SUPPLEMENTAL MATERIAL – Biosimilar Knowledge Among Oncology/Hematology Team Members in Colorado, USA: An Educational Initiative and Follow-Up Survey

BioDrugs

Rovshan M Ismailov1*, Zaytuna D Khasanova1

1. Complex Mechanisms of Disease, Aging and Trauma (CMDAT) Research Foundation, P.O. Box 460722 Denver, CO 80246, USA
   *Corresponding author’s phone number: 1 720 492 4193, email address: dr.ismailov@cmdat.org

Survey questions

Section I. General information

1. What is your specialty? Please check all that apply
   - Oncology nurse or oncology nurse practitioner
   - Patient navigator
   - Palliative care doctors and nurses
   - Physician assistant
   - Oncology social worker
   - Pathologist
   - Registered dietician
   - Diagnostic radiologist
   - Rehabilitation therapist
   - Other

2. How many years in practice?
   - Less than 5 years
   - Between 5 to 10 years
   - More than 10 years

3. Which age group do you belong to?
   - 21 – 30
   - 31 – 40
   - 41 – 50
   - 51 – 60
   - 61 and older
Section II. Section II is multiple choice questions. Please select only one that, in your opinion, is the best answer.

4. What is “biosimilar”?

- A biosimilar is a biologic that is highly similar to the licensed biologic drug. However, because of difference in manufacturing processes, biosimilars are not identical to the licensed biologic drugs.
- A biosimilar is a generic version of the licensed biologic drugs
- A biosimilar is an identical copy of the licensed biologic drugs

5. Which of the following is the correct statement regarding biosimilar regulation in the US?

- Biosimilar market is regulated by the US Food and Drug Administration
- Biosimilar market is regulated by the World Health Organization
- Biosimilar market is not regulated in the US

6. Which of the following is the correct statement regarding interchangeability?

- Under no circumstances biosimilars can be interchanged with the licensed biologic drugs
- In the case of switch or alternate, interchangeable products are expected to have no less efficacy and no more safety risk when switched or alternated with the referenced product
- At the patient's request, biosimilars are freely interchangeable with the licensed biologic drugs

7. Pharmacists may sometime substitute a prescription medication for a generic one although there is no prior consent of the treating physician. This is also known as “automatic substitution”. Which of the following is the correct statement regarding automatic substitution and biosimilar products?

- Automatic substitution can never be applied to biosimilar products
- Although automatic substitution is not allowed for biosimilar products in Colorado, however, if it cannot be avoided, such event must be recorded accurately
- In the future, if a pharmacist in Colorado decides to substitute a referenced biologic product for a biosimilar, he/she should notify the prescribing physician and make a patient aware of such substitution. Prescribing physicians may still write “dispense as written” if they do not want a biologic substitution made. Remember, the substituted product must be designated as interchangeable by the FDA
8. Biosimilar products that are currently both regulated and marketed have shown no specific safety concerns. Nevertheless:

- Any suspected serious adverse reactions associated with use of biosimilar products should be reported by the treating physician and other prescribers
- A manufacturer must follow a specific drug safety plan
- All of the above

9. The development of biosimilar products in the field of oncology can help to:

- Improve patient access to biological therapies in a safe way
- Reduce both cancer drug costs and cancer drug shortage
- All of the above

10. Lower cost of biosimilar products as compared to the licensed biologic drugs may help to improve:

- Adherence to treatment among oncology patients
- Overall access to cancer treatment as well as enhance price competition to biologics overall
- All of the above

11. How older patients with cancer may benefit from the future development, evaluation and approval of biosimilar products?

- By having fewer adverse outcomes
- By having less intensive treatment
- By having better access to cancer treatment options

Section III. Agreement statements. Please select if you fully agree, somewhat agree, neither agree nor disagree, somewhat disagree and fully disagree with the following statements. Please select only one answer for each statement.

12. Biosimilar products will eventually play a greater role in the optimal combination therapy for cancer:

- Fully agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
13. Knowledge gaps among oncology/hematology staff members regarding biosimilar products may prevent oncology patients from access to optimal combination therapy for cancer:

- Fully agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Fully disagree

14. Biosimilars may have a substantial impact on the range of treatment options in the oncology/hematology settings:

- Fully agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Fully disagree

15. Oncology/hematology staff members should be knowledgeable concerning various issues related to the role of biosimilar products in the optimal combination therapy for cancer:

- Fully agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Fully disagree

16. As biosimilars may cost less than referenced biologic products, patient access to optimal combination therapy for cancer will be improved:

- Fully agree
Somewhat agree
Neither agree nor disagree
Somewhat disagree
Fully disagree

Section IV. Overall level of interest in the subject, the motivation to complete training related to biosimilars in the future and overall assessment of study participants interest in sharing biosimilars information with colleagues and patients.

17. Please indicate your overall interest in the subject ("biosimilars") on the scale from 1 to 10, with 1 referring to not interested at all and 10 referring to extremely interested:
   - 1
   - 2
   - 3
   - 4
   - 5
   - 6
   - 7
   - 8
   - 9
   - 10

18. How motivated are you to complete future trainings focused on biosimilars, with 1 referring to not motivated at all and 10 referring to extremely motivated:
   - 1
   - 2
   - 3
   - 4
   - 5
   - 6
   - 7
   - 8
   - 9
   - 10

19. How interested are you to share information gained from this training regarding biosimilars with colleagues and patients, with 1 referring to not interested at all and 10 referring to extremely interested:
20. In what ways do you think you may use the information you learned in the program in your practice?

21. Are there topics concerning biosimilars which are not well understood and for which directed education is needed?

22. In your opinion, what is the best way to learn more about biosimilars (e.g., other enduring materials such as flyers, seminars, focused groups, webinars etc)