Research Overview

Peter S. Kim
President, Merck Research Laboratories
Merck’s Research and Development Update

• Merck’s Late Stage Pipeline Review
• Merck’s New Research & Development Model
  – Focusing on Priority Disease Areas
  – Leveraging Key Product Enablers
  – Moving Towards Differentiated, Targeted Therapies
  – Accelerating Development and Increasing Efficiencies
  – Increasing Productivity: Building on our Momentum
Key Late Stage Development Highlights

- Three NDA submissions in 2005
- Three anticipated filings in 2006
- Five programs in Phase III by 1Q06
- Eight programs in Phase IIb by 1Q06
## Merck’s Development Pipeline
### December 15, 2005

<table>
<thead>
<tr>
<th>2005 Submissions</th>
<th>2006 Anticipated Filings</th>
<th>Phase III</th>
<th>Phase IIb</th>
</tr>
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<tbody>
<tr>
<td>GARDASIL Cervical Cancer</td>
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T=Target
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T=Target
JANUVIA: A New Mechanism for the Treatment of Type 2 Diabetes

• JANUVIA (MK-0431) is efficacious in Type 2 diabetes
  – Potent and highly selective inhibitor of dipeptidyl peptidase IV (DPP-4)
  – Once-daily dosing
  – Substantial reduction in A1C levels observed

• Incidence of hypoglycemia similar to placebo

• Effect on body weight similar to placebo

• Overall adverse experience profile similar to placebo

• JANUVIA is generally well-tolerated
JANUVIA is Efficacious in Patients with Type 2 Diabetes Results at 12 weeks: 100 mg Once Daily Therapy

Reference: Herman G et. al., American Diabetes Association, June, 2005
JANUVIA: Potential for Disease Modification

Restoration of Pancreatic Islet β Cells in Mice
Following 10 week Treatment with JANUVIA analog

Diabetic Mice | Diabetic Mice + DPP-4 Analog | Lean Control Mice

Reference: Zhang, B et. al., American Diabetes Association, June, 2005
JANUVIA: 2006 NDA Filing Anticipated

- JANUVIA is a novel efficacious treatment for Type 2 Diabetes
- JANUVIA has a favorable safety and tolerability profile
- Phase III program is progressing on target
  - Additional data to be submitted to the American Diabetes Association Meeting (June, 2006)
# Merck’s Development Pipeline
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MK-0431A: MK-0431 Combination with Metformin

- Metformin is the most commonly used therapy for Type 2 diabetes
  - Monotherapy
    - Well-established safety, tolerability and efficacy profile
      - Lowers hepatic glucose output
      - Not associated with hypoglycemia
    - Extensive combination therapy usage

- MK-0431A Product Profile
  - MK-0431 + Metformin combination
    - Phase III initiated 2005
    - Anticipated NDA filing 2007
MK-0431A: Provides Efficacy in Patients with Inadequate Glycemic Control on Metformin Monotherapy

Reference: Brazg et. al., American Diabetes Association, June, 2005
MK-0518: A Novel Mechanism Compound for HIV-1 Infection

- Resistance is a major problem with current HIV therapy\(^1,2,3\)
  - More than 76% are resistant to one class of therapy
  - \(~ 50\%\) are resistant to multiple classes of therapy
  - Resistance in treatment-naïve patients has increased to \(>20\%\) from 8% in 1999

- MK-0518 is an inhibitor of integrase, an enzyme necessary for integration of the virus’s genetic information into the host cell

\(^1\) UNAIDS; WHO 2004 Report
\(^2\) Richman DD et al. AIDS 2004, 18:1393–1401
MK-0518: A New Mechanism for the Treatment of HIV-1 Infection

- MK-0518 is a potent inhibitor of HIV-1 integrase

- Product profile
  - Potent antiretroviral activity demonstrated in treatment-naïve patients and salvage patient population
    - Data in salvage patient population to be presented in 2006
      - Conference on Retroviruses and Opportunistic Infections
    - MK-0518 is generally safe and well-tolerated

- Initiation of Phase III program anticipated 1Q06

- Anticipated NDA filing 2007
  - Fast Track designation for salvage indication
MK-0518 HIV Integrase Inhibitor: Effect on HIV RNA Levels in Treatment Naïve Patients

Change from Baseline in HIV RNA (log_{10} copies/mL) vs. Days on Therapy

Gaboxadol: A New Mechanism for the Treatment of Insomnia

- Gaboxadol is selective for extrasynaptic GABA-A receptors containing δ subunits
  - Highly expressed in brain areas regulating sleep (e.g., thalamus)
  - Does not interact with the benzodiazepine binding site
- Results of Early Clinical Studies:
  - Improved sleep quality
  - Increased slow-wave sleep without suppressing REM sleep
- Gaboxadol was generally safe and well-tolerated
- Joint Lundbeck/Merck Phase III development program progressing on target
  - Additional clinical data to be submitted to the American Psychiatric Association (APA) 2006 Annual Meeting
- Anticipated NDA Filing 1Q2007
H. Lundbeck A/S Alliance

**Gaboxadol Improves Sleep Initiation and Maintenance in Patients with Primary Insomnia**

**Phase II Polysomnography Study**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Placebo</th>
<th>15 mg Gaboxadol</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latency to Persistent Sleep (min)</td>
<td>30.0</td>
<td>23.6</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Total Sleep Time (min)</td>
<td>409</td>
<td>420</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Subjective Assessment of Sleep Quality (mm)</td>
<td>51.4</td>
<td>59.7</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Slow Wave Sleep Duration (min)</td>
<td>93.9</td>
<td>114</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>REM Duration (min)</td>
<td>92.7</td>
<td>85.2</td>
<td>NS</td>
</tr>
</tbody>
</table>

Gaboxadol: Unique Effects on Sleep Architecture

Gaboxadol Increases Time Spent in Slow Wave Sleep
MK-0524A: Lipid management beyond LDL-C

Low HDL-C and Increased CHD Risk

- There is a significant unmet medical need for reducing the risk of cardiovascular events.
- NCEP, ISA and ESC guidelines identify patients with low HDL-C as at increased CHD risk.
- Roughly 50 million Americans have low HDL-C (25% of adults).

Source: Framingham Heart Study
Proven Cardiovascular Benefits Associated with Niacin Treatment in Clinical Studies

- Crystalline niacin was first used in 1955
- Early outcome study indicated a beneficial effect of niacin in heart disease
  - Coronary Drug Project
- Atherosclerosis studies indicated vascular improvement with niacin
  - HATS (HDL Atherosclerosis Treatment Study)
    - Coronary angiographic study
  - ARBITER 2
    - Carotid artery intima-media thickness study

1 Canner PL et. al. JACC 1986; 8(6):1245-55
2 Brown BG et. al. NEJM 2001; 345:1583-1592
3 Taylor AJ et. al. Circulation 2004; 110(23):3512-7
Limitations of Niacin HDL-C Raising Therapy

- 90% of patients experience flushing with niacin therapy
  - Worst at first dose
  - Chronic, intermittent and unpredictable
  - Extended-release niacin, pretreatment with aspirin, and other measures only partially reduce the flushing associated with niacin

- Poor tolerability limits use despite favorable efficacy\(^1\)
  - Only 10% of prescriptions are written at the target 2 gram dose

\(^1\)National Disease and Therapeutic Index: data gathered between 4Q01-1Q04 (3600 office-based physicians)
MK-0524: A Novel Niacin Flushing Pathway Inhibitor

Prostaglandin D2 Receptor Antagonism Suppresses Niacin-Induced Vasodilation in the Mouse

Flushing (% increase)

Time (minutes)

-5 0 5 10

Placebo

MK-0524 (low dose)

MK-0524 (high dose)
MK-0524: A Novel Niacin Flushing Pathway Inhibitor

% of Days with Moderate/Severe Flushing

Niacin Dose: 1 gram
Niacin Dose: 2 grams

Weeks on Treatment

% of Days with Moderate/Severe Flushing

NIASPAN
NIASPAN + MK-0524
Placebo
MK-0524A & MK-0524B: A Novel Approach to Lipid Management with Proven Outcomes

MK-0524A
- Merck’s extended-release niacin combined with a novel flushing pathway inhibitor
- Target 2 gram dose of niacin routinely attainable
- HDL-C increase of 20-25% and triglyceride decrease of 25-30%
- Can be used with any statin
- Phase III initiation – December, 2005
  - Anticipated NDA filing – 2007

MK-0524B
- Simvastatin combined with MK-0524A
- Phase III initiation – anticipated 1Q06
  - Anticipated NDA filing – 2007

Additional data to be submitted in 2006 to:
American College of Cardiology & American Heart Association
Merck’s New Research & Development Model

- Focusing on Priority Disease Areas
- Leveraging Key Product Enablers
- Moving Towards Differentiated, Targeted Therapies
- Accelerating Development and Increasing Efficiencies
- Increasing Productivity: Building on our Momentum
Merck’s Nine Priority Areas of Focus

<table>
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<th>Area</th>
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<tr>
<td>Alzheimer’s Disease</td>
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<tr>
<td>Atherosclerosis</td>
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<tr>
<td>Cardiovascular</td>
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<tr>
<td>Diabetes</td>
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<tr>
<td>Novel Vaccines</td>
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<tr>
<td>Obesity</td>
</tr>
<tr>
<td>Oncology (Targeted Therapies)</td>
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<tr>
<td>Pain</td>
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<tr>
<td>Sleep Disorders</td>
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## Areas of Targeted Research

<table>
<thead>
<tr>
<th>1. Antibiotics</th>
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<tbody>
<tr>
<td>2. Antifungal</td>
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<tr>
<td>3. Antiviral (HCV, HIV)</td>
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<td>4. Asthma</td>
</tr>
<tr>
<td>5. COPD</td>
</tr>
<tr>
<td>6. Neurodegeneration</td>
</tr>
<tr>
<td>7. Ophthalmology</td>
</tr>
<tr>
<td>8. Osteoporosis</td>
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<tr>
<td>9. Schizophrenia</td>
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<tr>
<td>10. Stroke</td>
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Example of Prioritization: Merck’s Pipeline in Atherosclerosis, Cardiovascular, Diabetes & Obesity

### Phase I
- Atherosclerosis, MK-0354
- Atherosclerosis, MK-0633
- Cardiovascular, MK-0448
- Diabetes, MK-0941
- Diabetes, MK-0893
- Diabetes, MK-0533
- Hypertension, MK-0736
- Obesity, Nastech PYY3-36

### Phase II
- Obesity, MK-0493
- Obesity, MK-0364
- Atherosclerosis, MK-0859 (T-1Q06)

### Phase III
- Atherosclerosis, MK-0524A
- Atherosclerosis, MK-0524B (T-1Q06)
- Diabetes, MK-0431A

### 2006 Anticipated Filings
- Diabetes, JANUVIA (MK-0431)

As of December 15, 2005

Back-ups not included

\[ T = \text{Target} \]

Licensed, alliance, or acquisition (Pipeline)
Leveraging Biomarkers as Key Product Enablers: Example in Atherosclerosis

- Novel Pharmacogenomic Collaboration with FoxHollow Technologies
  - Focused on identification of new biomarkers of atherosclerotic disease progression
  - Integrated into Merck’s Research and Development programs
- FoxHollow will provide exclusive access to atherosclerotic plaque samples from patients with cardiovascular disease
  - SilverHawk Plaque Excision System
    - Minimally invasive catheter system which removes atherosclerotic plaque
    - Device is used to treat peripheral arterial disease
Oncology: Leading the Way Towards Differentiated, Targeted Therapies

- AVEO
- Agensys
- Notch Inhibitor
- Vertex VX680
- Vorinostat (SAHA)

- Preclinical
- Ph I
- Ph II
- Ph III
- Launch

- Rigel
- Pierre Fabre F50035
- Geron
- KSP Inhibitor

Partnerships

- Internal Programs

- Tools and Academic Relationships
  - Alnylam, NKI, Celera, RNAi
  - (numerous unannounced)

Rosetta
Vorinostat: Histone Deacetylase Inhibitor for Cancer

- SAHA (suberoylanilide hydroxamic acid)
- NDA Filing for Cutaneous T-cell Lymphoma (CTCL) anticipated in 2006
  - Positive Phase IIa data
  - Vorinostat was generally well-tolerated
  - Additional data to be submitted to the American Society of Clinical Oncology (June, 2006)
- Evaluation in hematological cancers and solid tumors underway
- Monotherapy and combination therapies being evaluated
## Accelerating Early Development Timelines: First in Man to Initiation of Phase III

### Typical Timeline for Early Development

<table>
<thead>
<tr>
<th>Ph I</th>
<th>Ph II</th>
<th>Total time from FIM to Phase III</th>
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<tr>
<td></td>
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<td>3.5 years</td>
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<td>MK-0518</td>
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Increasing Efficiencies in Late Development: Decreasing Cycle Time

<table>
<thead>
<tr>
<th></th>
<th>Protocol Approval</th>
<th>Last Patient In</th>
<th>Last Patient Out</th>
<th>WMA</th>
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<tbody>
<tr>
<td>2005-2006: Anticipated Cycle Time</td>
<td>4 Month reduction</td>
<td>3 Month reduction</td>
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<tr>
<td>Reductions</td>
<td></td>
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<tr>
<td>2006-2007: Anticipated 2 months</td>
<td></td>
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<tr>
<td>reduction in Development Processes</td>
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20% increase in throughput without increasing operational costs

Continuous improvement productivity gains anticipated
New Candidates Entering Merck Pipeline: Internal & Licensed Candidates

- Internal Preclinical Candidates (GLP studies), including back-ups
- Licensed Preclinical (GLP studies) and Clinical Candidates

Year

# Candidates

% to Phase I

2001 | 33% | >50%*
2002 |    | >57%*
2003 |    | >28%*
2004 |    | >28%*
2005 |    | >50%*

* Lower limit since some candidates remain in preclinical development
Programs Entering Phase I Development

![Bar chart showing the number of programs entering Phase I Development from 2001 to 2005.](image)

- **2001**: 5 programs
- **2002**: 7 programs
- **2003**: 10 programs
- **2004**: 16 programs
- **2005**: 23 programs
Programs Entering Phase II Development

<table>
<thead>
<tr>
<th>Year</th>
<th># Programs</th>
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<tr>
<td>2001</td>
<td>1</td>
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<tr>
<td>2002</td>
<td>4</td>
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<td>2003</td>
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<td>2004</td>
<td>11</td>
</tr>
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<td>2005</td>
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R&D Pipeline Overview

- **Phase III**
  - Specific compounds

- **Phase I and II**
  - Specific compounds by MK number
    - The most advanced compound with a specific mechanism in a given therapeutic area
    - MK number consistent with other external databases (e.g., ClinicalTrials.gov)

- **Not included**
  - Pre-clinical compounds
  - Back-up compounds, regardless of their phase of development
  - Additional indications in the same therapeutic area
### Merck Pipeline – December 15, 2005

#### Phase I
- Alzheimer’s Disease, MK-0752
- Arthritis, MK-0822
- Atherosclerosis, MK-0354
- Atherosclerosis, MK-0633
- Cancer, MK-0429
- Cancer, MK-0752
- Cancer, Agensys
- Cancer, MK-0731
- Cancer, VX-680
- Cancer Vaccine
- Cardiovascular, MK-0448
- Diabetes, MK-0941
- Diabetes, MK-0893
- Diabetes, MK-0533
- Endocrine, MK-0974
- Flu Vaccine
- Glaucoma, MK-0987
- Glaucoma, MK-0994
- Hypertension, MK-0736
- Insomnia, MK-0454
- Obesity, Nastech PYY3-36
- Osteoporosis, MK-0773
- Pain, MK-0686
- Parkinson’s Dis, MK-0657
- Psychiatric Dis., MK-0249
- Respiratory Dis, MK-0633
- S. Aureus Vaccine
- **Licensed, alliance, or acquisition (Pipeline)**

#### Phase II
- Arthritis, MK-0873
- Arthritis, MK-0686
- Athero., MK-0859 (T-1Q06)
- Cancer (CTCL), Vorinostat
- Endocrine, MK-0677
- HIV Vaccine
- HPV Vaccine*
- Multiple Sclerosis, MK-0812
- Obesity, MK-0364
- Obesity, MK-0493
- Osteoporosis, MK-0822
- Pain, MK-0974
- Pain, MK-0759
- Pediatric Vaccine
- Psychiatric Disease, MK-0364
- Psychiatric Dis., Lurasidone
- Stroke, ONO 2506**
- Urinary Incont., MK-0634
- Urinary Incont., MK-0594 (T-1Q06)

#### Phase III
- AIDS, MK-0518 (T-1Q06)
- Arthero., MK-0524B (T-1Q06)
- Arthero., MK-0524A
- CINV, MK-0517
- Diabetes, JANUVIA (MK-0431A)
- Diabetes, JANUVIA (MK-0431)

#### Under Review
- HPV and related cervical cancer and genital warts GARDASIL*
- Rotavirus Gastroenteritis ROTATEQ
- Shingles ZOSTAVAX

#### Approvable
- Arthritis/Pain ARCOXIA

#### 2005 Approvals
- Osteoporosis FOSAMAX Plus D
- Pediatric Vaccine PROQUAD

---

**Advanced since December, 2004**

*Licensed, alliance, or acquisition (Pipeline)*

T =Target

*Multiple Licenses, including CSL, Ltd.

**Merck is in discussions with its licensing partner regarding further plans for this compound.
# Merck’s Late Development Pipeline with Supplemental Indications – December 15, 2005

<table>
<thead>
<tr>
<th>Phase III</th>
<th>2006 Anticipated Filings</th>
<th>2005 Submissions</th>
<th>2005 Approvals</th>
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<tbody>
<tr>
<td>MK-0431A</td>
<td>JANUVIA (MK-0431)</td>
<td>GARDASIL</td>
<td>FOSAMAX Plus D Osteoporosis</td>
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<td>Type 2 diabetes</td>
<td>Type 2 Diabetes</td>
<td>Cervical Cancer</td>
<td>PROQUAD Pediatric Vaccine</td>
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<td>Hypertension</td>
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T=Target
Merck’s Research and Development Summary

- Increasing Late Stage Development Portfolio
  - Three NDA submissions in 2005
  - Three anticipated filings in 2006
  - Five programs in Phase III by 1Q06
  - Eight programs in Phase IIb by 1Q06

- Merck’s New Research & Development Model
  - Focusing on Priority Disease Areas
  - Leveraging Key Product Enablers
  - Moving Towards Differentiated, Targeted Therapies
  - Accelerating Development and Increasing Efficiencies
  - Increasing Productivity: Building on Our Momentum
Question & Answer