Innovation beyond the drug
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Member of the Pharmaceutical Executive Committee

Dresden, October 8th, 2014
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founded in 1668

66 countries

4 pharmaceutical und chemical divisions

over 39,000 employees

€1.5 billion for research and development in 2013

€11.1 billion total revenues in 2013
Merck
Merck Serono is Biopharmaceutical Division of Merck

- Merck is the oldest pharmaceutical and chemical company in the world founded in 1668 in Darmstadt, Germany.

- Merck KGaA, Darmstadt is a publicly listed company in the DAX at the Frankfurt Stock exchange. The Merck family holds 70% of the shares.

- We operate under the name of EMD Serono in North America.

- EMD, stands for Emmanuel Merck, Darmstadt, reflecting these roots in Germany.
### Our Corporate Structure
Merck Serono is the Largest Division

<table>
<thead>
<tr>
<th>Division</th>
<th>Sales (€ m)</th>
<th>Businesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merck Serono</td>
<td>5,954</td>
<td>Oncology, Immunology/NDD*, Immunology, Fertility, Endocrinology &amp; General Medicine</td>
</tr>
<tr>
<td>Consumer Health</td>
<td>477</td>
<td>Everyday health protection, Women’s and children’s health, Cough and cold</td>
</tr>
<tr>
<td>Performance Materials</td>
<td>1,642</td>
<td>Liquid Crystals, Pigments &amp; Cosmetics</td>
</tr>
<tr>
<td>Merck Millipore</td>
<td>2,628</td>
<td>BioScience, Lab Solutions, Process Solutions</td>
</tr>
</tbody>
</table>

1: Sales figures represent global divisional sales figures

* NDD: Neurodegenerative Diseases

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Merck Serono R&D
Investing in Innovation

- **€ 1,183 million** invested in R&D in 2013
- **More than 2,300** professionals worldwide
- **Self-initiative, creativity, and innovation:**
  - Supporting scientists, students, entrepreneurs, employees and their innovative ideas in many ways by giving grants, offering awards, sponsoring initiatives
  - Example: Global Grants Program with annual €20 million investment to advance innovation and medical education
- **€ 150 million** managed by MS Ventures to access early innovation
  - **€ 10 million** allocated to Israel Bioincubator for strategic seed investment in Israeli Start-ups
  - **€ 30 million** allocated to the creation of spin-off companies around Merck Serono’s assets and talents
  - **Approx. 20 portfolio companies** currently managed through the fund
Research and Early Development
Structured along three Translational Innovation Platforms (TIPs)

- 3 years business plan
- Organized in Innovation Clusters
- Independent Advisory Board
Our R&D Portfolio
Diverse Portfolio of Small Molecules and Biologics

Phase I
- ATX-MS-1467 Immune tolerizing agent
  Multiple sclerosis
- Pimasertib<sup>1</sup> MEK inhibitor
  Solid tumors
- Pimasertib<sup>2</sup> MEK inhibitor
  Solid tumors
- MSC2156119 C-Met kinase inhibitor
  Solid tumors
- TH-302 Hypoxia-activated prodrug
  Hematologic malignancies and solid tumors
- Sym004 Anti-EGFR mAbs
  Solid tumors
- MSC236318A p70S6K and Akt inhibitor
  Solid tumors
- BGB-283 BRAF inhibitor
  Solid tumors
- MSB0010718C Anti-PD-L1 mAb
  Solid tumors
- NHS-IL12<sup>3</sup> Cancer immunotherapy
  Solid tumors
- ALX-0761 Anti IL-17 nanobody
  Normal volunteers

Phase II
- Plovamer acetate (PI –2301) 2<sup>nd</sup> generation peptide copolymer
  Multiple sclerosis
- Abituzumab (Di17E6) Anti-integrin mAb
  Colorectal cancer
- Abituzumab (Di17E6) Anti-integrin mAb
  Prostate cancer
- Pimasertib MEK inhibitor
  Pancreatic cancer
- Pimasertib MEK inhibitor
  Melanoma
- Pimasertib<sup>1</sup> MEK inhibitor
  Ovarian cancer
- Sym004 Anti-EGFR mAbs
  Squamous cell carcinoma of the head and neck
- Sym004 Anti-EGFR mAbs
  Colorectal cancer
- TH-302 Hypoxia-activated prodrug
  Melanoma
- MSB 0010445 (NHS-IL2)
  Cancer immunotherapy
- Sprifermin Fibroblast growth factor 18
  Osteoarthritis
- Atacicept Anti-Blys/anti-APRIL fusion protein
  Systemic lupus erythematosus

Phase III/ registration
- TH-302 Hypoxia-activated prodrug
  Soft tissue sarcoma
- TH-302 Hypoxia-activated prodrug
  Pancreatic cancer
- Tecemotide (L-BLP25) MUC1 antigen-specific cancer immunotherapy
  Non-small cell lung cancer
- Kuvan® (Sapropterin dihydrochloride)<sup>4</sup>
  Phenylketonuria in children less than 4 years of age
- Pergoveris® (follitropin alfa and lutropin alfa)
  Assisted reproductive technology, poor ovarian responders
- Erbitux® (cetuximab) Anti-EGFR mAb
  Squamous cell carcinoma of the head and neck (China)
- MSB 0010445 (NHS-IL2)
  Cancer immunotherapy
- ALX-0761 Anti IL-17 nanobody
  Normal volunteers

Status: June 17, 2014

<sup>1</sup> Novel combination with PI3K/mTOR inhibitor (SAR245409) from Sanofi, conducted under the responsibility of Merck
<sup>2</sup> Novel combination with hDM2 inhibitor (SAR405838) from Sanofi, conducted under the responsibility of Sanofi
<sup>3</sup> Sponsored by the National Cancer Institute (USA)
<sup>4</sup> Post-approval request by the European Medicines Agency
MS Ventures
Investing in Innovation

“Our investment philosophy is to create and support companies that we believe could be winners in the quest to develop novel drugs to benefit patients in therapeutic areas strategic to our parent’s current and future business.”

Roel Bulthuis, VP and Managing Director, MS Ventures

“We are proud of our fruitful collaborative relations with external partners. MS Ventures allows us to establish those relations early on to facilitate broader collaborations as technologies mature.”

Susan Jane Herbert, EVP GBD&AM

www.ms-ventures.com
Merck Serono Partnerships
Around the globe

We seek the best partners from everywhere in the world
Merck Serono Partnerships
Our deal scope ranges from technology to marketed products
## Our R&D Portfolio

**A strong Portfolio through successful Partnerships**

### Phase I

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<thead>
<tr>
<th><strong>ATX-MS-1467</strong></th>
<th>Immune tolerizing agent</th>
<th>Multiple sclerosis</th>
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### Phase II

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<th>Multiple sclerosis</th>
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<td>Abituzumab (DI17E6)</td>
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⁴ Post-approval request by the European Medicines Agency
Merck Serono – Mature Product Portfolio
Sales 2013 by Therapeutic Area and Product

Sales: € 5,954 million

- Total revenues grew organically by 3.2%
- Highest absolute organic sales increases coming from the General Medicine franchise (including CardioMetabolic Care) and the oncology drug Erbitux®
- Rebif®: organic growth of 1.4%
- Erbitux®: organic growth of 5.9%

Figures may not add up to 100 percent due to rounding.
Strategic priorities for sustainable success: New revenue streams and maximizing existing franchises

1. ENFORCE STABILITY IN EXISTING BUSINESSES
   - Market positioning
   - Regions / emerging markets capabilities
   - Life-cycle management including superior devices

2. CREATE SUSTAINED GROWTH
   - Deliver on R&D pipeline
   - Payor-centric devices strategy
   - Expand regional portfolio through in-licensing

Please refer to [http://www.merck.de/de/investoren/merck_serono_day.html](http://www.merck.de/de/investoren/merck_serono_day.html) for full presentation
INNOVATION BEYOND THE DRUG
TROUGH PARTNERSHIPS
Partnership based on regional development
Expansion of our Oncology franchise with BeiGene-283
a second generation BRAF inhibitor, BeiGene

- Global co-development and commercialization of BGB-283 with BeiGene, a China based company
- Leveraging the best from both partners
- BeiGene is responsible in China
- Merck Serono is responsible for the rest of the world.
Partnership based on clinical network
Strategic Alliance with Nordic Bioscience for Sprifermin in Osteoarthritis of the Knee

- Under the terms of the agreement, Nordic Bioscience will provide clinical development services to Merck on a shared-risk basis
- Merck retains full responsibility for the development and commercialization of the investigational drug
- The alliance draw on the joint expertise and resources for Merck and Nordic Bioscience
General Medicine – Strong Emerging Markets platform enables continued growth

Four strategic priorities to build on track record

1. Foster role as solid cash generator based on strong brands, focused life-cycle management and customized innovation model with ring-fenced R&D budget

2. Accelerate growth in already strong Emerging Markets platforms, especially in China, Brazil, Russia, Middle and Near East

3. Renew and strengthen portfolio through life-cycle management, e.g. Concor FDCs\(^3\), Glucophage label changes, Euthyrox reformulations

4. Continue to recover main growth levers in core markets and assets (e.g. BMS China)

General Medicine\(^1\)

Sales\(^2\)

~40% of portfolio

Outlook 2015 +

- Solid organic sales growth
- Rising earnings contribution from growth initiatives

\(^1\) Including Cardiometabolic Care, Endocrinology, General Medicine and Others; \(^2\) FY 2013; \(^3\) FDC = Fixed-dose combination

Please refer to [http://www.merck.de/de/investoren/merck_serono_day.html](http://www.merck.de/de/investoren/merck_serono_day.html) for full presentation
Merck Serono Partnership example
Collaboration With Bristol-Myers Squibb for Glucophage in China for Treatment of Type 2 Diabetes

- Merck and Bristol-Myers Squibb co-promote Glucophage in China through a profit-sharing arrangement
- Collaboration seeks to expand the geographic distribution of Glucophage as well as provide diabetes-related health and medical information including education for health professionals
Merck Serono Partnership example
Broadening General Medicines Portfolio in Emerging Markets through strategic partnership with Lupin Limited

- Lupin will support Merck Serono in the implementation of the company’s General Medicines portfolio expansion initiative in emerging markets, addressing the local needs for affordable high-quality medicines.
- First product launches expected in 2016
- Focus especially on cardiovascular and diabetes diseases
- Lupin will provide product dossiers and supply finished products.
- Merck Serono as marketing authorization holder will leverage its strong commercial and medical teams in emerging markets.
New pharmaceutical manufacturing facility
Strengthening our presence in China

€80 million investment in new pharmaceutical manufacturing facility in China

- Focusing on Merck’s leading brands referenced in China’s essential drug list
- Serving the country’s expanding healthcare needs:
  Diabetes, cardiovascular diseases and thyroid disorders
- Commercial production to start in 2017
Erbitux® – First choice in personalized treatments for mCRC and champion in head and neck

Top 4 priorities to support Erbitux

1. Further focus on the value of personalized treatments
2. Highlight importance of RAS testing\(^2\), raise RAS testing rates and roll out blood-based RAS test (Sysmex collaboration)
3. Continue to market evidence for superiority in targeted patient populations based on current data (Fire3, CALGB-80405, new Crystal retrospective)
4. Maximize head and neck opportunity globally, especially in Japan and other Asian countries

Erbitux

Sales\(^1\)

~15% of portfolio

Outlook 2015 +
- Stable to slight organic sales growth
- Growing balance between mCRC\(^3\) and SCCHN\(^4\)
- Testing to offer upside potential

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Merck Serono Partnership example
A new Collaboration with Sysmex Inostics on a Blood-Based RAS Biomarker Test

- Development and commercialization agreement on blood-based RAS biomarker mutation status test for metastatic colorectal cancer (mCRC)
- This collaboration reflects Merck Serono’s commitment to leveraging the company’s expertise in personalized medicine and predictive biomarkers
Fertility – Expanding the franchise to the next level: beyond drugs

Top 3 strategic priorities

1. Expand leadership position and build on No.1 brand growing globally, especially in high-potential Emerging Markets

2. Bolster underlying growth with potential label expansion (e.g. Pergoveris) and life-cycle and devices management versus entry of biosimilars competition

3. Leverage existing strong presence and knowledge in the fertility clinic channel to provide innovative technologies & services in the ART\(^2\) lab to drive innovation and increase success rates

Fertility

Sales\(^1\)

~15% of portfolio

Outlook 2015 +

- Continuous sales growth driven by changing demographics in EM
- Ongoing contribution from beyond drugs strategy in Europe and Canada

\(^1\) FY 2013; \(^2\) ART = Assisted reproductive technology

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Merck Serono Partnership example
Exclusive License Agreement with Auxogyn for Eeva Test

Merck Serono has received commercialization rights from Auxogyn for the Eeva® (Eeva Early Embryo Viability Assessment) Test, designed to provide objective embryo viability data to assist clinicians in improving IVF (in vitro fertilization) patient outcomes.

The license agreement builds on a successful relationship between the companies that was started in 2010 through an investment of MS Ventures.
Rebif® – Capitalizing on efficacy and active life-cycle management to support long-term prospects

Top 4 priorities to drive Rebif

1. Focus on Rebif’s efficacy in preventing relapse rates and delaying disease progression in modern multiple sclerosis population

2. Raise differentiation via smart injection devices and online patient applications as tools to drive efficacy and improve patient experience

3. Defend Rebif’s leadership position in Europe within the injectables segment and strengthen position in the US; implement tactics to drive patient acquisition and retention

4. Secure long-term profitability upgrade of the US franchise after Pfizer contract expiry

Rebif

Sales

~30% of portfolio

Outlook 2015 +

- Manage revenue erosion
- Leverage profitability
- Maximize payers’ value (devices)

Please refer to [http://www.merck.de/de/investoren/merck_serono_day.html](http://www.merck.de/de/investoren/merck_serono_day.html) for full presentation
Medical devices – Further enhancing the value of Merck Serono and harnessing existing strengths

Device-supported franchises at Merck Serono¹

- Rebif
- Fertility
- Saizen
- Other
- Device-supported

Current product offering²

Rebib
- Rebidose
- Rebiject
- Rebislide
- RebiSmart

Fertility
- Family of pens for Gonal-F, Pergoveris, Ovidrel

Saizen
- Easypod
- Cool.click2

¹supported by Merck Serono’s current portfolio of 13 medical devices; based on FY 2013 sales; ²Not all devices are available in all markets

Strategy
- Build on existing competencies in devices and integrate across therapeutic areas
- Drive innovation and differentiation versus competition in existing product franchises
- Expand to selected specialty chronic diseases
- Provide solution to payers to better manage healthcare costs

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**Medical devices – Driving Merck Serono towards an integrated business model**

**Top 3 strategic priorities**

| 1. | Enhance existing competencies in devices and integrate across therapeutic areas |
| 2. | Drive development of long-term Chronic Treatment Solution Platform on the basis of advanced MS care concept* |
| 3. | Expand current technological lead to specialty chronic diseases outside of current multiple sclerosis franchises |

**Devices**

**Outlook 2015 +**

- Ongoing product and concept development (currently 21 projects in all therapeutic areas)
- Launch MS care concept in multiple sclerosis as blueprint business model
- Potential first drug-agnostic revenue stream after 3 years

*Not all devices are available in all markets*

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