

# **SCOTT FORAKER**

VICE PRESIDENT AND GENERAL MANAGER, BIOSIMILARS



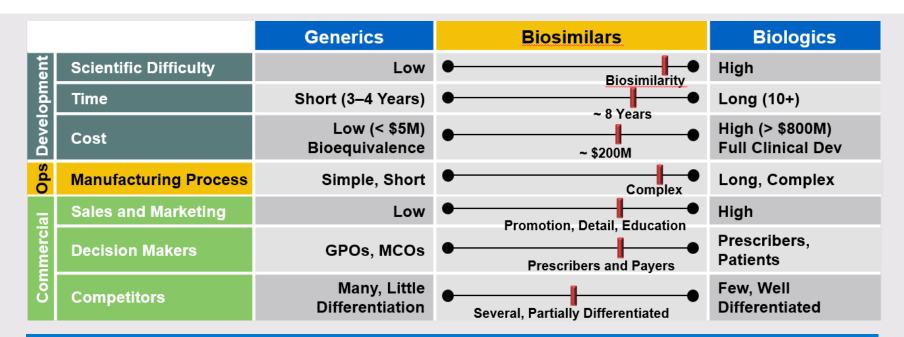
#### SAFE HARBOR STATEMENT

This presentation contains forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including statements about estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of June 15, 2016 and expressly disclaims any duty to update information contained in this presentation.

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This presentation includes GAAP and non-GAAP financial measures. In accordance with the requirements of SEC Regulation G, reconciliations between these two measures, if these slides are in hard copy, accompany the hard copy presentation or, if these slides are delivered electronically, are available on the Company's website at www.amgen.com within the Investors section.

# WE EXPECT THE BIOSIMILARS BUSINESS TO LOOK MORE LIKE BRANDED BIOLOGICS THAN SMALL MOLECULE GENERICS



Deep scientific skills and strong branded commercial capabilities required for success



# **CHALLENGES AND THE AMGEN SOLUTION**

## **Challenge**

- Scientifically complex and difficult to design and manufacture
- Uncertain and complex regulatory and legal/patent requirements
- Overcoming stakeholder uncertainty
  - Compromise in quality?
  - Biosimilars not all the same and each represents distinct therapeutic choice
- Reliability of supply
- High capital commitment

# **Amgen Solution**

- Deep biologics scientific skills and strong biologics manufacturing heritage
- Core biologics regulatory and legal/patent expertise with strong track record
- Branded commercial capabilities and Amgen brand equity

- Amgen heritage = "every patient every time"
- Return on capital criteria



### FDA STANDARD FOR BIOSIMILARS

The biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components

#### **AND**

There are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product



# BIOSIMILAR SCIENCE IS COMPLEX, TYPICALLY REQUIRING A MATCH OF ~ 100 CRITICAL ATTRIBUTES NECESSARY TO SHOW BIOSIMILARITY

**Product Example** 

Amgen Biosimilar Attributes Compared to U.S. and EU Reference Product

General Properties
Primary Structure
High-Order Structure
Biological
Product-Related Substances and Impurities
Process-Related Impurities
Particles and Aggregates
Thermal-Forced Degradation

	ABP vs. U.S. Reference Product	ABP vs. EU Reference Product
Attributes Matched	91	93
Attributes Not Matched but Not Critical	4	2
Attributes Not Matched and Critical	0	0



# SAFE, RELIABLE BIOLOGICS MANUFACTURING

- Customers want safe, effective and reliable supply of biologic medicines
- Our biosimilars will be manufactured with the same high Amgen standards as our originator biologics
- Most biosimilars will be manufactured using next-generation technologies







### STRONG BRANDED COMMERCIAL CAPABILITIES

- Branded commercial strategies are a key to success in the EU and likely will be needed for success in the U.S.
- Amgen has deep, branded biologic commercial capabilities in core therapeutic areas that can be leveraged to sell Amgen biosimilars
  - Sales and marketing
  - Pricing and reimbursement
  - Patient services
  - Contracting
- Specific product commercial strategies are being developed
- A deep, high-quality portfolio will help international expansion, leveraging Amgen brand equity



# KEY QUESTIONS YET TO BE ANSWERED IN EVOLVING BIOSIMILARS MARKET

- Timing of market entry
- Number of competitors
- Discounts offered by biosimilar competitors and originators
- Potential delays caused by patent disputes
- Policies that continue to shape the biosimilars environment (reimbursement, naming, labeling, interchangeability and state pharmacy laws)



# **AMGEN'S POSITION ON KEY ISSUES**

Biologics Price Competition and Innovation Act (BPCIA)	Amgen supported enactment of BPCIA
Extrapolation of Indications	Supportive, given sufficient pharmacological and clinical evidence
Interchangeability	Manufacturers should demonstrate that patients face no additional risk by alternating or switching products
Naming Convention	Unique nonproprietary names serve to identify manufacturers, promoting traceability and minimizing unwarranted class attribution



# OUR UNIQUE CAPABILITIES POSITION US FOR LEADERSHIP IN BIOSIMILARS

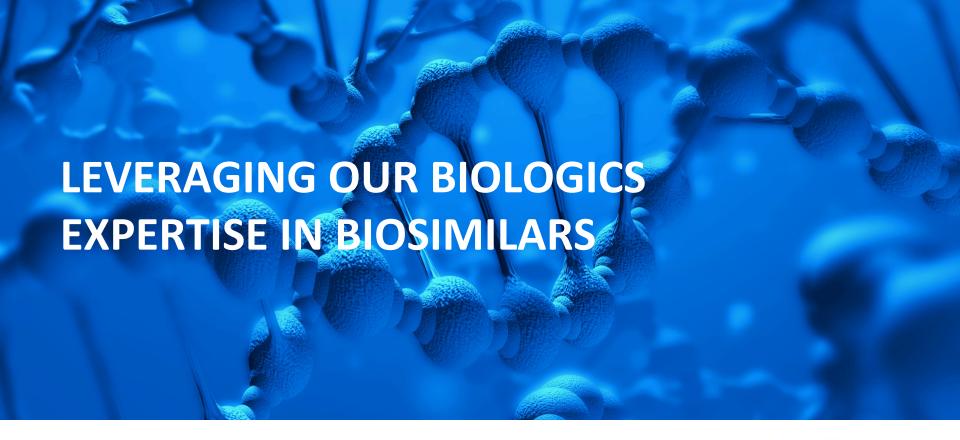
	Status	Originator Worldwide 2016 Sales*
ABP 501	FDA approved	HUMIRA® ~ \$16B
ABP 980	Phase 3 breast cancer completed	Herceptin <sup>®</sup> ∼ \$7B
ABP 215	Filed for approval	Avastin® ~ \$7B
ABP 710	Phase 3	REMICADE® ~ \$8B
ABP 798	Phase 3	RITUXAN® ~ \$8B
ABP 959	Phase 1	Soliris <sup>®</sup> ∼ \$3B
ABP 494	Process development	ERBITUX® ~ \$2B
Molecules #8-#10	Process development	~ \$11B
Total		~ \$60B+



# AMGEN BIOSIMILARS REPRESENT A COMPELLING GROWTH OPPORTUNITY

- Biosimilars are more like branded biologics than generics, requiring deep scientific skills and branded commercial capabilities
- Amgen has significant competitive advantages and is making good progress
- Big opportunity (\$3B+ annual revenue potential)





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