extended care facilities due to their psychotic illnesses and/or associated behavioral disorders so these facilities and the clinicians that deliver care within them remain important targets for RISPERDAL. Within the nursing home setting, the important prescribers are the consulting psychiatrists, medical directors, attending physicians and nurse practitioners. Other influencers we will appropriately interact with include consultant pharmacists, Directors of Nursing and the nursing staff. Many nursing homes are struggling to survive within a highly structured regulatory and reimbursement environment. Organizations that survive are often plagued with reduced reimbursement, low census and a high turnover among an often inadequately trained staff.

Assisted Living Facilities, Community Mental Health centers and even home-based care are emerging as alternatives to nursing homes and are important target segments for RISPERDAL. There is an opportunity for RISPERDAL to strengthen its focus to deliver appropriate information to those serving within the outpatient setting and to more effectively and appropriately target family practice, geriatricians, nurse practitioners, neurology and psychiatry.

Both family caregivers and professional caregivers (for example, the certified nurse assistant in a nursing home) are on the front line in dealing with resident's symptoms. They often communicate the symptoms and behaviors of a patient to the prescriber. Caregivers are an important audience to appropriately educate on issues of symptom recognition and how to effectively manage symptoms using both pharmacological and non-pharmacological treatments.

Our primary competitors, Zyprexa and Seroquel continue to make inroads in the LTC/Geriatric market.

**Zyprexa** has been very active:

- Zyprexa's second double-blind placebo controlled study in patients with dementia authored by Street et. al. was published (Archives of General Psychiatry, October 2000 issue) and is being used aggressively by Lilly via WLF with prescribers and influencers.

- Lilly has recently expanded its field force to a total of 160 LTC representatives and is recruiting consultant pharmacists. They have redirected up to 1300 PCP representatives in support of Zyprexa that has expanded Zyprexa's reach into this community of prescribers.
- Lilly is actively pursuing a claim for Zyprexa in the psychosis associated with Alzheimer's Disease and our market intelligence indicates they may be up to 6 or more months ahead of our timelines.

**Seroquel** has been also been aggressive in the elderly market.

- They are making significant efforts via posters and presentations of re-analyzed data. Astra is promotionally using this data in sales brochures and other vehicles delivering this information via its sales representatives.
- Astra is having an impact among prescribers by focusing and leveraging the sedating properties of Seroquel, which is viewed by some as an advantage.
- Seroquel has only minimal efficacy data and therefore focus on an overall perceived better safety profile - this has made it an attractive agent.
- Among neurologists, Astra has created support for Seroquel's use in the management of psychosis associated with Parkinson's Disease and raised general concerns about movement disorders. OMP's Neuroscience representatives have been calling on a core group of neurologists since early October and this will blunt this impact and maximize our RISPERDAL opportunity with neurologists. Additional tactics with OMP are planned for 2001.

**Zeldox** most likely will enter the market in 1Q'01 with an indication for the manifestation of psychosis in schizophrenia.

- To date, clinical data on Zeldox in geriatrics has neither been posterized or published.
- Since the product is associated with QTc interval prolongation this safety precaution will likely be a significant deterrent to its usage in the vulnerable elderly patient population.

### **III. PRODUCT PERFORMANCE SUMMARY:**

RISPERDAL remains the #1 prescribed antipsychotic in the LTC/Geriatrics market with a current TRx share of 34%. RISPERDAL in LTC/Geriatrics is the #2 market for the molecule and is expected to maintain this position in 2001. With the possible addition of other uses to our mix in 2001 the importance of the elderly market to RISPERDAL will continue to be significant.

The RIS-63 (Katz) study (published in February 1999) has been a powerful and convincing study supporting RISPERDAL efficacy and safety. In July of 2000 the long-term extension to RIS-63, RIS-70 (Jeste) was published. Both articles have been approved via FDAMA and we begin dissemination in February 2001. These two studies and others will form a significant foundation for our brand's medical education programs.

The launch of the J&J LTC group has been an effective way to partner with the LTC pharmacy providers. Our ElderCare sales force has been effective despite its limited reach among our target audiences. Both teams have consistently and effectively delivered critical messages on the benefits of RISPERDAL to our target audiences - nursing homes, consultant pharmacists, primary care physicians and psychiatrists.

Astra and Lilly have recognized the importance of this market and increased their promotional activities toward prescribers/influencers within it and are deploying significant resources against it.

#### **2000 Critical Success Factors**

- Close the Perception Gap on safety with Zyprexa and Seroquel;

- Expand reach and frequency and grow market share with PCPs;
- Disseminate clinical data under WLF
- Rep and MSL coverage of top Opinion Leaders

#### IV. SWOT ANALYSIS, KEY ISSUES:

An assessment of RISPERDAL's strengths and weaknesses in the current market reveals the following:

##### Strengths

- ElderCare: Janssen's #1 strategic objective
- Efficacy/safety data (RIS-63 & RIS-70)
- Continued market leadership
- J & J LTC/ElderCare team
- Performance based contracts
- Dosing flexibility and cost advantage

##### Weaknesses

- EPS liability
- Sub-optimal deployment against emerging customers (PCPs, Neuros, NPs)
- Lack of geriatrics/dementia data in label
  - Limitations in use of our clinical data and lack of comparative data

##### Opportunities

- New geriatrics markets (e.g., elderly psychosis)
- Residency Programs, Training Centers,
- Professional & Family Caregivers, State
- Surveyors & other influencers
- New LTCPP Market Share Tier Programs
- Clinical/outcomes data
- Accelerate conversion of conventionals
- RIS/REM position/synergies
- e-business
- FDAMA dissemination of RIS-63 & 70

##### Threats

- Seroquel/Zyprexa: expanding geriatric focus
  - sales force, marketing & clinical
- Zeldox geriatric focus?
- ACHEIs/AC/AD positioning in behaviors
- Reimbursement environment:
- PPS/Medicare; Medicaid?
- RIS not first with indication

#### KEY ISSUES

- Increased competition from atypicals and other drug classes, i.e., ACHEIs, AC, and AD.
- Untapped market opportunities (e.g. elderly psychosis)
- Educational needs on appropriate use and benefits of atypicals not being met across diverse customer base
- Current labeling unfavorable
- RISPERDAL & REMINYL co-positioning

#### V. 2001 STRATEGIC OBJECTIVES:

Grow RISPERDAL leadership position in LTC/Geriatrics market and prepare for approval of the new indication.

Our positioning in the LTC/Geriatric market has remained consistent: RISPERDAL has the best combination of efficacy and safety while providing needed dosing flexibility.

Our support for this positioning has been strengthened with the launch of a new effective and appropriate promotional platform and the wide acceptance of lower dosage strengths (0.25mg and 0.5mg)

Our core messages in the 2001 are:

##### Outstanding Efficacy

- Significant improvement in psychotic symptoms and behaviors
- Improvement as soon as one week

- Efficacy maintained for one year

**Excellent Safety Experience**

- Low incidence of excessive sedation
- Benign anticholinergic profile
- Minimal EPS at recommended low doses

**Custom-Tailored Dosing**

- Available in 0.25 and 0.5mg dosage strengths as well as oral liquid formulation

**VI. KEY BUSINESS STRATEGIES:**

1. Strengthen efficacy/safety positioning vs. the competition and grow our leadership dominance in LTC/Geriatrics and prepare for approval of the new indication.
2. Expand effectively and appropriately into additional geriatrics market opportunities.
3. Expand reach/educate a diverse audience:
  - PCPs, Neurologists, NP
  - Training Centers (ADRC, GRECC/VA, Residency Programs)
  - State Surveyors
  - Professional and Family Caregivers
4. Effectively position and maximize RISPERDAL/ REMINYL

**VII. KEY PROGRAMS AND TACTICS:**

**Strategy #1: Strengthen efficacy/safety positioning vs. the competition and prepare for approval of the new indication**

Program	Volume/Description
Advisory Boards (Home Office)	9 programs
Regional Advisory Boards	9 programs
Speaker Training	250 physicians
CME Senior Care Seminars	1100 Programs (5 / Rep)
CME Distance Learning Network	1 Program
CME Teletopics	2 Programs (16 dates each)
Quality Indicator Program	Multiple tactics (symposia, SCS, Promotion)
LTC Pull-through	Market share targets

Other tactics include:

- Promotional platform
- Publications
- Medical Meetings/Symposia
- Medical Affairs
- FDAMA: Dissemination of published studies in dementia
- Label changes in dosing/precautions section of PI

**Strategy #2: Expand effectively and appropriately into additional geriatrics market opportunities**

Program	Volume/Description
Elderly Psychosis Program/ Parkinson's	Multiple tactics: DLN, CME web-based program, GMR website, posters, symposia

**Strategy #3: Expand reach/educate a diverse audience**

Program	Volume/Description
Primary Care Outreach	Multiple tactics: Target Prozac writers; SCS audiotape; Direct mail; AAFP Symposium, NP/PA Symposium; Journal supplement
Nurse Education	Magic pen/training for CNAs
Neurology	Multiple tactics: OMP Neuroscience reps, promo materials, SCS, Ad boards, NIH consensus conference

Other tactics:

- CNS Summit
- Keystone 3
- AAGP Stepping Stones
- AAGP Training Directors Program
- Summer Research Institute
- Education initiatives: state surveyors, nurse practitioners, caregivers, nurses
- Residency Program (Primary Care/Geriatrics)
- AMDA Futures Program
- ADRC/GREC/VA Program
- Adopt-a-doc
- Assisted Living Pilot (Alterra)

**Strategy #4: Effectively position and maximize RISPERDAL/ REMINYL**

- SCS
- Advisory Boards
- Speaker Bureaus and Training
- Symposia/Enduring Materials
- Caregiver Education
- Sales Training/Preceptorships



### VIII. SUCCESS PREDICTORS:

To be successful in this marketplace, certain things must happen. The brand team will play a key role in driving each of these success predictors:

- Execution of new studies & dissemination of clinical data that at a minimum matches the output of our competitors
- Psychosis in Alzheimer's disease indication trials must remain on timelines
- Drive alignment and focus around the key issues, strategies and tactics by EC/CNS I-Reps/ LTC/ MSL/OMP SL/ Medical Affairs, Sales Training & JRF
- Strengthen label related to geriatrics
- Maximize FDAMA
- Maximize RISPERDAL/REMINYL positioning & synergies

#### Sales Plan Summary - Long-Term Care / Janssen-ElderCare 2001 Business Plan - Highlights

After a very successful 2000, the LTC/EC teams are poised for another outstanding year in 2001. The expansion of the EC sales force to 135 representatives with the addition of 50 EC specialists will allow us to stay competitive in this market and regain our leadership position as the number one company in ElderCare.

The expansion and training is scheduled for completion by end of March 2001. This will expand our reach to 73% of the PCP APS 3 - 9 from 2,700 to 5,090. The call average is targeted for 7 per day, with a frequency of 12 calls per year on 90% of the key targets. RISPERDAL call activity by customer segment is summarized as follows:

	#Targets	Frequency
PC/IM	5,090	12.0
Med. Dir. & Attending Phys.	9,000	6.0
Psych Consultants	2,250	6.0
Psychs	2,932	12.0
VA NH Facilities	62	6.0
LTC Facilities NH	4,500	6.0

Working closely with the brand team the EC/LTC team will be utilizing among others - CME/CE accredited speaker programs, teletopics and advisory boards to accelerate growth for our key strategic brands.

Our efforts will be focussed on harnessing the power of technology to expand our reach and give us a distinct competitive advantage. Two major initiatives are the Dr to Patient web hosting program and the launch of Janssen-ElderCare.com. Differentiating the EC/LTC teams from competitors will continue to be the focus throughout 2001.

Human resources development and improving the standards of performance to ensure that over 65% of the sales force is in stage II of the standards of leadership will be a priority for the management team.

To stay competitive in this market place the LTC group will work on creative contracting programs to curtail the intense competitive activities and stay ahead.