



# *Biosimilars*

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**AMGEN**<sup>®</sup>

Pioneering science delivers vital medicines™

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

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- **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
<b>ABP 501/adalimumab</b> (HUMIRA®)	Phase 3 psoriasis study met primary endpoint Phase 3 RA
<b>ABP 980/trastuzumab</b> (Herceptin®)	Phase 3 breast cancer
<b>ABP 215/bevacizumab</b> (Avastin®)	Phase 3 NSCLC
<b>ABP 710/infliximab</b> (REMICADE®)	Clinical ready
<b>ABP 798/rituximab</b> (RITUXAN®)	Clinical ready
<b>ABP 494/cetuximab</b> (ERBITUX®)	Process development
<b>Molecules #7–9</b>	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 by such, contains forward-looking statements, actual results may vary materially; Amgen disclaims any duty to update.

# 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**

\*Per EvaluatePharma (February 5, 2014)

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# We Expect the Biosimilars Business to Look More Like Branded Biologics Than Small Molecule Generics

		Generics	Biosimilars	Biologics
Development	Scientific Difficulty	Low	●-----● Biosimilarity	High
	Time	Short (3–4 yrs)	●-----● ~ 8 Years	Long (10+)
	Cost	Low (< \$5M) Bioequivalence	●-----● ~ \$200M	High (> \$800M) Full Clinical Dev
Ops	Manufacturing Process	Simple, Short	●-----● Complex	Long, Complex
Commercial	Sales and Marketing	Low	●-----● Promotion, Detail, Education	High
	Decision Makers	GPOs, MCOs	●-----● Prescribers and Payers	Prescribers, Patients
	Competitors	Many, Little Differentiation	●-----● Several, Partially Differentiated	Few, Well- differentiated

Deep scientific skills and strong branded commercial capabilities required for success

GPO = group purchasing organization; MCO = managed care organization

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# Challenges and the Amgen Solution

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## 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

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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

	ABP vs US Reference Product	ABP vs 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		
<b>Attributes Matched</b>	<b>91</b>	<b>93</b>
<b>Attributes Not Matched, but Not Critical</b>	<b>4</b>	<b>2</b>
<b>Attributes Not Matched and Critical</b>	<b>0</b>	<b>0</b>

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# Strong Branded Commercial Capabilities Required for Success

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- **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**

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- **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**