

Biosimilars

Scott Foraker
Vice President and General Manager, Biosimilars



Amgen Biosimilars Represent a Compelling Growth Opportunity and a Good Strategic Fit

- Meaningful revenue and profit potential
- Leverages existing biologics capabilities
- Supports international expansion, leveraging Amgen brand equity
- Creates unparalleled portfolio of biologics
- Serves patients by increasing access to high-quality biologics in Amgen's core therapeutic areas



Six Biosimilars Are Progressing Well and Three New Products Added

Amgen Biosimilars Program Status

	Status	
ABP 501/adalimumab (HUMIRA®)	Phase 3 psoriasis study met primary endpoint Phase 3 RA	
ABP 980/trastuzumab (Herceptin®)	Phase 3 breast cancer	
ABP 215/bevacizumab (Avastin®)	Phase 3 NSCLC	
ABP 710/infliximab (REMICADE®)	Clinical ready	
ABP 798/rituximab (RITUXAN®)	Clinical ready	
ABP 494/cetuximab (ERBITUX®)	Process development	
Molecules #7-9	Process development	

We expect five launches 2017–2019

ABP = Amgen biosimilar product; RA = rheumatoid arthritis; NSCLC = non-small-cell lung cancer Provided October 28, 2014, as part of an oral presentation and is qualified



Opportunity for Amgen to Capture Meaningful Value

	Originator Worldwide 2013 Sales*	
HUMIRA®	~ \$11B	
REMICADE®	~ \$8B	
Avastin [®]	~ \$7B	
Herceptin [®]	~ \$6B	
RITUXAN®	~ \$8B	
ERBITUX®	~ \$2B	
Molecules #7-9	~ \$5B	
Total	~ \$47B	

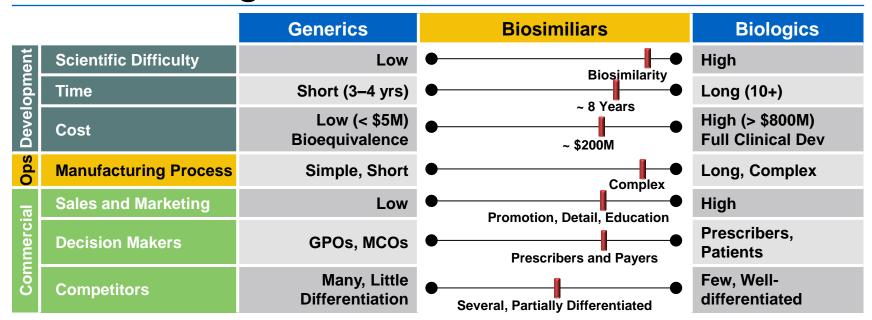
Amgen biosimilars have the potential to deliver \$3B+ in annual revenue

Provided October 28, 2014, as part of an oral presentation and is qualified by such, contains forward-looking statements, actual results may vary materially; Amgen disclaims any duty to update.



^{*}Per EvaluatePharma (February 5, 2014)

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

Amgen assumptions: Appropriately high-approval standard; extrapolation of indications is possible; no interchangeability initially



Biosimilar Science Is Complex, Typically Requiring a Match of ~ 100 Critical Attributes Necessary to Show Biosimilarity

Amgen Biosimilar Attributes Compared to US and EU Reference Product

Product Example

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

	ABP vs US 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



Strong Branded Commercial Capabilities Required for Success

- Branded commercial strategies are a key to success in the EU and likely will be needed for success in the US
- Amgen has deep, branded biologic commercial capabilities in core therapeutic areas that can be leveraged to sell Amgen biosimilars
 - Marketing
 - Sales force
 - 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
- Actavis will provide commercial support as needed for the oncology products



Amgen Biosimilars Represent a Compelling Growth Opportunity and a Good Strategic Fit

- Big opportunity (\$3B+ annual revenue potential)
- 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

