Product Pipeline

Worldwide Prescription Products / **April 2003**

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Early Phase

Adenosine 2a Receptor Antagonist
Parkinson's Disease

CCR5 Receptor Antagonist
HIV Infection

▶ **PDE5 Inhibitor**
Erectile Dysfunction

PEG-INTRON
Variety of Solid Tumors

Phase II

Pure Anti-Estrogen
Post-Menopausal Studies

REMICADE [1]
Psoriasis

SARASAR
Leukemia
Variety of Solid Tumors

TEMODAR
Variety of Tumors

Phase III

ASMANEX
Asthma (Metered-Dose Inhaler)

CLARINEX-D 24 Hour
Seasonal Allergic Rhinitis

CLARITIN/*Singulair* [2]
Seasonal Allergic Rhinitis

INTEGRILIN
Acute Myocardial Infarction

NOXAFIL
Opportunistic Fungal Infections

PEG-INTRON
Malignant Melanoma

REMICADE [1]
Early Rheumatoid Arthritis
Psoriatic Arthritis
Ulcerative Colitis

SARASAR
▶ Non-Small-Cell Lung Cancer

ZETIA/*Zocor* [2]
Lipid Lowering (Single Tablet)

NDA/BLA/PLA/HRD Filed

ASMANEX
Asthma (Dry Powder Inhaler)

CLARINEX Syrup
Chronic Urticaria
Seasonal Allergic Rhinitis

REMICADE [1]
Ankylosing Spondylitis

▶ Phase advance ▶ Indication advance [1] International rights only [2] J.V. with Merck

Product Name	Market Size	Indications	U.S. Status	International Status
Adenosine 2a Receptor Antagonist Oral formulation	Prevalence in major world markets – 2.6 million	Treatment of Parkinson's disease	Studies planned	Conducting Early Phase studies
ASMANEX Anti-inflammatory steroid Oral inhaler	Oral inhaled steroid market: U.S. market – $1.5 billion Int'l market – $1.6 billion	Treatment of asthma: – Dry powder inhaler – Metered-dose inhaler	 Approvable 10/99 Phase III	 Launched in UK 1/03 Conducting studies
CCR5 Receptor Antagonist Oral formulation	Market projections premature	Treatment of HIV infection	Early Phase	Conducting Early Phase studies
CLARINEX Nonsedating antihistamine Oral formulation	Oral antihistamine market: U.S. market – $4.6 billion Int'l market – $1.8 billion	Treatment of allergies: – CLARINEX Syrup – CLARINEX-D 24 Hour	 Approvable 10/01 Phase III	 HRD approved 4/02 Conducting studies
CLARITIN/*Singulair* Nonsedating antihistamine/ leukotriene inhibitor Oral formulation	U.S. allergy market – $7.2 billion	Dual-action approach to treating allergies – Seasonal allergic rhinitis	J.V. with MRK Phase III/Evaluating clinical program	U.S. only
INTEGRILIN Glycoprotein IIb/IIIa platelet aggregation inhibitor Injectable formulation	Total patients with AMI: U.S. market – 410,000 Int'l market – 360,000	Treatment of acute myocardial infarction (AMI)	Phase III	Studies planned
NOXAFIL Triazole antifungal Oral formulation	Worldwide antifungal market – in excess of $4.0 billion	Treatment of opportunistic fungal infections	Phase III	Conducting studies
PDE5 Inhibitor Oral formulation	Prevalence in major world markets – 47.5 million	Treatment of erectile dysfunction	Studies planned	Conducting Early Phase studies

Product Name	Market Size	Indications	U.S. Status	International Status
PEG-INTRON Long-acting antiviral/biological response modifier Injectable formulation	Worldwide interferon market – in excess of $1 billion	Cancer indications: – Malignant melanoma – Variety of solid tumors	 Phase III Early Phase	Conducting studies
Pure Anti-Estrogen Oral formulation	Market projections premature	Post-menopausal studies	Phase II/On hold	No ongoing studies
REMICADE Monoclonal antibody Injectable formulation	Prevalence in int'l markets: Ankylosing spondylitis – 1.5 million Rheumatoid arthritis – 4 million Psoriatic arthritis – 650,000 Ulcerative colitis – 200,000 Psoriasis – 6.3 million	Treatment of inflammatory diseases: – Ankylosing spondylitis – Early rheumatoid arthritis – Psoriatic arthritis – Ulcerative colitis – Psoriasis	International only	 CPMP recomm. approval 2/03 Phase III Phase III Phase III Phase II
SARASAR Farnesyl transferase inhibitor Oral formulation	Incidence of non-small-cell lung cancer: U.S. market – 144,000 Int'l market – 174,000	Treatment of cancer: – Non-small-cell lung cancer – Leukemia – Variety of solid tumors	 Phase III Phase II Phase II	 Conducting studies Conducting studies Conducting studies
TEMODAR Cytotoxic chemotherapeutic agent Oral formulation	Market projections premature	Treatment of a variety of tumors	Phase II	Conducting studies
ZETIA/*Zocor* Lipid-lowering agent Oral formulation	Cholesterol-lowering market: U.S. market – $12.9 billion Int'l market – $7.8 billion	Dual-action approach to treating high cholesterol – Single tablet	J.V. with MRK Phase III	J.V. with MRK (ex-Japan) Conducting studies

Early Phase

PDE5 Inhibitor
New to this phase is the PDE5 Inhibitor as a treatment for erectile dysfunction.

Phase II

Pure Anti-Estrogen
The post-menopausal studies in Phase II have been put on hold, pending the outcome of FDA guidance regarding development of hormone replacement therapy products.

TENOVIL
TENOVIL is no longer in development for inflammatory diseases and has been removed from the *Product Pipeline*. SGP has decided that further development is not warranted.

Phase III

CLARINEX-D 24 Hour
This formulation has been broken out of the "Various line extensions" category. Therefore, the "Various line extensions" category has been removed from the *Product Pipeline*.

Marimastat
Marimastat is no longer in development for pancreatic cancer and has been removed from the *Product Pipeline*.

SARASAR
SARASAR for the treatment of non-small-cell lung cancer has advanced to this phase.

NDA/HRD Filed

CAELYX
On Jan. 14, SGP announced that the European Union granted marketing authorization for CAELYX in metastatic breast cancer. Therefore, this compound has been removed from the *Product Pipeline*.

CLARINEX-D 12 Hour
CLARINEX-D 12 Hour Extended Release Tablets, a twice-daily treatment in combination with the decongestant pseudophedrine sulfate, was the subject of an October 2001 "approvable" letter from the FDA. Based on an analysis of the "approvable" letter, SGP has determined that it intends to reformulate the product and seek approval for a new version with improved stability.