

# Building on Leading Market Positions

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Merck KGaA  
Darmstadt · Germany



## Disclaimer

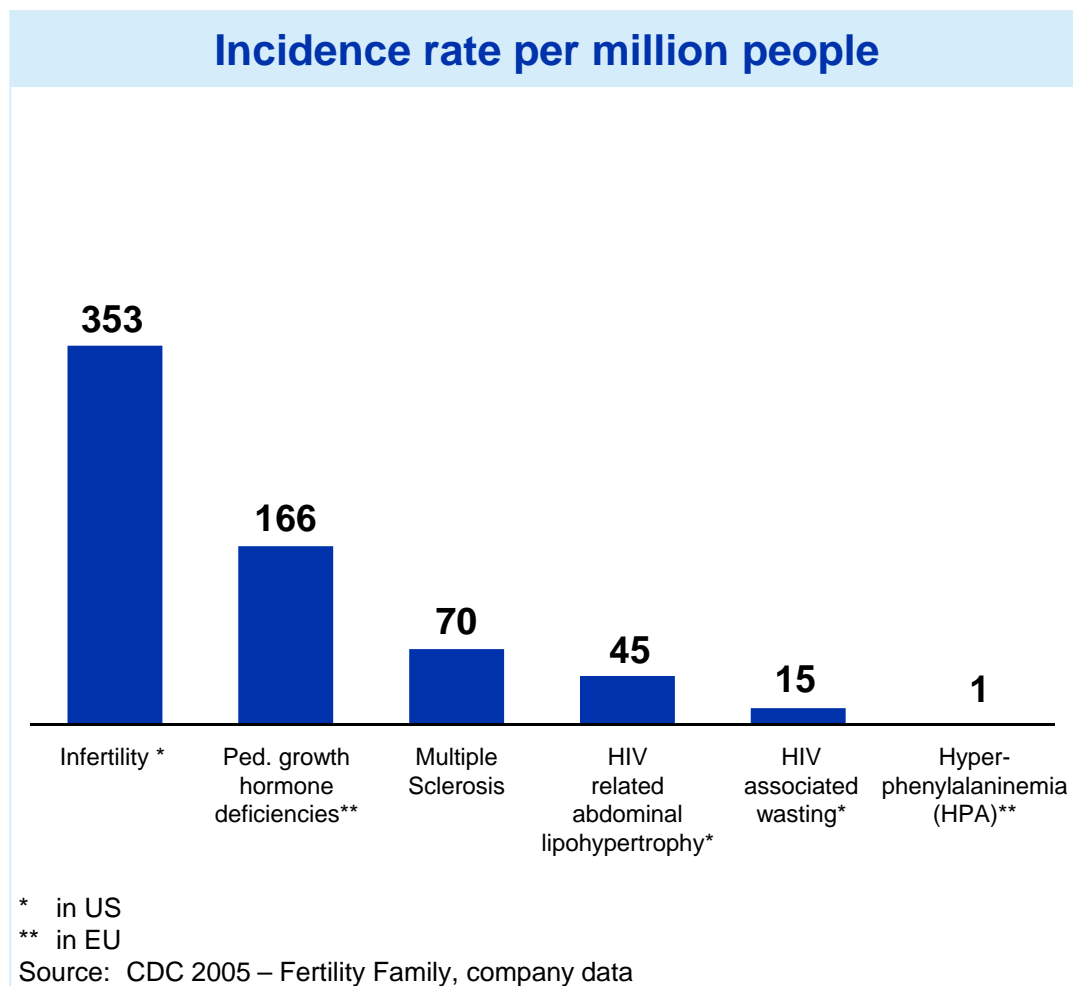
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# Agenda

- 1. Introduction**
2. Rebif: Defending the franchise
3. Fertility: Capitalizing on market leadership
4. Endocrinology: Serving attractive niche markets
5. Summary

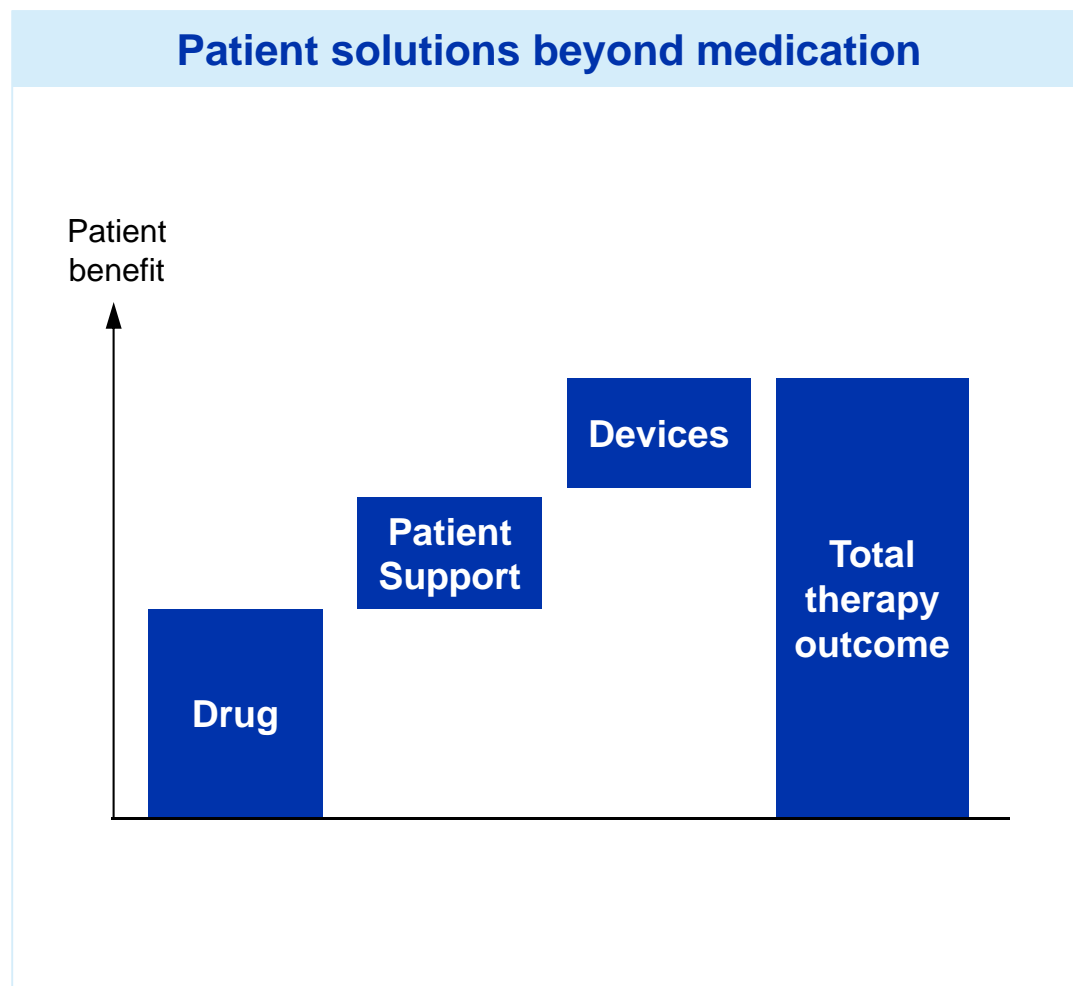
## Our focus is on specialist therapies for low incidence diseases



### Common market characteristics:

- Diseases with low incidence rates
- Individual patient needs vary significantly
- Diagnosis and therapy managed by medical specialists/clinical centers rather than General Practitioners
- Added value and differentiation through:
  - Devices
  - Patient support services
  - Field nurses

# Devices and support add benefit for patients and create opportunities for differentiation



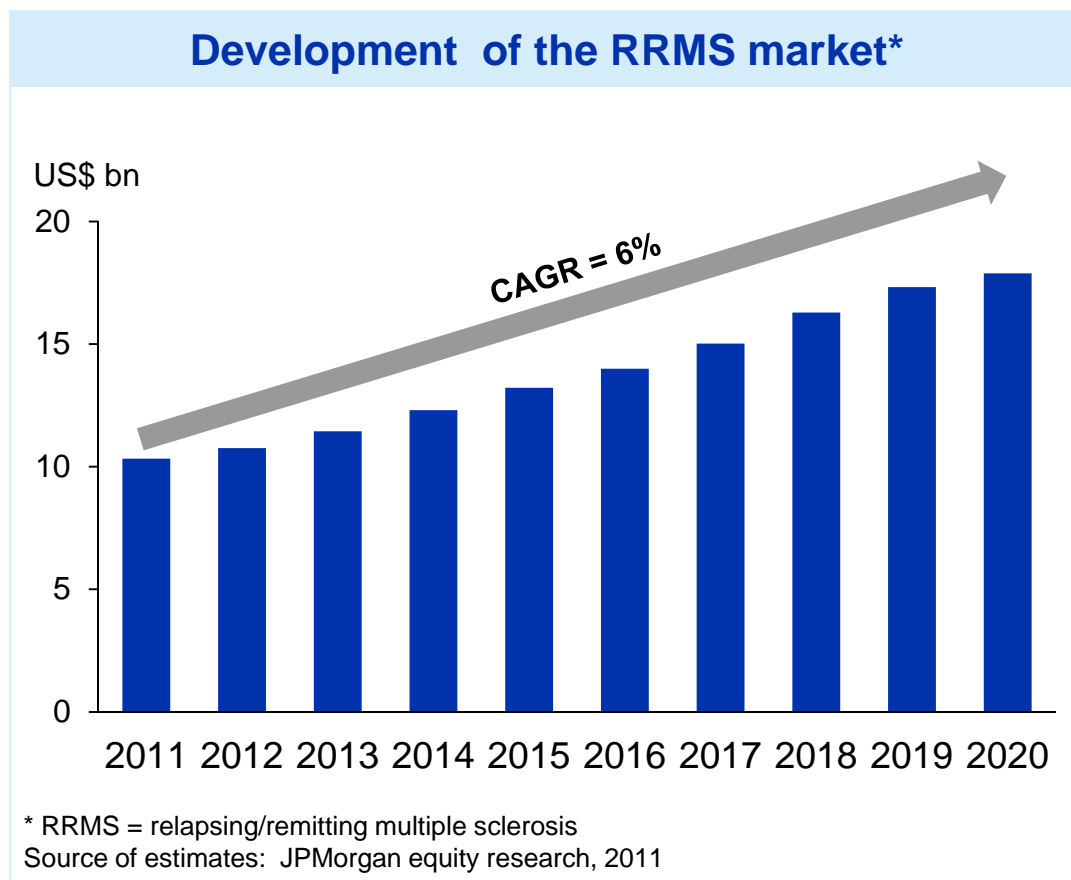
## Patient support and devices help to:

- Address concerns about safety and administration
- Maximize outcome of injectable drug therapies by:
  - Avoiding misdosage
  - Minimizing “needle phobia“
  - Promoting adherence to therapy

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# Multiple Sclerosis: A \$10 billion market with opportunities for growth



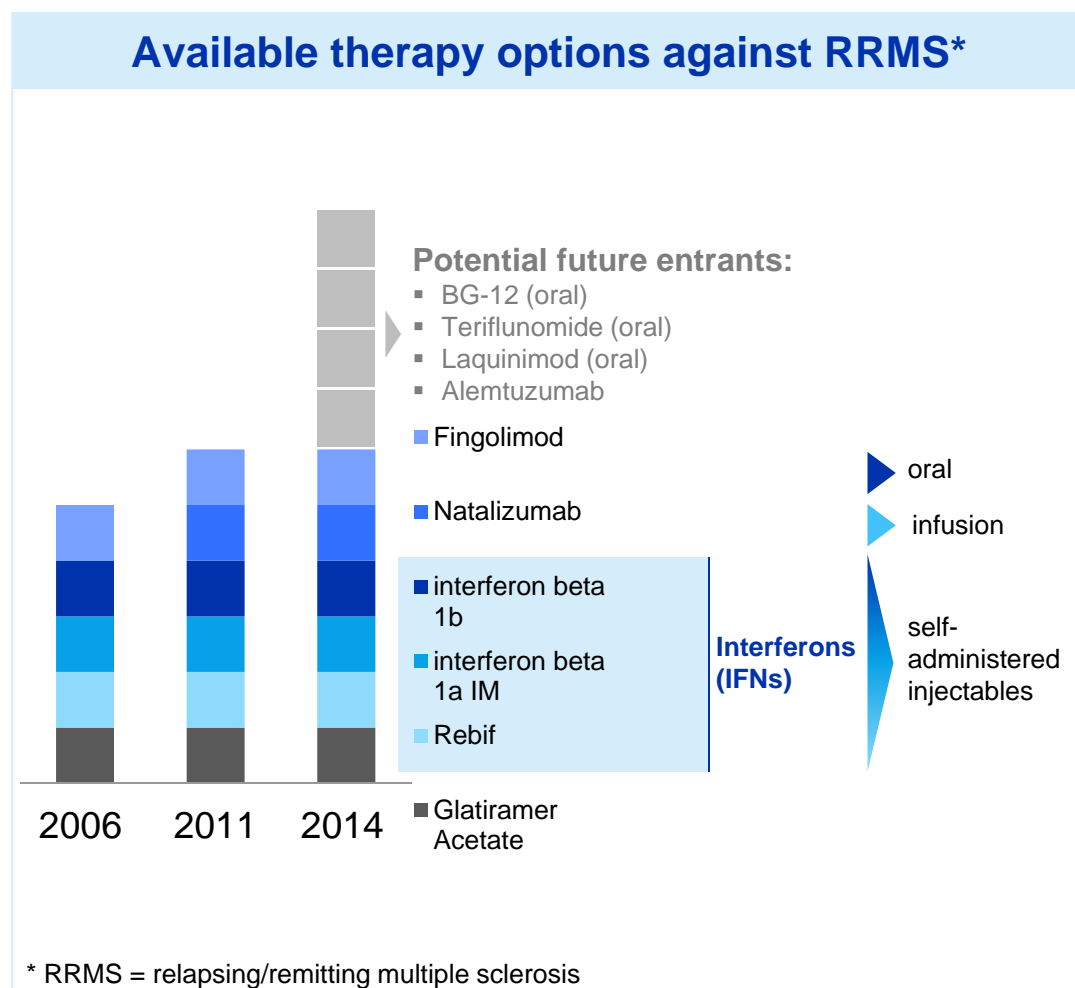
## Growth drivers:

- Number of eligible patients
- Increasing market penetration in Emerging Markets
- Higher treatment rates due to:
  - Earlier diagnosis and earlier initiation of treatment
  - New entrants offering additional therapeutic options



**The Multiple Sclerosis market will grow mid-single digit**

# New entrants provide more options, creating opportunities to differentiate



## Drivers for treatment choice:

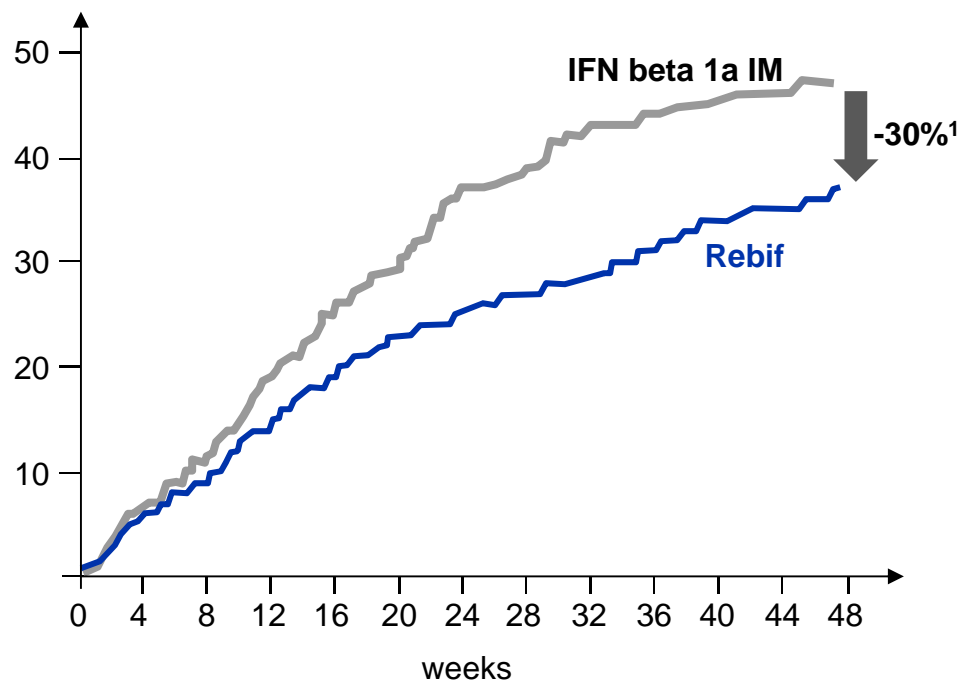
- Reducing relapse rate
- Slowing of disability progression
- Reducing development of brain lesions as seen on MRI
- Positive QOL impact
- Long-term safety
- Tolerability
- Convenient administration



# Rebif delivers against key efficacy measures and showed superiority vs. IFN beta 1a IM

## Probability of time to first relapse

Cumulative probability of time to first relapse (%)




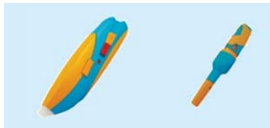

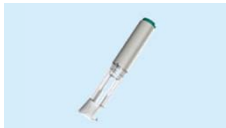






Source: 1. Schwid, Arch. Neurol. 2005; 62:785-92 (EVIDENCE study)  
2. Panitch, Neurology 2002;59:1496-1506.

## Key messages:

- Proven efficacy across all three key metrics:
  - reducing relapse rate
  - slowing disability progression
  - reducing development of brain lesions (MRI)
- Over 64 weeks:
  - Rebif reduced the risk of relapse vs. IFN beta 1a IM<sup>1</sup>
  - More patients on Rebif had no new or enlarging lesions detected on MRI vs. IFN beta 1a IM<sup>1</sup>
- Transitioning from IFN beta 1a IM to Rebif offers additional treatment benefit<sup>2</sup>

# We offer the broadest portfolio of application devices among all injectables in Europe

Devices available for injectable MS drugs				
4				
3				
2				
1				
	Glatiramer acetate	Interferon beta 1b	Interferon beta 1a IM	Rebif

## Rebif devices:

- **Rebismart:**
  - “Only-in-class” electronic autoinjector
  - Offers the possibility to monitor adherence
- **RebiSlide:**
  - A multi-dose solution for titration
  - For patients desiring more manual injection control
- **RebiDose:**
  - For patients wanting fast injections that fit around their daily routine
- **RebiJect II:**
  - Manual autoinjector designed to make injections easier

# We provide individualized support and further improve patients experience worldwide

## Biopharmaceuticals' portfolio of support services

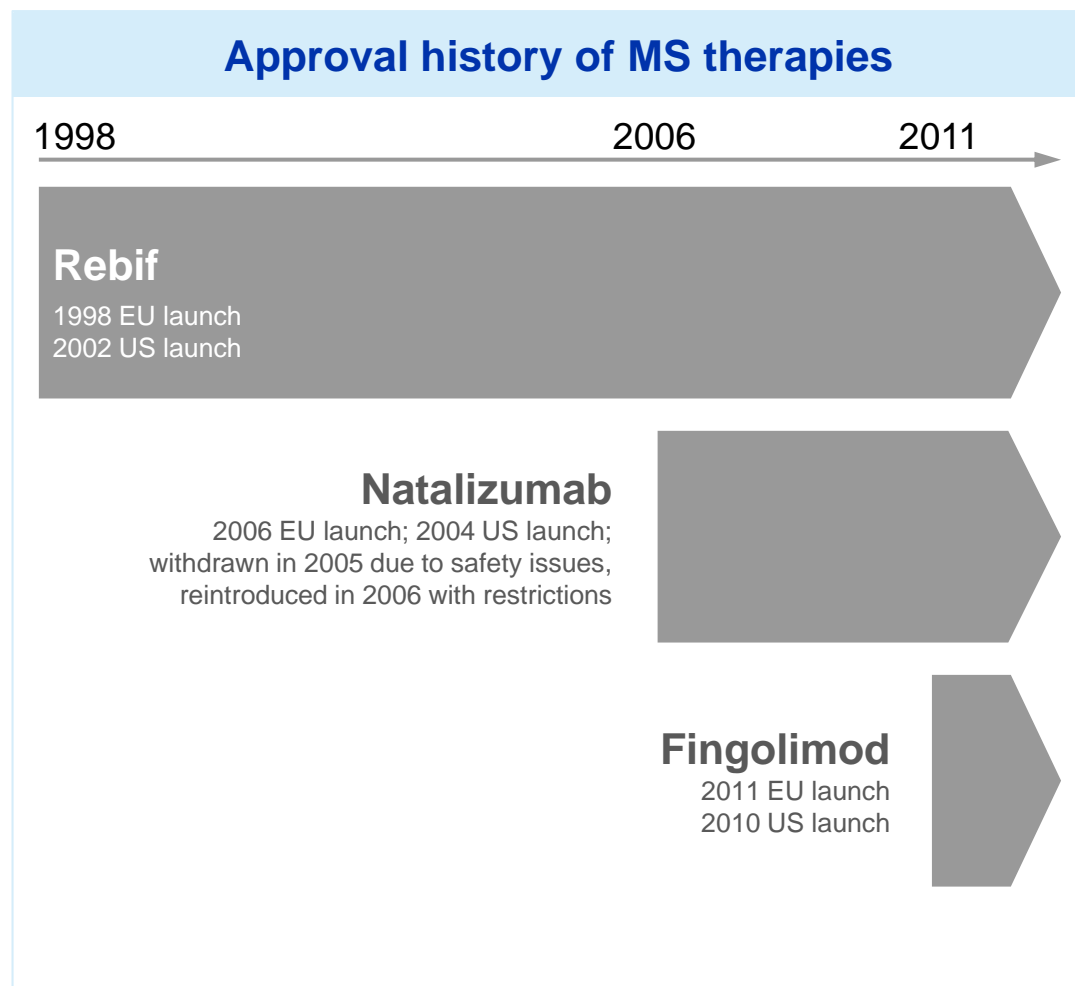


## Support services recognized by patients and industry awards include\*:

- Nurse home visits
- Nurse calls
- Psychological support
- Injection training
- Technical support
- 24/7 Call centers
- Patient Educational Events
- Reimbursement assistance
- Websites & Blogs
- Smart Phone Apps

\* Regional availability may vary according to local regulations

# Life-long diseases like MS require efficacy and a well established safety profile



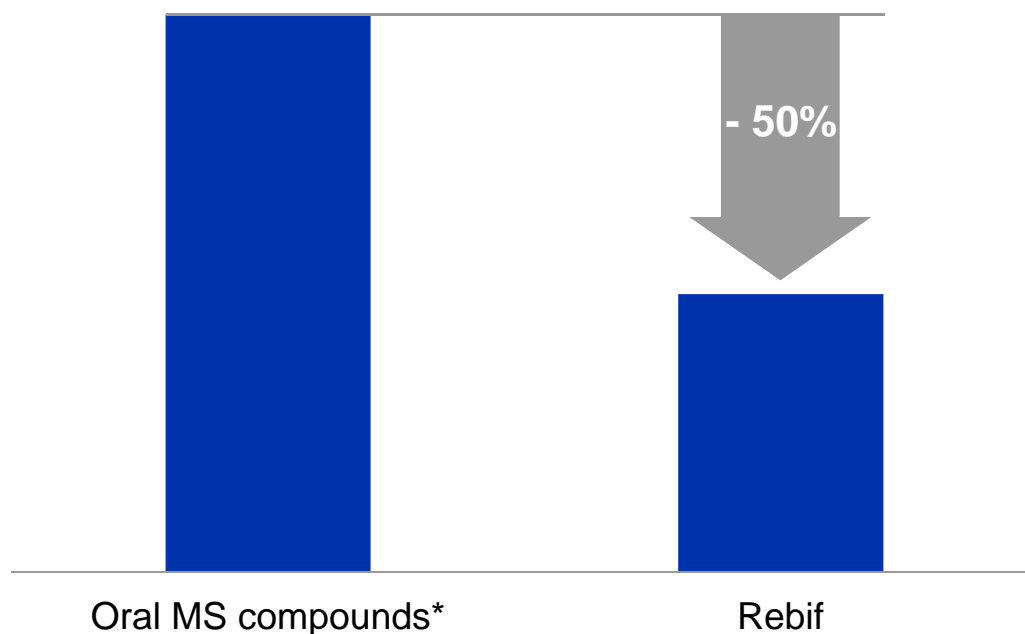
## Rebif's safety profile:

- Rebif can build on a well-established safety profile, with over 18 years of clinical trial and patient experience → allows for long-term administration from first attack onwards

# Rebif is dosed 50% less frequently than oral MS compounds\*

## Dosing scheme of oral MS compounds\* vs. Rebif

Dosing frequency



\* incl. compounds submitted for approval

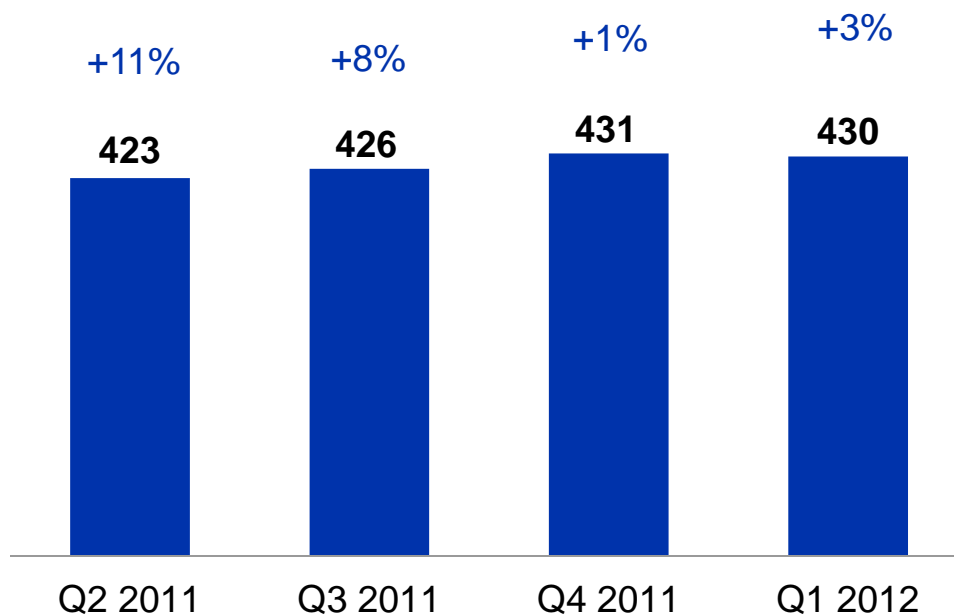
## Key messages:

- Oral therapies need to be taken at least once daily
- In contrast to oral therapies electronic autoinjectors like Rebismart offer possibility to monitor adherence

## Rebif's recent performance has been solid despite market entry of the first oral therapy at end of 2010

### Rebif sales and organic growth year-on-year

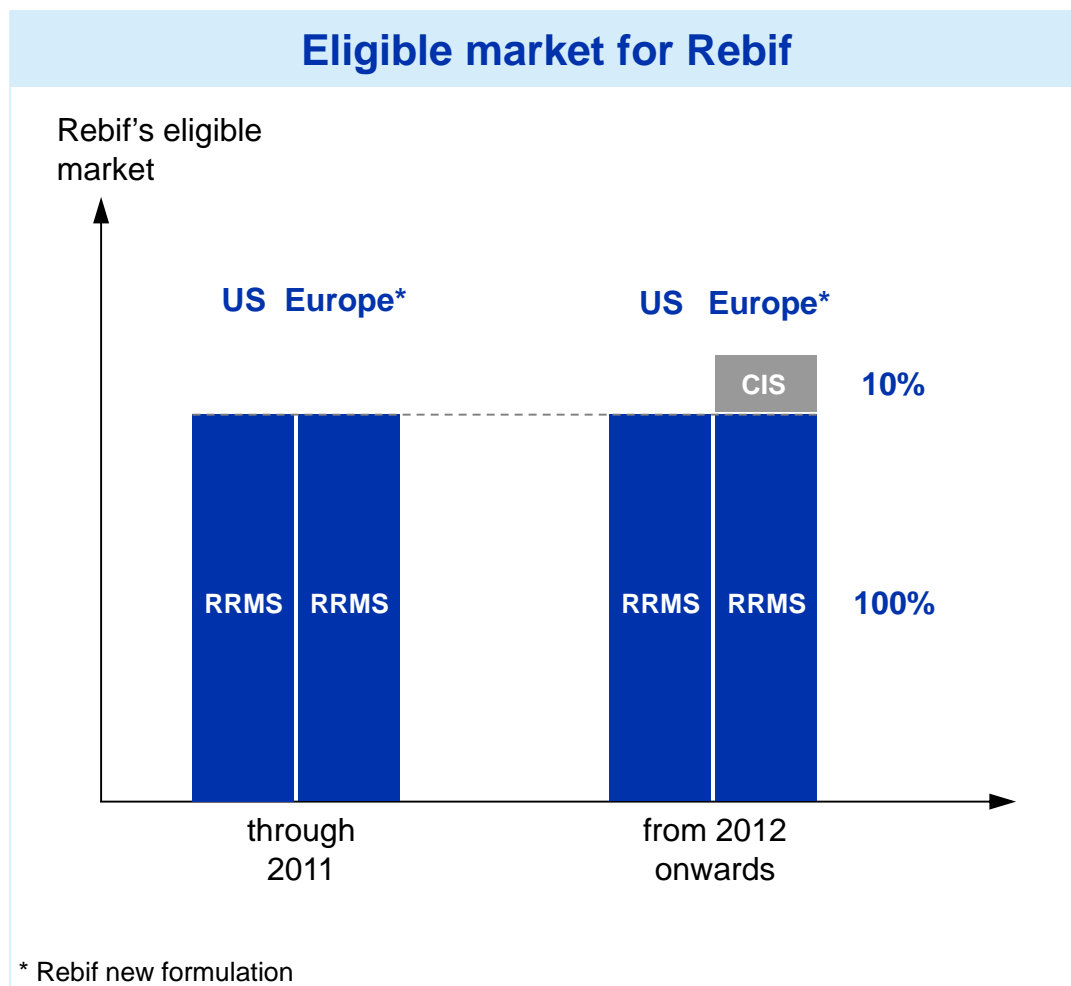
€m (last 4 quarters)



### Drivers of recent growth:

- Europe: higher volumes (backed by leading portfolio of devices) partially offset by softer pricing from austerity measures
- US: price increases and patient retention initiatives

## Rebif's label expansion into CIS in Europe enlarges the eligible market by ~10%



### Rebif's approval status:

- **Through 2011:** Rebif had global approval for relapsing and remitting Multiple Sclerosis (RRMS) and relapsing secondary progressive MS (SPMS)
- **2012:** Rebif\* gained additional approval in EU to treat Clinically Isolated Syndrome (CIS), an early form of MS that can develop into clinical definite MS

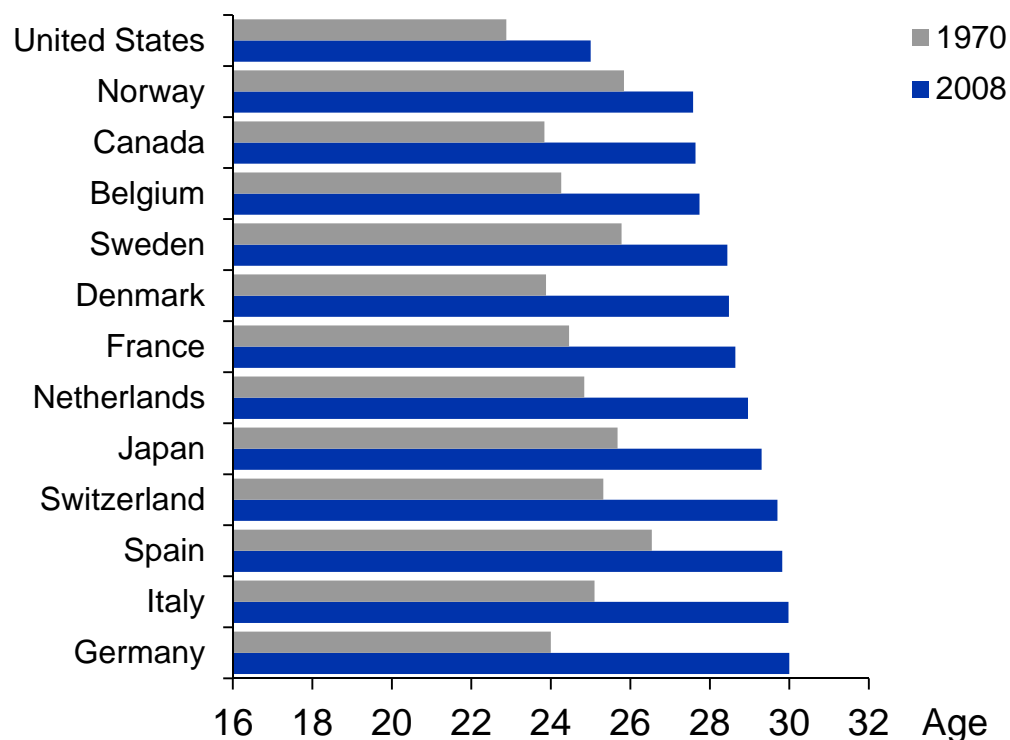
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# Women will increasingly face difficulty to get pregnant without fertility treatments

## Average age of women's first childbirth

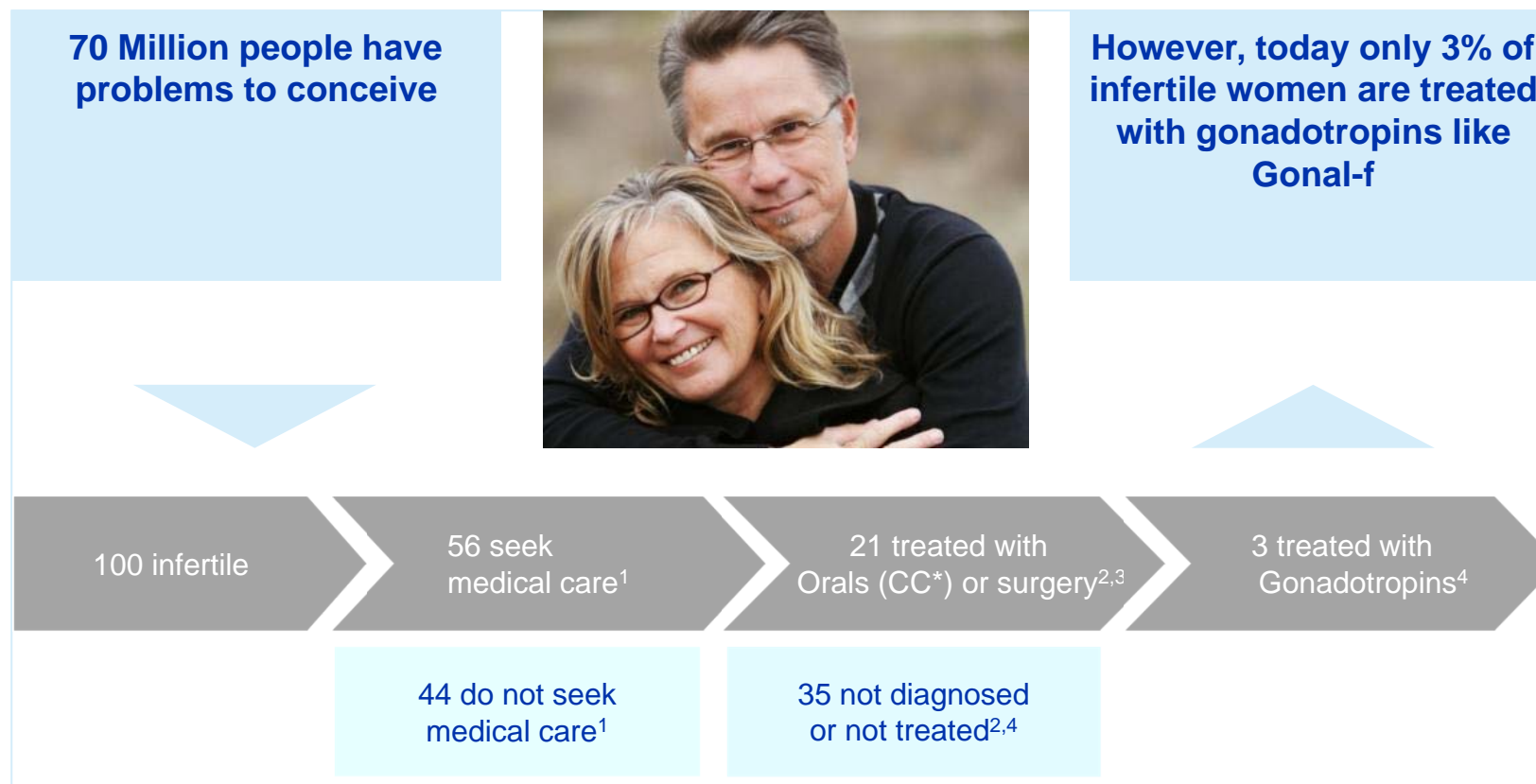


Source: Eurostat (2010) and United Nations Statistical Division (2010) and National Statistical Offices

## Key messages:

- Average age of women's first childbirth has significantly increased in key markets
- Women's chances of having a baby drops with increasing age:
  - Declining ability of ovaries to release eggs
  - Shrinking number of eggs left
  - Decreasing healthiness of eggs
  - Increasing likelihood of miscarriage

# Only 3% of couples with infertility problems are treated with Gonadotropins



\* Clomiphene citrate

Source: 1. Boivin J. *et al.* Human Reprod. 2007; Vol 22(6):1506-1512.

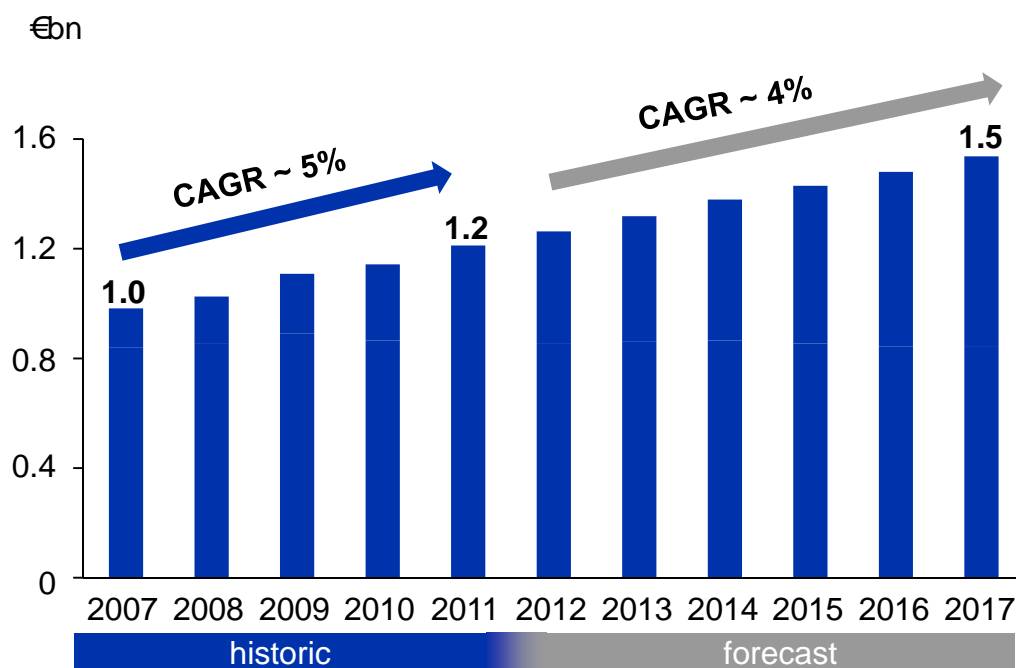
2. Collins J. A. *et al.* Human Reprod. 2004; Vol 10(4):309-316.

3. Datamonitor 2008 'Stakeholder Insight: Infertility'.

4. Company data

# The global market for Gonadotropins has been growing steadily

## Development of the Gonadotropin drug market\*



\* Internal company estimates

## Growth drivers:

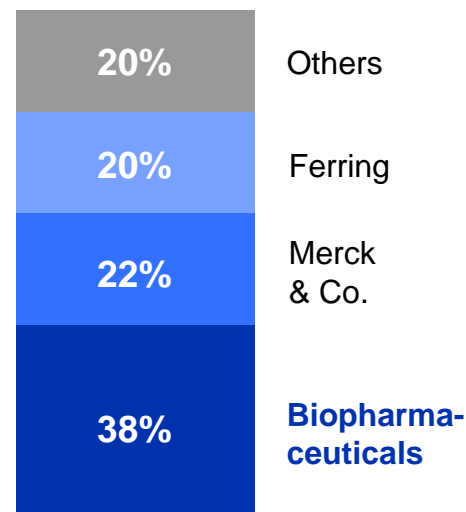
- Trend to postpone first pregnancy to a later phase in life → increasing childbearing age
- Higher awareness of and availability of fertility treatments
- Population growth and economic development in emerging markets



**Solid foundation for further growth**

# We have a leading market position built on unique strengths

Market shares of gonadotropin drugs\* (2011)



\* Internal company estimates (includes external data providers)

## Biopharmaceuticals' unique value proposition:

- First gonadotropin in the market in the 1950's
- Broadest product offering

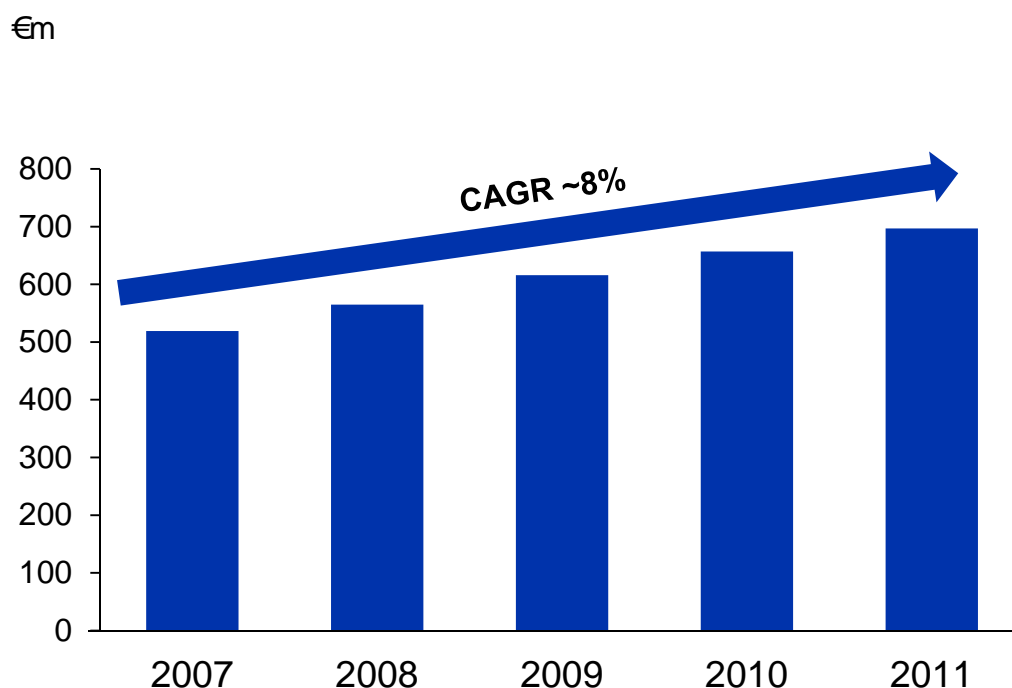


- "Easy-to-learn" therapy: „Family of Pens” – one device technology for easy administration



# We have outperformed the market despite strong competition and cheaper alternatives

Sales development of the BU Fertility



## Why **doctors** prefer Biopharmaceuticals:

- Full portfolio of high quality products and excellent brand reputation with often first mover advantage
- Commitment to advancement of scientific research in Fertility
- Deepest customer knowledge

## Why **patients** prefer our products:

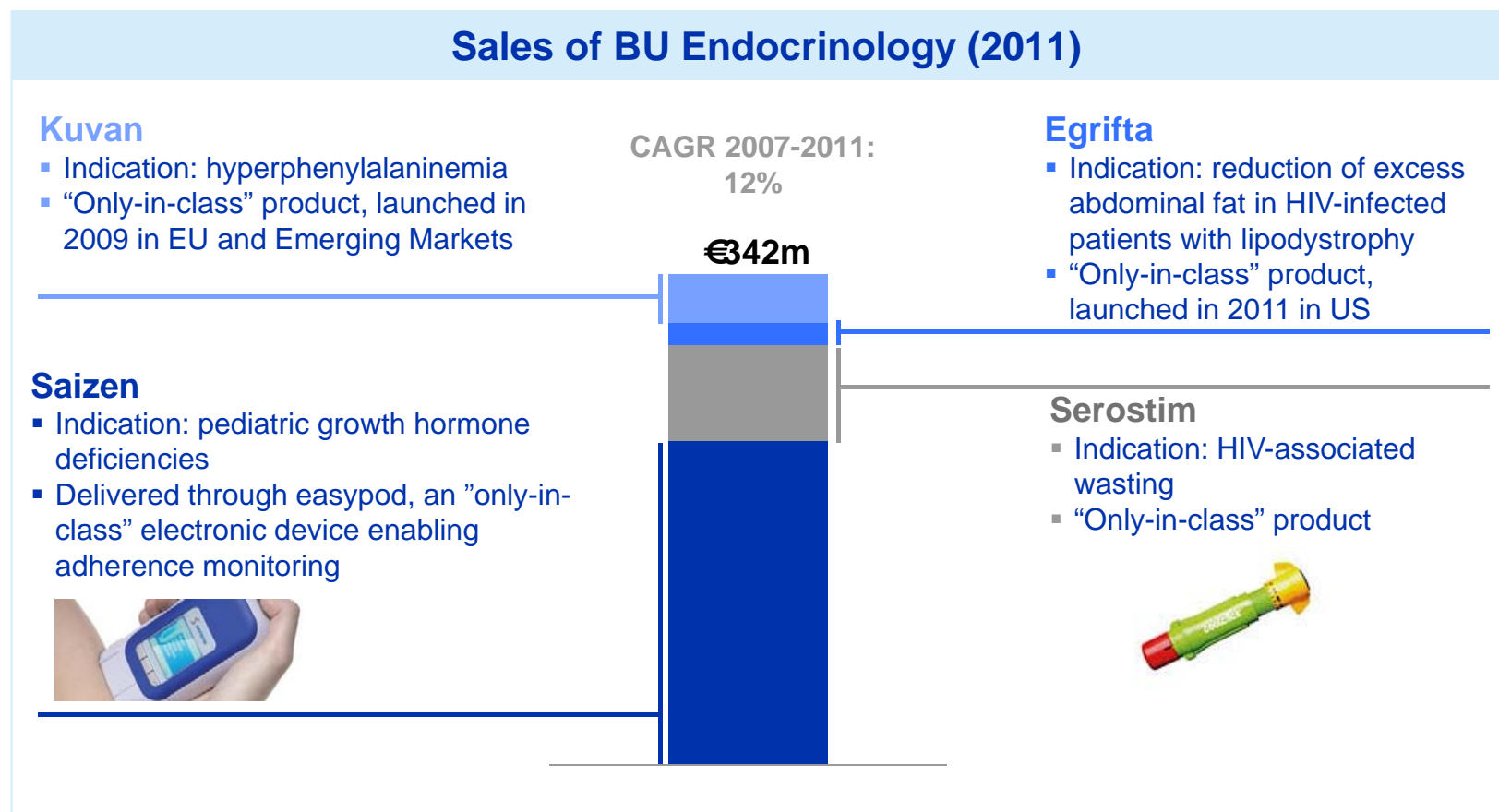
- Convenience:  
Easy-to-use products
- Quality and reliability

Quality and brand reputation is key

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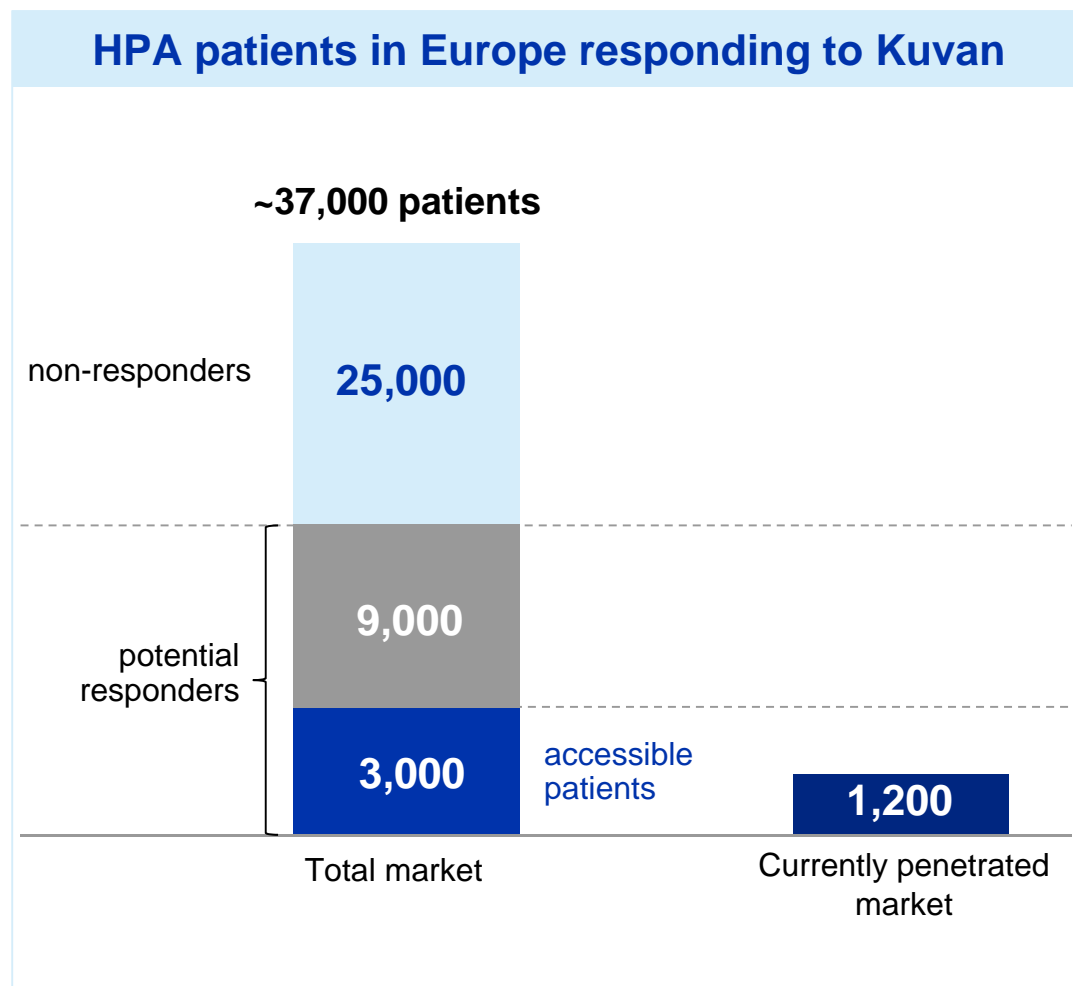
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# Performance built on "only-in-class" therapies and devices



**Capitalizing on our attractive portfolio**

# Kuvan growth driven by continued penetration of the European market



## Key facts Kuvan:

- Marketing rights in-licensed from Biomarin for all regions outside North America and Japan
- Orphan drug
- Launched in EU in 2009
- Only therapy to treat hyperphenylalaninemia (HPA)
- Market exclusivity until 2018



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# Summary

- 1 We have leading positions in the attractive neurodegenerative diseases, fertility and endocrinology markets
- 2 We provide significant value-add to our patients and differentiation vs. our competitors through unique devices and services
- 3 Rebif's safety, efficacy and convenience puts it into a strong position vs. existing treatment options and potential new market entrants
- 4 Our Fertility franchise will continue to outperform the market backed by strong brands
- 5 We will further capitalize on our "only-in-class" drug portfolio in Endocrinology to generate continued growth