Clinical Use of Biosimilars in Oncology Practice

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View faculty bios at www.ashpadvantage.com/biosimilarsinoncology

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Clinical Use of Biosimilars in Oncology Practice

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1.0 hr CE

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Sandra Cuellar- speakers bureau for Genentech; advisory board for Coherus Biosciences, Inc.

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Learning Objectives

• Compare the approved indications and biobetters of currently available oncology biosimilars with reference products.
• Discuss efficacy and safety data for oncology biosimilars, including necessary monitoring parameters.
• Describe interprofessional education strategies for patients on the safety and monitoring of biosimilar products.

Abbreviations

• AE- adverse event
• AUC- area under the curve
• EBC- early breast cancer
• EMA- European Medicines Agency
• EP/PR- estrogen receptor/progesterone receptor
• FDA- Food & Drug Administration
• PK/PD- pharmacokinetic/pharmacodynamics
Biosimilars in Oncology

Sandra Cuellar, Pharm.D., BCOP

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologic</td>
<td>An approved product composed of proteins, nucleic acids, or combinations of these, or living entities such as cells and tissues, which is isolated from natural sources (humans, animals, microorganisms) and produced by biotechnology methods and other cutting edge technology</td>
</tr>
<tr>
<td>Biosimilar</td>
<td>A biologic product developed such that there are “no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency” and “demonstrates similarity to the reference product in terms of quality characteristics, biological activity, and efficacy based on a comprehensive comparability exercise”</td>
</tr>
<tr>
<td>Biobetter</td>
<td>A biological that has been structurally and/or functionally altered to achieve an improved or different clinical performance</td>
</tr>
</tbody>
</table>

Clinical Use of Biosimilars in Oncology Practice

**Trends in Health Care Expenditures**

- **Biologic agents have revolutionized the treatment of cancer**
- **Biologic agents account for 37% of U.S. drug spending**
- **Global market was estimated to reach $66.4 billion in 2019**

### Top Antineoplastic Drugs by Expenditures in U.S. Clinics in 2019

<table>
<thead>
<tr>
<th>Drug</th>
<th>Expenditures ($ Thousands)</th>
<th>% Increase from 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pembrolizumab</td>
<td>5,298,142</td>
<td>57.6</td>
</tr>
<tr>
<td>Nivolumab</td>
<td>3,627,172</td>
<td>5.7</td>
</tr>
<tr>
<td>Rituximab</td>
<td>2,939,984</td>
<td>1.9</td>
</tr>
<tr>
<td>Bevacizumab</td>
<td>253,641</td>
<td>6.5</td>
</tr>
<tr>
<td>Trastuzumab</td>
<td>2,412,011</td>
<td>-2.3</td>
</tr>
<tr>
<td>Daratumumab</td>
<td>1,344,135</td>
<td>35.1</td>
</tr>
<tr>
<td>Pertuzumab</td>
<td>1,129,112</td>
<td>14.7</td>
</tr>
</tbody>
</table>


**Biosimilars are Needed to Disrupt Pharmaceutical Biologic Ecosystem**

- Biologics have revolutionized the treatment of cancer
- Biologics are expensive, and costs have **increased progressively**
- Introduction of biosimilars increases competition with reference (originator) biologic without compromising quality
- **Biologics Price Competition & Innovation (BPCI) Act of 2009**


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Biosimilars are Engineered to Reference Product

- **Biosimilar Program Objective:** Establish biosimilarity based on totality of evidence, not reestablish benefit
- Conducted in sensitive patient population with sensitive endpoints; designed to detect a difference

### Clinical Trials
- Clinical Immunogenicity
- Clinical Pharmacology
- Biologic and Functional Characterization
- Structural and Physicochemical Characterization

### Residual Uncertainty Decreases
- Conducted in sensitive patient population with sensitive endpoints; designed to detect a difference

### Clinical Trials
- Clinical Immunogenicity
- Clinical Pharmacology
- Biologic and Functional Characterization
- Structural and Physicochemical Characterization

### Biosimilar Program

#### Objective:
- Establish biosimilarity based on totality of evidence, not reestablish benefit

### Biosimilar

- **Biologic (Novel Therapeutic)**
- **Biosimilar (Competitive Bioequivalence)**
- **Biobetter (Improved efficacy/safety/administration)**

<table>
<thead>
<tr>
<th>Development cost</th>
<th>Biologic (Novel Therapeutic)</th>
<th>Biosimilar (Competitive Bioequivalence)</th>
<th>Biobetter (Improved efficacy/safety/administration)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$800 million</td>
<td>$100 - 300 million</td>
<td>$500 million</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time to market</th>
<th>Biologic (Novel Therapeutic)</th>
<th>Biosimilar (Competitive Bioequivalence)</th>
<th>Biobetter (Improved efficacy/safety/administration)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 – 10 years</td>
<td>7-8 years</td>
<td>10 years</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical studies</th>
<th>Biologic (Novel Therapeutic)</th>
<th>Biosimilar (Competitive Bioequivalence)</th>
<th>Biobetter (Improved efficacy/safety/administration)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I, II, III (efficacy and safety)</td>
<td>PK/PD studies in healthy volunteers Randomized comparison study in a sensitive population</td>
<td>Phase I, II, III (efficacy and safety)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Price</th>
<th>Biologic (Novel Therapeutic)</th>
<th>Biosimilar (Competitive Bioequivalence)</th>
<th>Biobetter (Improved efficacy/safety/administration)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Price</td>
<td>Reduced Price</td>
<td>Premium Price</td>
<td></td>
</tr>
</tbody>
</table>

**FDA. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Guidance for Industry. April 2015.**

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Extrapolation

Biosimilar Development & Extrapolation

Development of innovator product includes extensive preclinical and clinical studies for all indications. Development of biosimilar includes stepwise approach to demonstrating biosimilarity to reference product based on analytical studies, animal studies, and clinical studies.

Demonstrating analytical & functional similarity between biosimilar candidate and its reference product can reduce the number and scope of subsequent clinical trials.

If a biosimilar meets the requirements for biosimilarity, extrapolation of data may allow approval for additional indications for which the reference product is indicated without other dedicated clinical studies.


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Extrapolation: FDA Guidance

- Scientific justification for extrapolation should consider:
  - Mechanism of action (MOA) in each condition
    - Target/receptor(s) for product-relevant activity/function
    - Binding, dose/concentration response, and pattern of molecular signaling when product engages with target/receptor(s)
    - Relationships between target/receptor interactions and product structure
    - Target/receptor location and expression
  - PK, PD, and biodistribution of product in different patient populations
  - Immunogenicity of product in different patient populations
  - Differences in expected toxicities for each condition & patient population
  - “any other factor that may affect the safety or efficacy of the product in each condition of use and patient population for which licensure is sought”

Clinical Use of Biosimilars in Oncology Practice

## FDA Approved Biosimilars

<table>
<thead>
<tr>
<th>Filgrastim</th>
<th>Pegfilgrastim</th>
<th>Trastuzumab</th>
<th>Bevacizumab</th>
<th>Rituximab</th>
</tr>
</thead>
</table>
| • Filgrastim-sndz  
  • Filgrastim-aafi | • Pegfilgrastim-jmdb  
  • Pegfilgrastim-cbqv  
  • Pegfilgrastim-bmez | • Trastuzumab-dkst  
  • Trastuzumab-pkrb  
  • Trastuzumab-dttb  
  • Trastuzumab-qyyp  
  • Trastuzumab-anns | • Bevacizumab-awwb  
  • Bevacizumab-bvzr | • Rituximab-abbs  
  • Rituximab-pvvr |

## Extrapolation of Indications for Oncology Products

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### Clinical Use of Biosimilars in Oncology Practice

<table>
<thead>
<tr>
<th>Neupogen (Filgrastim) Indications</th>
<th>Zarxio Filgrastim-sndz</th>
<th>Nivestym Filgrastim-aafi</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemotherapy-induced febrile neutropenia</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Acute myeloid leukemia</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cancer patients receiving bone marrow transplants</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Peripheral blood progenitor cell collection and engraftment</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Severe chronic neutropenia</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Neulasta (Pegfilgrastim) Indications</th>
<th>Udenyca Pegfilgrastim-cbqv</th>
<th>Fulphila Pegfilgrastim-jmdb</th>
<th>Ziextenzo Pegfilgrastim-bmez</th>
</tr>
</thead>
<tbody>
<tr>
<td>To decrease chemotherapy-induced febrile neutropenia</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Hematopoietic radiation injury syndrome</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Avastin (Bevacizumab) Cancer Indications</th>
<th>Mvasi Bevacizumab-aawb</th>
<th>Zirabev Bevacizumab-bvzr</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSCLC</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Colon</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Recurrent glioblastoma</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cervical</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Renal cell carcinoma</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Epithelial ovarian, fallopian tube, or primary peritoneal cancer</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Herceptin (Trastuzumab) Cancer Indications</th>
<th>Ogivri Trastuzumab-dkst</th>
<th>Herzuma Trastuzumab-pkrb</th>
<th>Ontruzant Trastuzumab-dttb</th>
<th>Trazimera Trastuzumab-qyyp</th>
<th>Kanjinti Trastuzumab-anns</th>
</tr>
</thead>
<tbody>
<tr>
<td>HER2 + Breast</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>HER2 + Gastric</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

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Clinical Use of Biosimilars in Oncology Practice

### Rituxan (Rituximab)

<table>
<thead>
<tr>
<th>Indications</th>
<th>Truxima Rituximab - abbs</th>
<th>Ruxience Rituximab - pvvr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Hodgkins lymphoma CD 20 positive</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Chronic lymphocytic leukemia</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Granulomatosis with Polyangiitis and Microscopic Polyangiitis</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Moderate to severe pemphigus vulgaris*</td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>

*Data from reference product may not be extrapolated to support use of biosimilar for indication based on MOA, PK, PD, or immunogenicity.

---

### Biobetters

- May impact utilization of biosimilars
- New molecular entities
  - Unique dosing regimen, safety, efficacy, and immunogenicity
  - Indication may be different than for reference product
- Modifications to a reference molecule
  - Enhance efficacy & improve safety
    - Antibody-drug conjugates
  - Provide more convenient administration
    - Delivery administration (route of administration)
      - Subcutaneous
      - Auto-body injector

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### Oncology Biobetters

<table>
<thead>
<tr>
<th>Agent</th>
<th>Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pegfilgrastim</td>
<td>• Pegfilgrastim auto-injector</td>
</tr>
<tr>
<td>Rituximab</td>
<td>• Rituximab subcutaneous</td>
</tr>
<tr>
<td></td>
<td>• Obinutuzumab</td>
</tr>
<tr>
<td>Trastuzumab</td>
<td>• Trastuzumab subcutaneous</td>
</tr>
<tr>
<td></td>
<td>• Ado-trastuzumab emtansine</td>
</tr>
<tr>
<td></td>
<td>• Fam-trastuzumab deruxtecan-nxki</td>
</tr>
</tbody>
</table>

### Biobetters

<table>
<thead>
<tr>
<th>Existing Agent (pipeline)</th>
<th>Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trastuzumab Pertuzumab</td>
<td>• Trastuzumab/pertuzumab subcutaneous combination</td>
</tr>
<tr>
<td></td>
<td>• Submitted biologics license application (BLA) March 2020</td>
</tr>
<tr>
<td>Daratumumab</td>
<td>• Daratumumab subcutaneous</td>
</tr>
<tr>
<td></td>
<td>• Submitted BLA to FDA June 2019</td>
</tr>
</tbody>
</table>

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Onpro Pegfilgrastim vs. Biosimilar Pegfilgrastim

- Greater convenience
  - Reduce drug administration burden on health care system

- Device failures and higher cost compared with biosimilar

- Device failure rate reported to be 1 to 10%
  - May result in higher costs
- Patient preference
- Insurance coverage
  - Medicare
  - Medicaid
  - Commercial

Subcutaneous Biobetter vs. Intravenous Biosimilar

- Greater convenience
  - Reduce drug administration burden on health care system

- Higher cost compared with biosimilar

- Patient preference
- Fixed dosing
  - Less dosing errors
  - Less drug wastage
- Insurance coverage
  - Medicare
  - Medicaid
  - Commercial

Clinical Use of Biosimilars in Oncology Practice

Key Takeaways

- Biosimilars represent an opportunity to increase access and improve drug expenditures without compromising efficacy, safety, or quality
- Extrapolation of indications requires scientific justification in addition to “totality of evidence”
- Biobetters that modify formulation/delivery may impact utilization of select biosimilars due to enhanced convenience

Case Study: Trastuzumab

Adam Brufsky, M.D., Ph.D., FACP

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Case

A 35-year-old premenopausal woman is found to have an abnormal screening mammogram. Ultrasound of the breast confirms a suspicious mass in the right breast. Ultrasound-guided biopsy revealed a grade 2 invasive ductal carcinoma, ER/PR negative, HER2 positive (IHC3+). The patient undergoes lumpectomy and sentinel lymph node assessment. Pathology reveals a grade 2 1.9-cm invasive ductal carcinoma (IDC), with negative margins. Sentinel lymph nodes are negative (0/3).

Adjuvant systemic therapy is recommended, with weekly paclitaxel x 12 in combination with trastuzumab, followed by single-agent trastuzumab to complete a total of 1 year.

Would a trastuzumab biosimilar be an appropriate option for this patient?

a. Yes
b. No
c. Not enough information
d. Not sure
Clinical Use of Biosimilars in Oncology Practice

If this patient had metastatic disease, would you consider a trastuzumab biosimilar?

a. Yes  

b. No  

c. Not enough information  

d. Not sure

Considerations in Product Selection

• Factors favoring use of one biosimilar versus another

• Factors favoring use of a biobetter subcutaneous instead of a biosimilar or reference product

• Transition from one product to another
Trastuzumab Biosimilars

- Trastuzumab-dkst (MYL-14010; Mylan/Biocon; Ogivri)*
- Trastuzumab-pkrb (CT-P6; Celltrion; Herzuma)*
- Trastuzumab-dttb (SB3; Samsung; Ontruzant)*
- Trastuzumab-qyyp (PF-05280014; Pfizer; Trazimera)*
- Trastuzumab-anns (ABP 980; Amgen/Allergan; Kanjinti)*

- BCD-022 (Biocad)
- DMB-3111 (Meiji Seika)

Summary of Phase III Trials for Trastuzumab Biosimilars

<table>
<thead>
<tr>
<th></th>
<th>MYL-14010 (Trastuzumab-dkst)</th>
<th>CT-P6 (Trastuzumab-pkrb)</th>
<th>SB3 (Trastuzumab-dttb)</th>
<th>PF-05280014 (Trastuzumab-qyyp)</th>
<th>ABP-980 (trastuzumab-anns)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial</td>
<td>NCT02472964</td>
<td>NCT02162667</td>
<td>NCT02149524</td>
<td>NCT1989676</td>
<td>NCT01901146</td>
</tr>
<tr>
<td>Disease</td>
<td>Metastatic</td>
<td>EBC and Metastatic</td>
<td>EBC</td>
<td>Neoadjuvant Metastatic</td>
<td>EBC</td>
</tr>
<tr>
<td>No. of patients</td>
<td>500</td>
<td>549</td>
<td>800</td>
<td>225/707</td>
<td>725</td>
</tr>
<tr>
<td>Stage of development</td>
<td>FDA approved (December 2017)</td>
<td>FDA approved (December 2018)</td>
<td>FDA approved (January 2019)</td>
<td>FDA approved (March 2019)</td>
<td>FDA approved (June 2019)</td>
</tr>
</tbody>
</table>

*FDA/EC approval

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<table>
<thead>
<tr>
<th>Indication</th>
<th>Trastuzumab (Reference Biologic)</th>
<th>Trastuzumab -dkst, -pkrb, -dttb, -qyp, -anns (Biosimilar)</th>
<th>Trastuzumab emtansine (Biobetter)</th>
<th>Trastuzumab and hyaluronidase-oysk (Biobetter)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Cancer Gastric Cancer</td>
<td>Breast Cancer Gastric Cancer</td>
<td>Breast Cancer (metastatic and adjuvant)</td>
<td>Breast Cancer</td>
<td></td>
</tr>
<tr>
<td>Dose</td>
<td>Every-3-week dosing or every-week dosing</td>
<td>Same as reference product</td>
<td>3.6 mg/kg IV every 3 weeks</td>
<td>600 mg every 3 weeks</td>
</tr>
<tr>
<td>Administration</td>
<td>IV</td>
<td>IV</td>
<td>IV</td>
<td>Subcutaneous over 2-5 minutes</td>
</tr>
<tr>
<td>Price</td>
<td>Reference Price</td>
<td>Reduced Price</td>
<td>Premium Price</td>
<td></td>
</tr>
</tbody>
</table>

Safety & Immunogenicity of Trastuzumab Biosimilars

- European experience
  - recalls or safety concerns
**HERITAGE: Safety Profile at Week 24**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>MYL-1401O + Taxane (n = 247)</th>
<th>Trastuzumab + Taxane (n = 246)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious AE, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥1 serious AE</td>
<td>38.1</td>
<td>36.2</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>27.5</td>
<td>25.2</td>
</tr>
<tr>
<td>Neutropenia with fever</td>
<td>4.5</td>
<td>4.1</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>1.6</td>
<td>4.9</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>1.6</td>
<td>2.0</td>
</tr>
<tr>
<td>Deaths due to serious AEs, n</td>
<td>4*</td>
<td>4*</td>
</tr>
<tr>
<td>Median LFEV values, % (range)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>64.0 (51 to 82)</td>
<td>63.0 (51 to 84)</td>
</tr>
<tr>
<td>Week 24</td>
<td>63.5 (50 to 81)</td>
<td>63.0 (41 to 82)</td>
</tr>
<tr>
<td>Change from baseline to week 24</td>
<td>-1.0 (-13 to 21)</td>
<td>-1.0 (-19 to 13)</td>
</tr>
</tbody>
</table>

Rugo HS et al. ASCO 2016. Abstract LBAS03.

**HERITAGE: Immunogenicity and Population PK**

- Immunogenicity was similarly low for both MYL-1401O and trastuzumab arms
  - Overall antidrug antibody rates: 2.4% vs. 2.8%, respectively
  - Median titer in antibody-positive patients: 2.5 vs. 2.3, respectively
- Trough $C_{min}$ comparable between arms at week 15 (cycle 6)
  - Ratio of geometric LSMS: 103.88% (90% CI: 93.7% to 115.11%)
- Population pharmacokinetics similar between MYL-1401O and trastuzumab arms
  - Dose-normalized mean $C_{max}$: 0.4321 vs. 0.4196 μg/mL/mg, respectively
  - Dose-normalized mean AUC: 98.350 vs. 94.391 μg∙d/mL/mg, respectively

Clinical Use of Biosimilars in Oncology Practice

Incidence of AEs Is Low During Monotherapy

<table>
<thead>
<tr>
<th>AEs, patients, %</th>
<th>Combination therapy: weeks 1-24</th>
<th></th>
<th>Monotherapy: weeks 24-48</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trastuzumab-dkst + taxane N=247</td>
<td>Trastuzumab + taxane N=246</td>
<td>Trastuzumab-dkst N=179</td>
<td>Trastuzumab N=163</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>57.5</td>
<td>53.3</td>
<td>1.1</td>
<td>2.5</td>
</tr>
<tr>
<td>Asthenia</td>
<td>21.9</td>
<td>16.3</td>
<td>2.8</td>
<td>1.8</td>
</tr>
<tr>
<td>Nausea</td>
<td>19.8</td>
<td>13.8</td>
<td>2.2</td>
<td>2.5</td>
</tr>
<tr>
<td>Edema peripheral</td>
<td>14.2</td>
<td>11.4</td>
<td>0.6</td>
<td>1.8</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>12.1</td>
<td>4.5</td>
<td>2.8</td>
<td>1.2</td>
</tr>
<tr>
<td>Vomiting</td>
<td>10.5</td>
<td>7.7</td>
<td>1.7</td>
<td>3.1</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>8.5</td>
<td>6.5</td>
<td>0.6</td>
<td>2.5</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>6.1</td>
<td>1.6</td>
<td>2.2</td>
<td>1.2</td>
</tr>
<tr>
<td>Infusion-related reaction</td>
<td>6.9</td>
<td>4.5</td>
<td>0</td>
<td>0.6</td>
</tr>
</tbody>
</table>

AE, adverse event; TEAE, treatment-emergent AE.

Interprofessional Education Strategies

Sandra Cuellar, Pharm.D., BCOP

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Clinical Use of Biosimilars in Oncology Practice

Biosimilar Education

- Significant knowledge gaps in key stakeholders

**USA Surveys (2013-2016)**

- 30% of oncologists perceive biosimilars less safe than reference counterpart due to abbreviated regulatory pathway
- 12% indicate comfort with extrapolation


Biosimilar Education

Key stakeholders such as provider, payer, and patient understanding of safety and efficacy for successful implementation of biosimilars

- Biosimilar regulatory approval process
- Biologic manufacturing
- Product drift
- Extrapolation
- Switching
- Immunogenicity
- Pharmacovigilance


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Will Patients Accept Biosimilar Cancer Drugs?

• Cancer patients in the U.S. want to play a role in their care and have an open dialogue with their oncologist
  – Therapeutic use of biosimilars will likely take longer in the U.S. than in Europe and other parts of the world
• Safety and efficacy data must be communicated to patients effectively
• International study of 3200 patients (variety of diseases, including breast, lung, and colorectal cancer, and non-Hodgkin lymphoma)
  – Only 20% to 30% of patients were even aware of the term biosimilar
  – Roughly half of patients polled would be comfortable switching to a biosimilar from the innovator product


Resources for Patient Biosimilar Education

- Webcasts
- Fact Sheets
- Online Resources
  • Biosimilar council
  • Professional Organizations
  • Youtube videos: FDA, ACS CAN
  • Informational Pamphlets
Safety and Monitoring of Biosimilar Products

• Pharmacovigilance
  – Science and activities relating to the detection, evaluation, understanding, and prevention of adverse drug reactions or any other drug-related problems

• Post-marketing reports to FDA on:
  – all types of suspected reactions
  – suspected drug-drug or drug-food interactions
  – ADRs associated with drug withdrawal
  – medication errors or overdose
  – lack of efficacy


Biosimilar Pharmacovigilance

Monitor and Report

• FDA Medwatch
• Any healthcare provider can report

Correct attribution of safety event

• Biosimilar administered
• Consider transitions of care
Clinical Use of Biosimilars in Oncology Practice

Consider these practice changes. Which will you make?

- Educate other healthcare providers about biosimilars and their effective use.
- Educate patients with cancer about the appropriate, effective, and safe use of available biosimilars.
- Discuss with colleagues the logistical considerations for incorporating biosimilars at my organization.
- Recommend biologics/biosimilars to other healthcare providers for patients with applicable cancers.
- Discuss with colleagues the transition from originator products to biosimilars to guide the treatment of patients with applicable cancers.