Biopharmaceuticals Investor & Analyst Day

Biosimilars – a compelling fit for Merck KGaA, Darmstadt, Germany

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Merck KGaA, Darmstadt Germany and Biosimilars – a compelling fit

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Our capabilities

- Process development and manufacturing
- Market access capabilities
- Commercialization of mature biological products
- Device development
- Clinical & regulatory expertise
- Deployment of patient services and solutions

Our vision

- Leading player in biosimilars in emerging markets and over time a leading player globally
- Focus on providing access to quality alternatives to well-known biologics
- Help create a world where health care providers can offer life-changing therapies

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Agenda

Biosimilars market

Biosimilars at Merck KGaA, Darmstadt, Germany

Next wave of biosimilars offers increased access to therapeutics for disabling, life-threatening diseases

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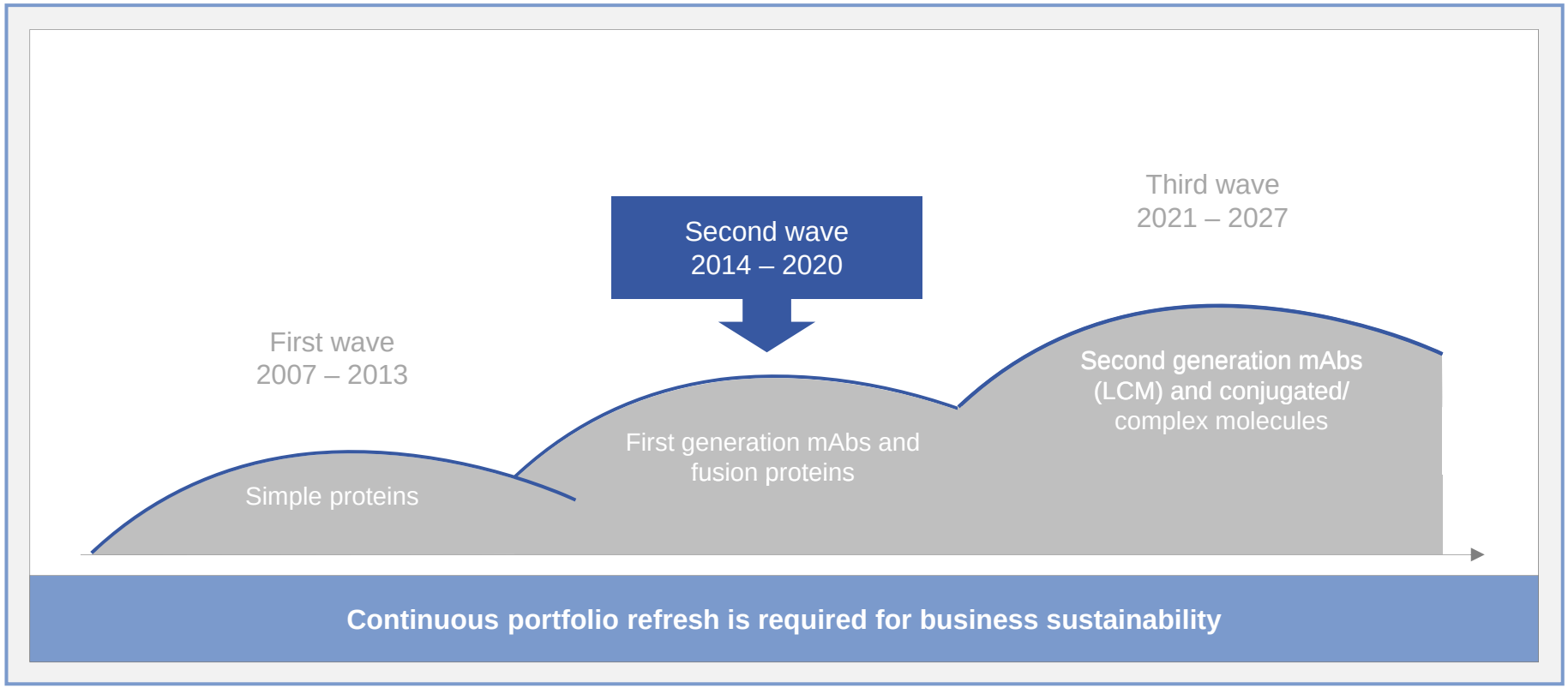

mAbs = monoclonal antibodies; LCM = life cycle management

Biosimilars in the G7: An estimated $18bn market by 2022

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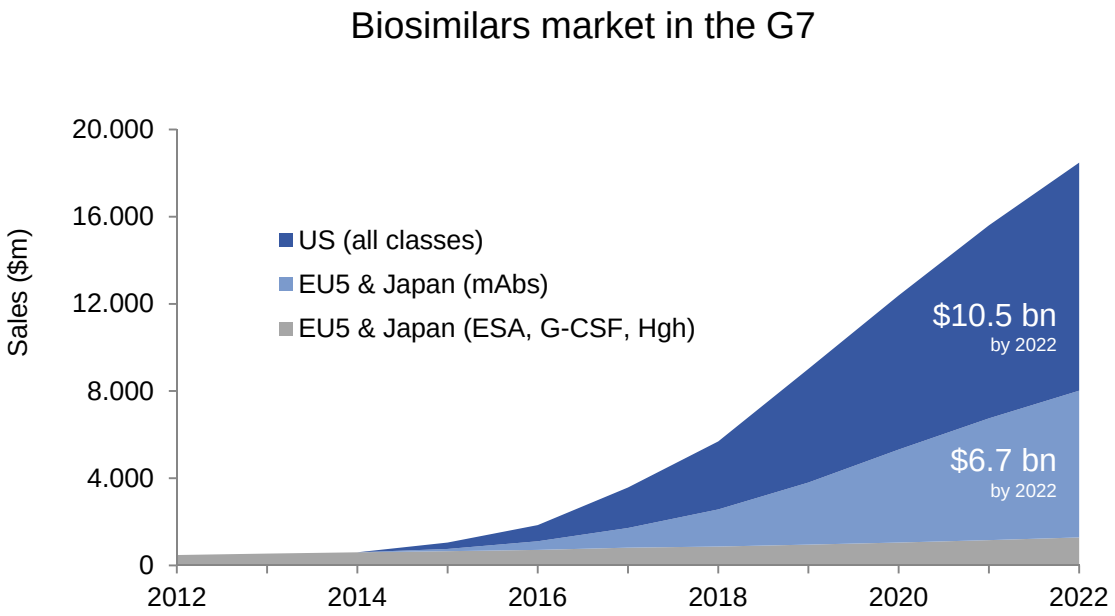
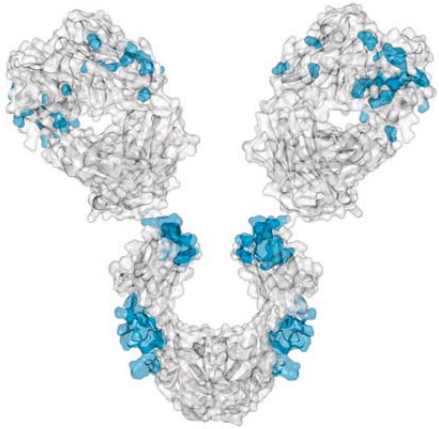


Key catalysts

- Number of product introductions
- Development of the US biosimilars markets



Source: Decision Resources Group / Bio Trends Research Group
mABs = monoclonal antibodies, ESA = erythropoiesis-stimulating agents, G-CSF = granulocyte-colony stimulating factor , Hgh = Human growth hormone

The evolution of the US market is another trend to watch

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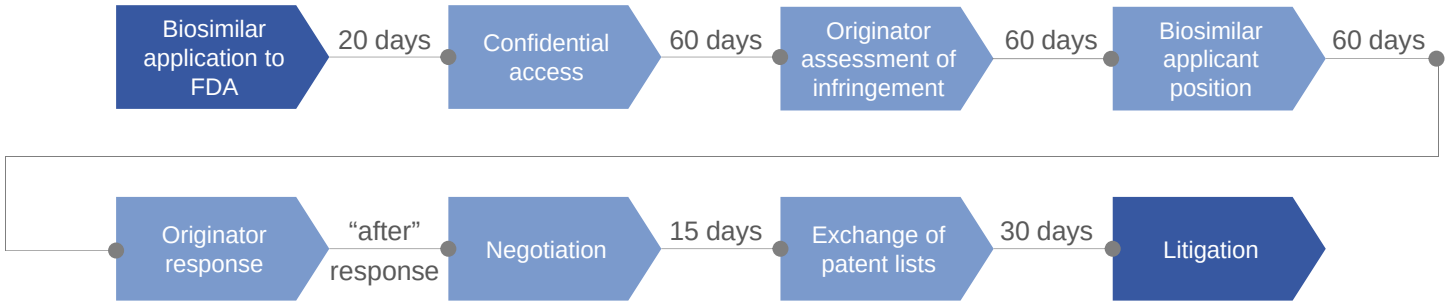
- Less clarity on biosimilars pathway: BPCIA[1] passed in 2010, final guidance still pending
- First two 351(k) applications submitted to the FDA[2] in July 2014
- Two lawsuits[3] involving potential biosimilar products have been filed prior to the submission of the corresponding application to the FDA

"…additional filed US patents that have not yet been issued…may be the most significant challenge to overcome to bring such products [biosimilars] to market" [4]



[1]Biologics Price Competition and Innovation Act; [2]Sandoz application for biosimilar filgrastim. Celltrion application for biosimilars Infliximab; [3]Sandoz vs Amgen (Etanercept), and Celltrion vs J&J (Infliximab)
[4]Humira Biosimilar Launches Could Be Delayed by IP Litigation, Pricing Unlikely to Drive Adoption, Jefferies/Holford, 01 Aug 2014

Different forces are at work on state level

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Interest conflict between payers and state

Payers

- Payers will drive the use of biosimilars to control costs

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UnitedHealth Group®

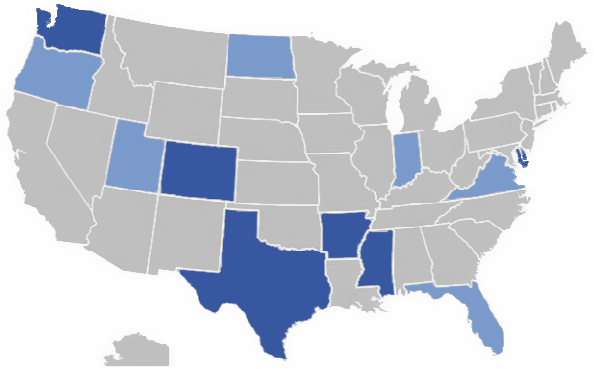
aetna™

BlueCross BlueShield Association

States

- Trend towards patient and physician notification and record keeping requirements
- Covers retail pharmacy distribution of biosimilars only

Rapidly evolving patchwork of state substitution laws



- States with regulations in place
- States which have failed to introduce legislation
- No/ pending legislation

State-level legislation governing substitution of biosimilars moving ahead of federal government discussions

Source: http://www.biopharma-reporter.com/Markets-Regulations/Biosimilars-bio-differences-Breakdown-of-US-State-substitution-laws

Those who can drive efficient development and commercialization processes in the future will win

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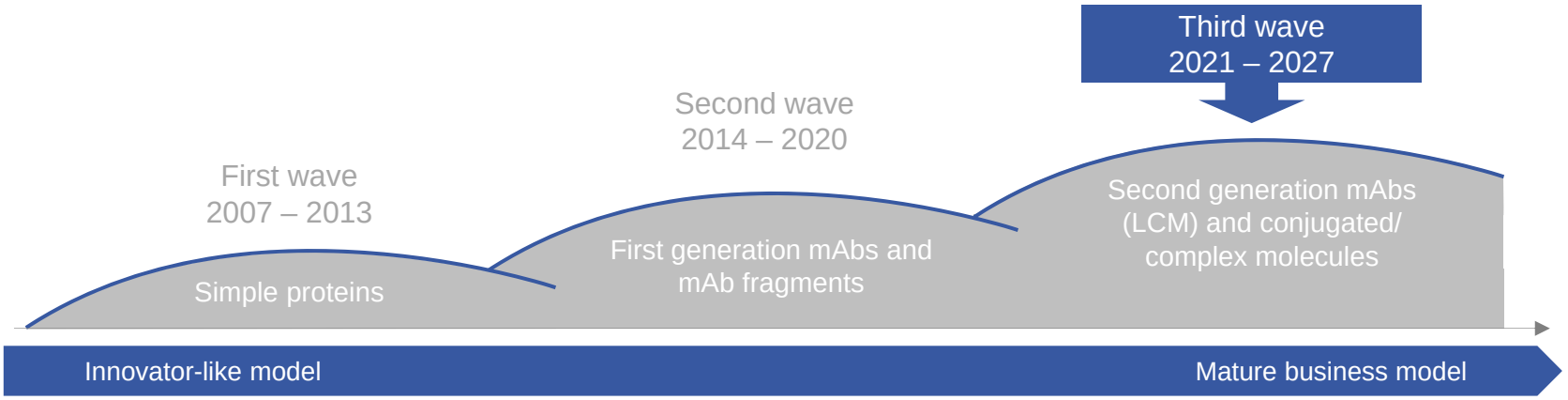

Criteria of success

- Build efficient biosimilars-product development capabilities to keep pace with evolution of standard of care
- Leverage manufacturing scale effects
- Evolve the commercial model from initially promotional intensive to leaner and customized models
- Support new developments by generating steady cash flow

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Biosimilars market

Biosimilars at Merck KGaA, Darmstadt, Germany

Unique in-house capabilities and strategic alliances across the biosimilars value chain already in place

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Biosimilars success factors

Clinical development and regulatory

- Leverage internal assets or source capabilities from suppliers
- Ensure compliance with regulatory requirements

Market access

- Market access capabilities across key markets including emerging markets
- Ability to deploy sales reps, KAM's, medical liaisons to support biological products

Manufacturing costs

- Scale up production to achieve economies of scale
- Commercial manufacturing capability and flexibility (more important in tender markets)

Sales and marketing

- Tailor go-to-market approach to local dynamics
- Device deployment, patient services and solutions (essential in markets with physician promotion)

We will leverage our strengths and heritage for future success

Intelligent decision making to ensure success in dynamic environment

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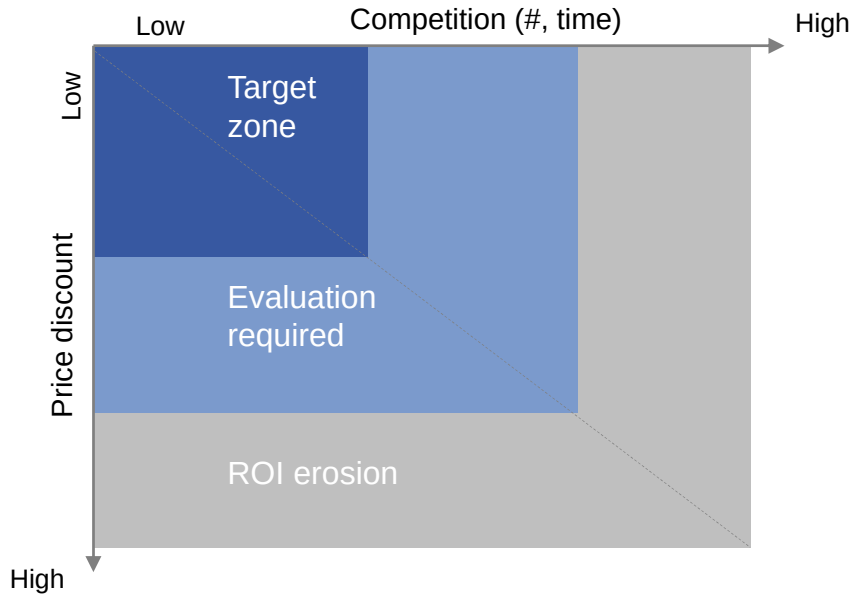
Market dynamics

- Early market entry is a competitive advantage
- Later market entrants gain market share by:
  - innovative commercialization strategies
  - price reductions
- Highest competition in higher value less technically complex products
- We will monitor our market entry position carefully up to the point of Phase III investment

Evaluation matrix



We have established partnerships to accelerate the pipeline and secure access to key markets

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In-house research and development

- Focused on developing molecules in the area of autoimmune disorders, oncology as well as other therapeutic indications

Key partnerships

- Dr. Reddy's:
  Co-development of several oncology compounds
- Partnership to be disclosed:
  In-licensing agreement for a late-stage biosimilar, initially for smaller emerging markets
- Bionovis:
  Multi-biological product collaboration to supply the Brazilian market under the Product Development Partnership (PDP) policy of the Brazilian Ministry of Health

2014 investment of ~€ 100 m;

2015E investment of € 130 m -150 m depending on portfolio development

Portfolio established through a combination of in-house development and partnerships

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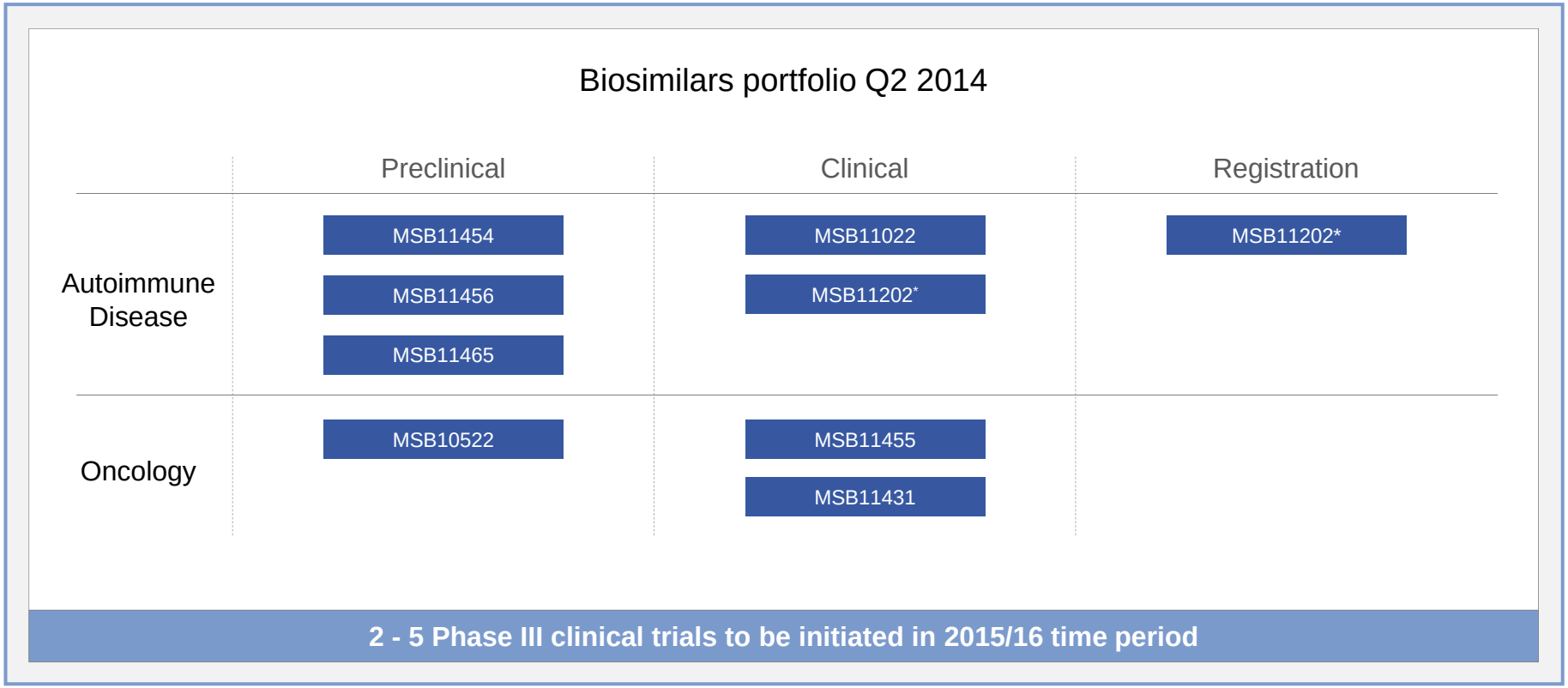

*Partnership to be disclosed

Conclusion

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- Biosimilars is an attractive market that requires intelligent decisions based on multiple external and internal factors
- We have the capabilities required for success
- EUR 100m+ growing with portfolio development
- First approval and initiation of Phase III trials expected from 2015/16 onwards

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