

PHA 5172 Biotechnology and Product Development and Practice

Student Product Presentations (Verbal & Written), Outline / Questions

1. What is the **type** of biologic product? E.g., What is its **biologic category** (e.g., Mabs vs Antisense)? Any unique **structural features** of the molecule within its category?
2. What is its **mechanism of action**? Especially any **unique feature as a biologic**, if any? Any significant **differences** from other drugs used for the target disease?
3. What is the **impact** of the biologic product on the therapy of its target disease (e.g., novel, me-too, additive)? Including therapy prior to and after approval of the biologic product? **Present clinical efficacy data** from the clinical studies in your references.
4. Are there any **special administration** issues? Route, rate, solutions, frequency, dosing, or added drugs used with the biologic?
5. Are there any **special monitoring requirements** for this biological, based on its mechanism of action, pharmacokinetics, or impact on the disease?
6. Are there any unique features of its **adverse events** profile (number, types, or severity)? Any **different from the drugs** being used for the target disease? **Present data** on adverse events from the clinical studies in your references.
7. Summarize the main **benefits** of and **problems** with your biological product?
8. Write the **overall clinical value** of your biological product for its disease, stated succinctly in **one sentence** that you would tell to patients or physicians.
9. Write an **advertising message** for this product extolling its benefits and/or impact on therapy? Keep it simple, e.g., one or two phrases or sentences.

Other guidelines:

- **Length:** no more than 3-5 typed, double-spaced pages.
- **Content:** Answer above questions in any order and try to add any other key issue, as needed based on the uniqueness of your product.
- **Style:** Use complete sentences.
- **Opinions:** Make sure to include **your** opinions about the product or any data in your discussions
- **References:** Use at least **5** references, including at least **two** journal publications of original clinical studies near the date of the product's first approval.
- **Time for Verbal presentation** to class: 10-15 minutes with 5 min. for questions.
- **Handouts and transparencies** (or power point slides) are optional but highly desired for the presentation
- **Grading:** 50 points out of 150 possible points