

Innovation beyond the drug

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Member of the Pharmaceutical
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Disclaimer

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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 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



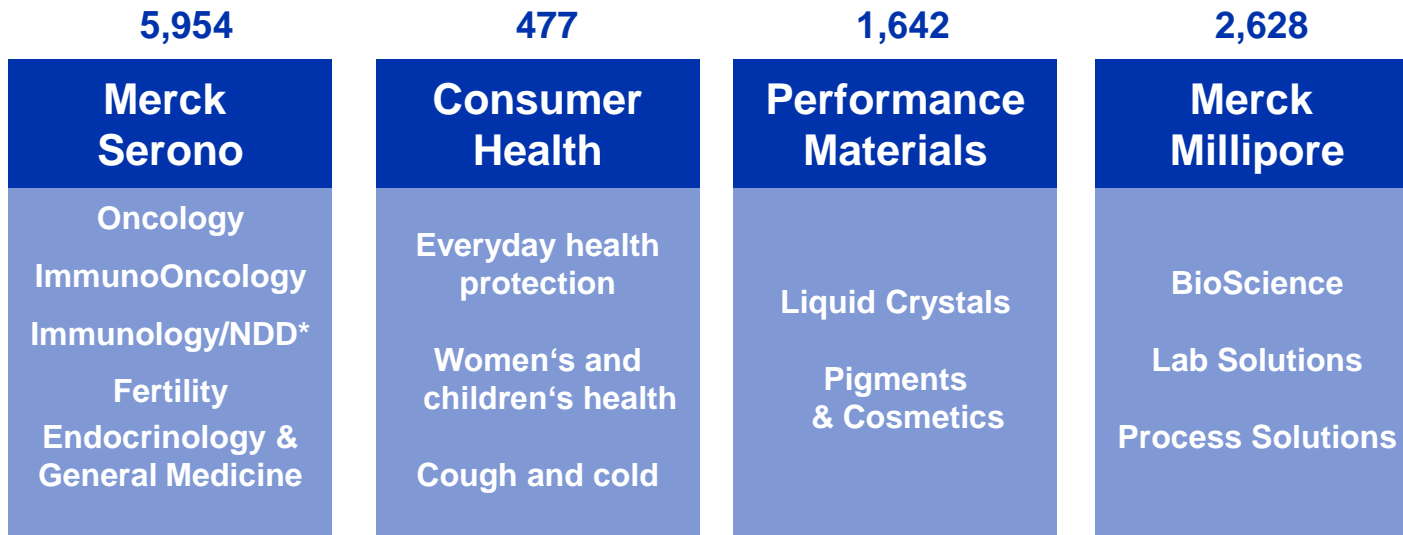
- We operate under the name of **EMD Serono** in North America

- **EMD**, stands for **Emmanuel Merck, Darmstadt**, reflecting these roots in Germany

Our Corporate Structure

Merck Serono is the Largest Division

Sales (€ m)¹ in 2013:



Divisions and their businesses

¹: Sales figures represent global divisional sales figures

* NDD: Neurodegenerative Diseases

Biosimilars

Allergopharma

Pharma Business

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 Biocubator 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

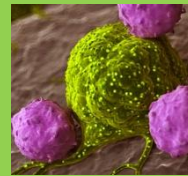


Research and Early Development

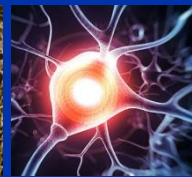
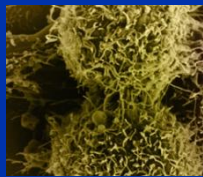
Structured along three Translational Innovation Platforms (TIPs)



TIP Oncology



TIP Immuno-Oncology



TIP Immunology
& NDD

- 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
- Pimasertib¹
MEK inhibitor
Solid tumors
- Pimasertib²
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
- MSC2363318A
p70S6K and Akt inhibitor
Solid tumors
- BGB-283
BRAF inhibitor
Solid tumors
- MSB0010718C
Anti-PD-L1 mAb
Solid tumors
- NHS-IL12³
Cancer immunotherapy
Solid tumors
- ALX-0761
Anti IL-17 nanobody
Normal volunteers

Phase II

- Plovamer acetate (PI -2301)
2nd 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
- Pimasertib¹
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
Melanoma
- Sprifermin
Fibroblast growth factor 18
Osteoarthritis
- Atacept
Anti-Bly/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)⁴
Phenylketonuria in children less than 4 years of age
- Pergoveris®
(follitropin alfa and lutropin alfa)
Assisted reproductive technology, poor ovarian responders
- Erbix® (cetuximab)
Anti-EGFR mAb
Squamous cell carcinoma of the head and neck (China)



- Neurodegenerative Diseases
- Oncology
- Immuno-Oncology
- Immunology
- Endocrinology
- Fertility
- In registration

¹ Novel combination with PI3K/mTOR inhibitor (SAR245409) from Sanofi, conducted under the responsibility of Merck

² Novel combination with hDM2 inhibitor (SAR405838) from Sanofi, conducted under the responsibility of Sanofi

³ Sponsored by the National Cancer Institute (USA)

⁴ Post-approval request by the European Medicines Agency

Status: June 17, 2014

MS Ventures

Investing in Innovation



Roel Bulhuis,
VP and Managing
Director,
MS Ventures

“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.”



Susan Jane Herbert,
EVP GBD&AM

“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.”

www.ms-ventures.com



Merck Serono Partnerships

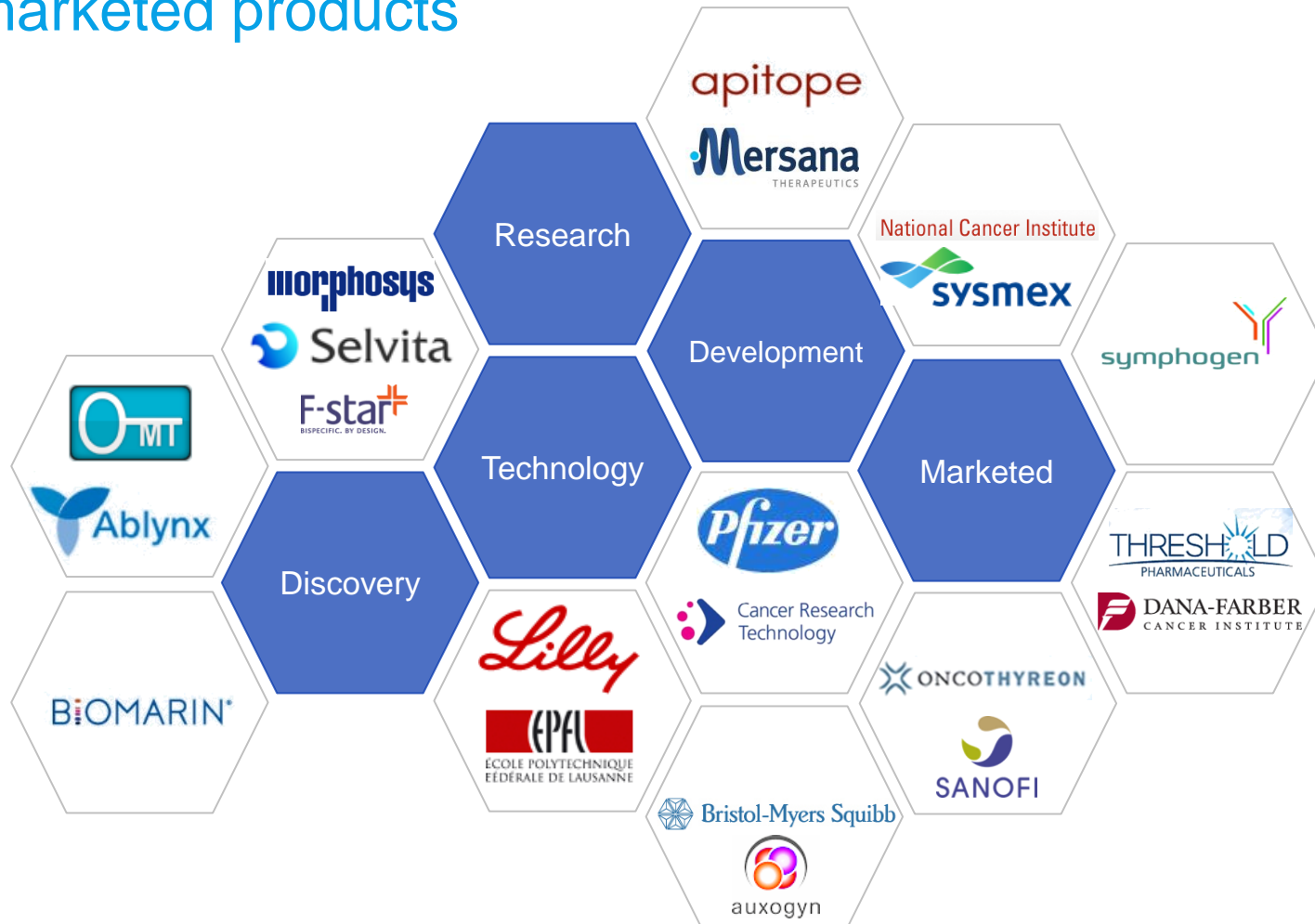
Around the globe

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

- **ATX-MS-1467**
Immune tolerizing agent
Multiple sclerosis
- **Pimasertib¹**
MEK inhibitor
Solid tumors
- **Pimasertib²**
MEK inhibitor
Solid tumors
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Hematologic malignancies and solid tumors
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- **BGB-283**
BRAF inhibitor
Solid tumors
- **MSB0010718C**
Anti-PD-L1 mAb
Solid tumors
- **NHS-IL12³**
Cancer immunotherapy
Solid tumors
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Anti IL-17 nanobody
Normal volunteers

Phase II

- **Plovamer acetate (PI -2301)**
2nd generation peptide copolymer
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Pancreatic cancer
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MEK inhibitor
Melanoma
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Pancreatic cancer
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MUC1 antigen-specific cancer immunotherapy
Non-small cell lung cancer
- **Kuvan®**
(Sapropterin dihydrochloride)⁴
Phenylketonuria in children less than 4 years of age
- **Pergoveris®**
(folitropin alfa and lutropin alfa)
Assisted reproductive technology, poor ovarian responders
- **Erbix® (cetuximab)**
Anti-EGFR mAb
Squamous cell carcinoma of the head and neck (China) R

- Neurodegenerative Diseases
- Oncology
- Immuno-Oncology
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- Endocrinology
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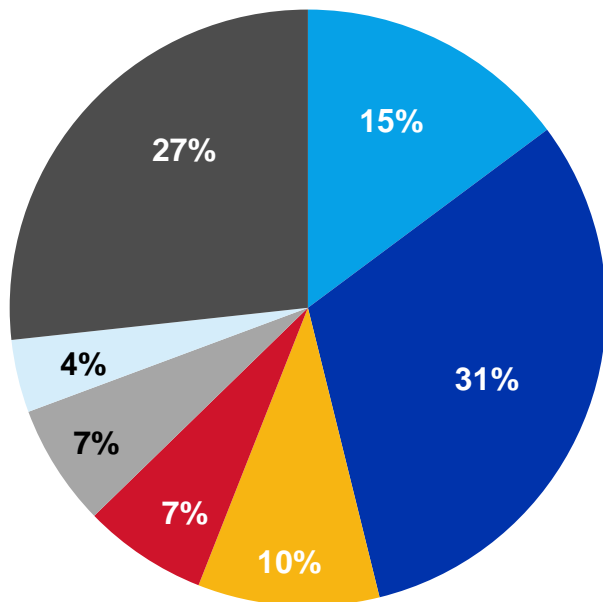
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Merck Serono – Mature Product Portfolio

Sales 2013 by Therapeutic Area and Product

Sales: € 5,954 million

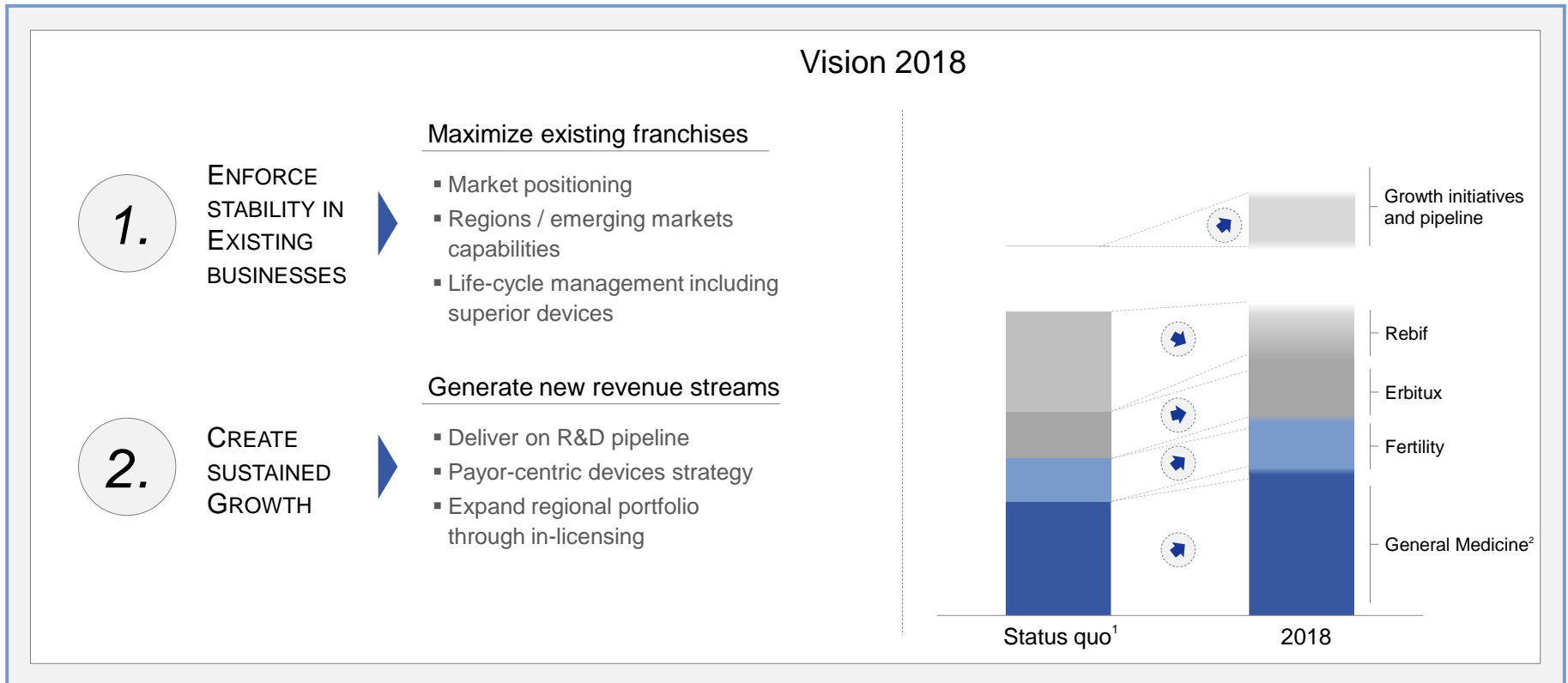


■ Erbitux ■ Rebif ■ Gonalf ■ Concor ■ Glucophage ■ Saizen ■ Others

Figures may not add up to 100 percent due to rounding

- **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%

Strategic priorities for sustainable success: New revenue streams and maximizing existing franchises



¹FY 2013; excludes Allergopharma and Biosimilars; ²including Cardiometabolic Care, Endocrinology, General Medicine and Others

Please refer to http://www.merck.de/de/investoren/merck_serono_day.html for full presentation

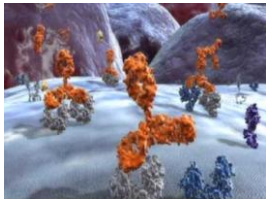
INNOVATION BEYOND THE DRUG

TROUGH PARTNERSHIPS



Partnership based on regional development

Expansion of our Oncology franchise with BeiGene-283
a second generation BRAF inhibitor, BeiGene



ONCOLOGY

MAY
2013



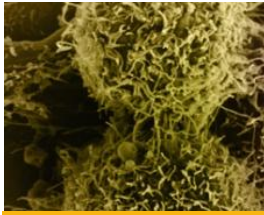
BeiGene

- 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.

2013
BayHelix-Elsevier
Award for
Alliance
of the Year

Partnership based on clinical network

Strategic Alliance with Nordic Bioscience for Sprifermin in Osteoarthritis of the Knee



IMMUNOLOGY

MAR
2013



NORDIC BIOSCIENCE

- 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

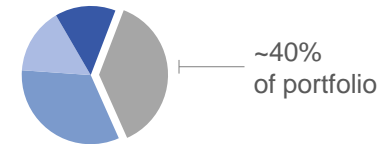
Four strategic priorities to build on track record

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 FDCs³, Glucophage label changes, Euthyrox reformulations
4. Continue to recover main growth levers in core markets and assets (e.g. BMS China)

General Medicine¹



Sales²



Outlook 2015 +

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

¹including Cardiometabolic Care, Endocrinology, General Medicine and Others; ²FY 2013; ³FDC = Fixed-dose combination

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Merck Serono Partnership *example*

Collaboration With Bristol-Myers Squibb for Glucophage in China for Treatment of Type 2 Diabetes



MAR
2013



- 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



SEP
2014



- 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

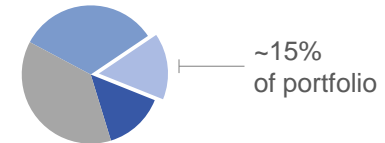
Top 4 priorities to support Erbitux

1. Further focus on the value of personalized treatments
2. Highlight importance of RAS testing², 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



Sales¹



Outlook 2015 +

- Stable to slight organic sales growth
- Growing balance between mCRC³ and SCCHN⁴
- Testing to offer upside potential

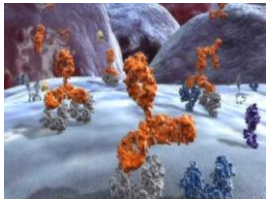
¹FY 2013; ²determination of tumor gene status for RAS in all patients with mCRC in the updated NCCN Guidelines v.1.2015; ³mCRC = metastatic colorectal cancer

⁴SCCHN = squamous cell cancer of the head and neck

Please refer to http://www.merck.de/de/investoren/merck_serono_day.html for full presentation

Merck Serono Partnership *example*

A new Collaboration with Sysmex Inostics on a Blood-Based RAS Biomarker Test



ONCOLOGY

June
2014



- 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

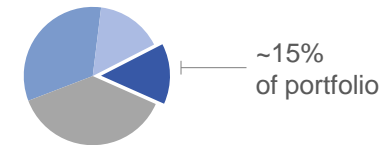
Top 3 strategic priorities

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 ART² lab to drive innovation and increase success rates

Fertility



Sales¹



Outlook 2015 +

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

¹FY 2013; ²ART = Assisted reproductive technology

Please refer to http://www.merck.de/de/investoren/merck_serono_day.html for full presentation

Merck Serono Partnership *example*

Exclusive License Agreement with Auxogyn for Eeva Test



APR
2013



- 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

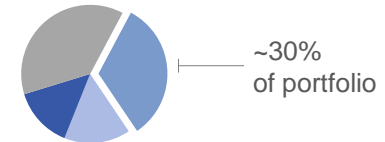
Top 4 priorities to drive Rebif

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*

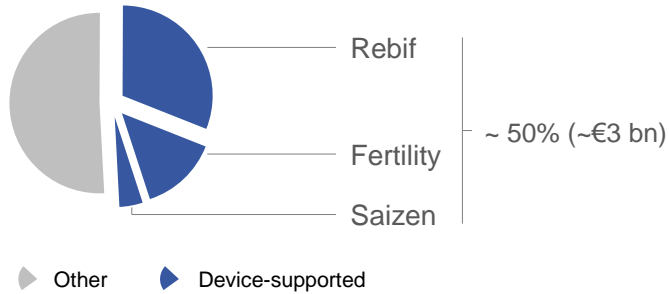


Outlook 2015 +

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

Medical devices – Further enhancing the value of Merck Serono and harnessing existing strengths

Device-supported franchises at Merck Serono¹



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

Current product offering²

Rebif

- 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

Please refer to http://www.merck.de/de/investoren/merck_serono_day.html for full presentation

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

Please refer to http://www.merck.de/de/investoren/merck_serono_day.html for full presentation