

## PHA 5172 Biotechnology and Product Development and Practice

### Student Product Presentations, Outline / Questions

1. What is the type of biologic product? E.g., What is its biologic category (e.g., Mabs)? Any unique structural features of the molecule?
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. What is the overall 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:

- Volume: no more than 3-5 typed, double-spaced pages.
- Outline: 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 its data in 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.
- Verbal presentation to the class: 10-15 minutes with 5 minutes for questions.
- Handouts (optional) and transparencies (or power point slides) are optional but highly desired for the presentation
- Grading: 40 points possible.