An Overview of Biologic and Biosimilar Products

Olajumoke Amuwo, PharmD, MPH, BCPS
Assistant Professor of Clinical Sciences, Roosevelt University College of Science, Health, & Pharmacy
Internal Medicine Clinical Pharmacist, Rush University Medical Center
oamuwo@roosevelt.edu

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1

Conflict Disclosure

- ✓I have no conflicts of interest or financial relationships to disclose
- ✓I will not discuss off label use and/or investigational use in this presentation

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2

Learning Objectives

Pharmacist Learning Objectives

1. Identify the most common diseases in which immunomodulating biologics are used and their mechanism of action in those disease states.
2. List the common and severe adverse effects, precautions, contraindications, black box warnings, testing, and screening considerations associated with immunomodulating biologics.
3. Recognize the key differences between reference biologic products and biosimilars and the FDA guidance and Illinois laws on their interchangeability.
4. Explain the 2021 nomenclature update from the World Health Organization (WHO) and International Nonproprietary Names (INN)

Pharmacy Technician Learning Objectives

1. Recall the history, types of molecules, process of manufacturing, regulation, naming and unique properties of biologics versus biosimilars
2. Identify common disease states in which biological products are used.
3. Describe the FDA guidance and state of Illinois regulation regarding interchangeability of reference biologic products for their biosimilars

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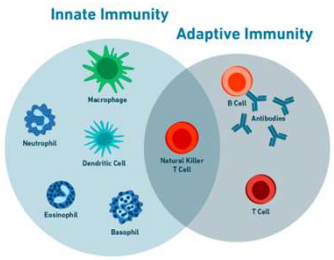
3

Immunology Review



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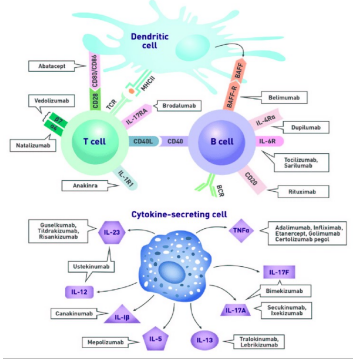
4

Immunological Targets of Biologics



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5

What are Biologic Products?

- Protein-based therapies derived from living organisms or their cells including plants, animals, and microorganisms such as yeast and bacteria
- Genetically engineered for a specific medical purpose
- Typically larger, more complex molecules when compared to traditional drugs
- Examples: vaccines, monoclonal antibodies, therapeutic proteins
- The Public Health Service (PHS) Act definition:
  - "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human beings."

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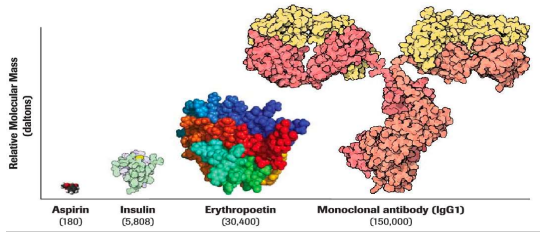
Ferro A, et al. *Br J Clin Pharmacol.* 2013
US Food and Drug Administration. 2015
Liossis SC, et. al. *Mediterr J Rheumatol.* 2019

6

Traditional small-molecule drugs vs. Biologics



Molecular size comparison of a small molecule drug (aspirin) to 3 different classes of biologics
(Relative molecular masses shown in parenthesis)

Reyes L, et. al. *Can Pharm J*. 2010.

7

7

How Are Biologics Manufactured?

1. Produce the master cell line coded with DNA to make the desired molecule (usually a protein)
2. Grow large numbers of the cells which are continually making the desired molecule
3. Isolate and purify the desired molecule
4. Isolated molecule then becomes the active ingredient and can be prepared for distribution

de Falla K. Arthritis-Health. 2017
Hawkins S. BioTechPrimer. 2020
How Are Biotechnology Medicines Made? Amgen. 2023

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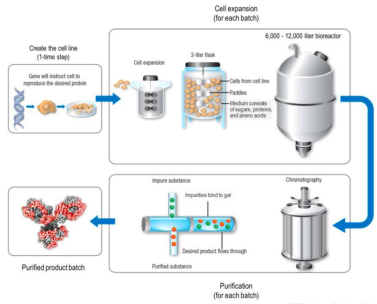
8

How Are Biologics Manufactured?



Al-Salehbach A, et. al. Semin Arthritis Rheum. 2016. doi: 10.1016/j.semarthrit.2016.01.002

9

9

How Are Biologics Administered?

Small Molecule Drugs	Biologics
Can be taken orally (i.e. tablets or capsules)	Cannot be given orally
Disintegrates in the GI tract, then absorbed into the bloodstream	Most are given parenterally via SQ, IM, or IV routes
Typically self administered	Administrated at prescriber's office, infusion center, or self-administered

US Food and Drug Administration. 2015.

10

10

Checkpoint

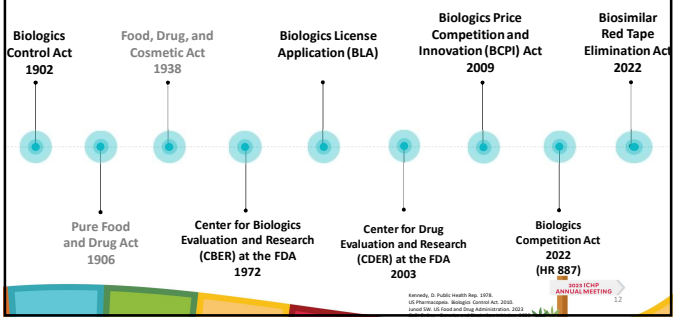
Which of the following is TRUE regarding biologics when compared with traditional small-molecule drugs?

A. Biologics are given orally due to high oral bioavailability
B. Biologics are less sensitive to light and temperature variations
C. Biologics are larger in molecular size and have more complex and fragile structures
D. Biologics are less costly to manufacture

11

11

Biologics Regulation Timeline



Kennedy, D. Public Health Rep. 1978.
US Pharmacopeia. Biologics Control Act. 2010.
Junod SW. US Food and Drug Administration. 2013

12

12

Test Your Knowledge #1: Pharmacists & Techs

Which of the follow department(s) regulate biological products for human use under applicable federal laws?

A. Center for Drug Evaluation and Research (CDER)
B. World Health Organization (WHO)
C. Center for Biologics Evaluation and Research (CBER)
D. United States Pharmacopeia (USP)
E. Both A & C

13

Immunomodulating Biologic Therapies

14

Diseases In Which Biologics Are Used

Dermatology
- Eczema, plaque psoriasis

Ophthalmology
- Uveitis, ocular surface disease, thyroid eye disease

Rheumatology
- Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis

Gastrointestinal diseases
- Crohn's disease, ulcerative colitis

Oncology
- Many types of cancers

15

Biologic Therapeutic Targets

Cytokine modulators	• TNF-α inhibitors • IL inhibitors
Lymphocyte modulators	• B lymphocyte depletion therapy

16

Cytokine Modulators

17

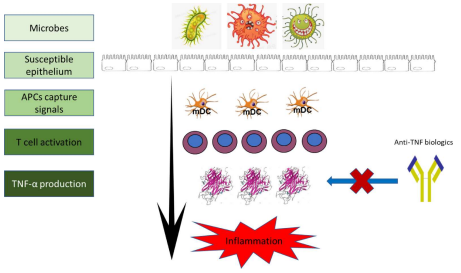
Cytokine modulators: TNF-α inhibitors

- TNF-α is a proinflammatory cytokine
- Inappropriate or excessive activation of TNF-α signaling leads to chronic inflammation and disease
- TNF-α inhibitors bind to the TNF receptor and blocks receptor and thus reduces the inflammatory process
- Commonly used in multiple autoimmune diseases
- Currently five agents on the market
  - Adalimumab (Humira®), infliximab (Remicade®), certolizumab (Cimzia®), golimumab (Simponi®), etanercept (Enbrel®)

Jang D-I, et. al. *Int J Mol Sci.* 2021.
Gerriets V, et. al. *StatPearls.* 2022.

18

Mechanism of Action, Example
Inflammatory Bowel Disease (IBD)



19

TNF-α Inhibitors: Clinical Pearls

Common Adverse Effects	Serious Adverse Effects	Contraindications	Black Box Warning	Pretreatment Screening
• Injection site or infusion reactions • Upper respiratory infections • Abdominal pain, nausea, diarrhea • Rash • Anemia • Headaches • Elevated LFTs	• Increased risk of malignancies • Serious infections: bacterial, viral, & fungal infections • CHF exacerbation • Demyelinating disorders (e.g., multiple sclerosis)	• CHF class III or IV • Hypersensitivity to any of part of the biologic product • Live vaccines	• Increased risk of serious infections that can lead to death • Increased risk of malignancies, especially lymphomas	• Hepatitis B & C, HIV, tuberculosis • CBC, BMP, LFTs • Vaccination status

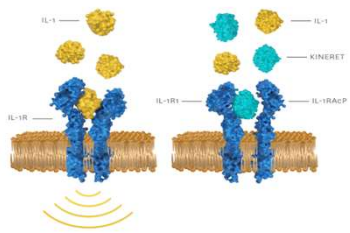
20

Cytokine modulators: IL-inhibitors

- Naturally occurring large group of cytokines
- Many interleukin types with varying effects
  - Pro-inflammatory and anti-inflammatory
- Targeting specific proinflammatory IL receptors to treat diseases
  - Travels to target cell and binds it via the receptor on the cell's surface
- Example: IL-6 receptor antagonist, tocilizumab (Actemra®) used in the treatment of rheumatoid arthritis

21

Mechanism of Action, Example
IL-1 receptor antagonist, Anakinra (Kineret®)



22

IL-inhibitors: Clinical Pearls

Common Adverse Effects	Serious Adverse Effects	Contraindications	Black Box Warning	Pretreatment Screening
• Neutropenia • Injection site or infusion reactions • Abdominal pain • URIs • Headaches • Elevated LFTs	• Anaphylaxis • GI adverse effects (e.g. diverticulitis, Crohn's disease exacerbation)	• Hypersensitivity to any of part of the biologic • Live vaccines	• Increased risk of serious infections that can lead to death, with some IL-inhibitors	• TB screening • LFTs • Baseline CBC

23

Lymphocyte Modulators

24

B Lymphocyte Depletion Therapy

- B cells play a key role in the pathogenesis of autoimmune diseases
  - Production of autoantibodies
  - Presentation of autoantigens to autoreactive T cells
  - Secretion of pro-inflammatory cytokines
- The main goal of B cell depletion therapy is to destroy harmful B cells while retaining protective B cell immunity
- Depletion is achieved through two main mechanisms:
  - Inhibition of the B-lymphocyte stimulator protein (BLyS)
  - Direct target by monoclonal antibodies against B-cell surface molecules, e.g. CD20 (most common)

Lee DSW, et. al. *Nat Rev Drug Discov.* 2021
Ramos-Casals M, et. al. *Am J Med.* 2012.
U. Wilkinson MG, et al. *Front Immunol.* 2019.

25

Mechanism of Action, Example

B Lymphocyte Depletion Therapy
Belimumab (Benlysta®)

Belimumab (Benlysta®) Prescribing Information for US HCPs. GSK. 2022
www.benlystahcp.com/lupus/mechanism-of-action

26

B Lymphocyte Depletion Therapy: Clinical Pearls

Examples	Belimumab (Benlysta®) Anti-BLyS	Rituximab (Rituxan®) Anti-CD20
Dosing	10 mg/kg IV q 2wks x 3, then q 4 wks OR 400 mg inj SQ wkly x 4, then 200 mg qwk	375 mg/m² BSA IV weekly × 4 OR 500-1,000 mg IV on days 1 and 15
Common adverse effects	Nausea, diarrhea, fever, bronchitis, nasopharyngitis, insomnia, depression, migraine, pharyngitis, infusion reaction	Lymphopenia/neutropenia, infection, asthenia, fever
Precautions	Serious infections, anaphylaxis, infusion reactions, psychiatric illnesses (e.g., depression, suicidal ideation), cancers	Tumor lysis syndrome, infections, cardiac adverse events, renal toxicity, bowel obstruction/perforation
	Live vaccines, concurrent use with other biologics	
Black Box Warnings	None	Fatal infusion-related reactions, severe mucocutaneous reactions, reactivation of hepatitis B virus, progressive multifocal leukoencephalopathy (PML) and death
Pretreatment screening	Depression and suicide risk	Hepatitis B, CBC

GlaxoSmithKline. Belimumab (Benlysta) [Package Insert]. 2012.
Genentech. Rituximab (Rituxan) [Package Insert]. 2018.

27

Test Your Knowledge #2: Pharmacists

Which of the following cytokine or lymphocyte modulators is contraindicated in patients with CHF Class III or IV

A. Interleukin (IL) inhibitors
B. TNF-alpha inhibitors
C. B cell depletion therapy
D. T cell activator

28

Checkpoint

Prior to initiating most biologics, which of the following screenings should be conducted? (select all that apply)

A. Hepatitis B and C
B. Tuberculosis
C. Liver Function Tests (LFTs)
D. Complete Blood Count (CBC)

29

Biologics → Biosimilars

30

Biologics Price Competition and Innovation (BCPI) Act

- Created an abbreviated licensure pathway for biological products shown to be *biosimilar* to or *interchangeable* with an FDA-licensed reference product
- The FDA provides guidance to industry regarding scientific considerations in demonstrating biosimilarity
  - MUST show comparable clinical effectiveness, safety, and purity to be approved as a biosimilar
- Helps to address the high cost of biologics and provides increased access to safe and effective, lower cost biosimilar alternatives

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Kogan L. Glob Trade Cust J. 2011.
US Food and Drug Administration

31

31

BCPI Act: Key Definitions

Reference Product
A reference product is the single biological product, already approved by the FDA, against with a proposed biosimilar product is being compared

Biosimilar Product
A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product

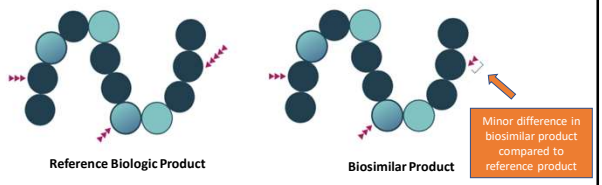
Interchangeable Product
- A biosimilar expected to produce the same clinical result as the reference product
- There is no safety risk of reduced efficacy associated with switching between the reference and interchangeable product
- May be substituted for reference product depending on state pharmacy laws

US Food and Drug Administration. Center for Biologic Evaluation and Research.

32

32

Reference Biologic vs. Biosimilar



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Adapted from the US Food and Drug Administration

33

33

Test Your Knowledge #3: Pharmacists & Techs

The difference between a biologic and a biosimilar is that a biosimilar is MUST:

A. Show sight differences in clinical effectiveness
B. Have similar safety
C. Meet purity standards
D. B and C
E. All of the above

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34

34

Biologics and Biosimilars Nomenclature

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35

35

Biologics Nomenclature

- The World Health Organization (WHO) is responsible for and manages the International Nonproprietary Names (INN) drug list
  - Provides a standardized, globally recognized structure for the naming of biologics
  - Reflect unique active ingredient of the drug
  - Typically includes a prefix, sub-stem and an official suffix, designated for that class of drugs

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36

36

2021 Update: New Naming of Monoclonal Antibodies

- WHO's INN program and the Unites States Adopted Names (USAN) have revised the nomenclature scheme for monoclonal antibodies
- **The suffix "-mab" has been replaced with four new suffixes (-tug, -bart, -mig,-ment), which further divide the classification of mAbs by their immunoglobulin (Ig) structure**
  - Now names using distinct random prefix, two substems, and a suffix
  - *Prefix* carries no specific meaning, but should be unique
  - *Substem A* relates to the target of the mAb
  - *Substem B* relates to the species used to manufacture the mAb
  - *Suffix* reflects the immunoglobulin structure of the molecule
- Applies to newly named monoclonal antibodies starting in December 2021 (drugs named prior will keep their original name)

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World Health Organization. New INN monoclonal antibody (mAb) nomenclature scheme. 2021

37

37

New Naming of Monoclonal Antibodies

Prefix	Substem A		Substem B		Suffix	Stem	
	Sub-stem	Target class	Sub-stem	Source species		Structure	
Random	-b(a)-	bacterial	-a-	Rat	-tug	Unmodified Ig	
	-c(i)-	cardiovascular	-e-	Hamster			
	-f(u)-	fungal	-i-	Primate	-bart	Antibody artificial	Example: Nepuvibart
	-gr(o)-	skeletal muscle mass related growth factors and receptors	-o-	Mouse			
	-k(i)-	interleukin	-u-	Human	-mig	Multi Ig	
	-l(i)-	immunomodulating	-xi-	Chimeric			
	-n(e)-	neural	-xizu-	Chimeric-humanized			
	-tox(a)-	toxin	-zu-	Humanized	-ment	Fragment	
	-t(u)-	tumor					
	-v(i)-	viral					

World Health Organization. 2021 Baicco R, et. al. Lancet. 2022.

38

38

Naming of Biosimilars

- The FDA provides specific guidance on the naming of biosimilars
- Biologics and biosimilars share a core name with the reference product hyphenated with four unique and meaningless lowercase letters as a distinguishing suffix
- Sharing a core name does NOT automatically infer interchangeability

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US Food and Drug Administration. Biosimilar and Interchangeable Products. 2017

39

39

Examples of Select Biosimilars

Reference Biologic	Select Biosimilar (FDA-approved products)
Adalimumab (Humira®)	Adalimumab-fkjp (Hulio®) Adalimumab-adbm (Cyltezo®)*
Infliximab (Remicade®)	Infliximab-abda (Renflexis®) Infliximab-dyyb (Inflectra®)
Etanercept (Enbrel®)	Etanercept-ykro (Eticovo™) Etanercept-szzs (Erelzi®)
Ranibizumab (Lucentis®)	Ranibizumab-nuna (Byooviz™)
Rituximab (Rituxan®)	Rituximab-arrx (Riabni™)
Filgrastim (Neupogen®)	Filgrastim-ayow (Releuko™) Filgrastim-sndz (Zarxio®)♀

♀ Zarxio® is the first FDA approved biosimilar product

*Cyltezo® is the first FDA approved monoclonal antibody biosimilar to be FDA approved as interchangeable

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US Food and Drug Administration. Biosimilar Product Information. 2022.

40

40

Purple Book Database of Licensed Biological Products

- Contains information on all FDA-licensed biological products regulated by CDER, including licensed biosimilar and interchangeable products, and their reference products
- Also includes information about FDA-licensed allergenic, cellular, gene therapy, hematologic, and vaccine products regulated by CBER
- The database can be accessed via PurpleBookSearch.fda.gov

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US Food and Drug Administration. Purple Book Database of Licensed Biological Products. 2023.

41

41

Test Your Knowledge #4: Pharmacists

In 2021 the World Health Organization (WHO) replaced the monoclonal antibody suffix "-mab" with four new suffixes and newer monoclonal antibodies manufactured after 2021 will now use the new suffixes. Which of the following is **NOT** one of the new suffixes for naming monoclonal antibodies?

A. "-tug"
B. "-bart"
C. "-cel"
D. "-mig"

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42

42

Biosimilar Interchangeability Laws – Illinois

Senate Bill 455 (2015) amended section 5 of the Pharmacy Practice Act

A pharmacist may substitute an interchangeable biosimilar for the biologic product ONLY if:

- The biosimilar has been FDA-approved as interchangeable with the biologic product
- The prescribing physician does not designate orally, in writing, or electronically that substitution is prohibited
- The pharmacy informs the patient of the substitution

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43

Illinois General Assembly. Senate Bill 0455. 2015.

43

Test Your Knowledge #5: Pharmacists & Techs

Which of the following should be referenced to determine the interchangeability of a biosimilar with a reference biologic product?

A. Drug package insert
B. FDA Biologic Database
C. Orange Book
D. Purple Book

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44

Summary

- Biologic therapeutics is a constantly evolving field, providing life-saving therapies to severe disease conditions
- Since biologics are made from living organisms, their manufacturing process is complex and costly
- Nomenclature for monoclonal antibodies have recently changed from "-mab" to "-tug, -bart, -mig, and –ment"
- Biosimilars are an affordable alternative to biologics, but interchangeability is based on the guidance from the FDA
- Increased awareness of the interchangeability is important to improve access, reduce cost, and allow clinicians to be better advocates for their patients

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45

45

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46

46

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47

47

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2023 ICHP ANNUAL MEETING

48

48

Questions?

oamuwo@roosevelt.edu

49