Making Medicines Affordable

Is Product/Indication Specific Guidance Already Necessary and Meaningful? 3.2.

London, 24 Oct 2011

Nicole Filser

Senior Director Clinical Development – Biologics
Mylan

Current EMA development Guidance

- Product/Class specific
- Indication specific
- General
  - Overarching biosimilar guideline
  - Biosimilar guideline on nonclinical and clinical

Product/Class specific Guidance

- **Product specific**
  - EPO, FSH, LM-Heparin, INF alpha, GCSF, hGH, Insulin
- **Class specific:**
  - Blood derived products
  - Radiopharmaceuticals
  - Herbal medicine
  - *Biosimilar mAbs*

Indication specific Guidance

Main indication of mAbs:

- **Oncology**
  - Solid tumour
  - Haematologic malignancy
- **Immunology**
  - Musculo-skeletal system: RA, PA, AS
  - Dermatology: Plaque Psoriasis
  - Alimentary tract: Crohn's disease

➔ For all indications, disease specific guidance available

➔ Limited relevance to biosimilar development

Class specific Guidance

- **Biosimilar mAb draft guideline contains all product specific guidance sections plus refers to indication specific issues**
  - **Section 5.3, Clinical Efficacy, 326-331**
    « For most of the clinical conditions that are licensed for mAbs, specific CHMP guidance on the clinical requirements exists. However, to establish biosimilarity, deviations from these guidelines (choice of endpoint, timepoint of analysis of endpoint, nature or dose of concomitant therapy, etc) may be warranted. Such deviations need to be fully scientifically justified. In such circumstances it is recommended, where feasible, to include the usually recommended endpoints for a certain condition as secondary endpoint. »
  - **Section 5.3.1,**
    Additional considerations for mAbs licensed in anticancer indications

➔ ***Clarifies that Indication specific guidance not fully applicable to Biosimilars***

Any further Guidance needed/meaningful?

- Biosimilar mAbs are already under development and Scientific Advice (SA) has been provided by various Authorities
- Product specific biosimilar guidance only released after “fast movers” entered late phase of product development
- SA provides flexibility to negotiate case by case
  - to identify well justified development pathways
  - keeps the competitive edge of “fast movers”

➔ EGA’s position: no additional mAb product specific guidance necessary

Conclusion

- **Biosimilar mAb draft guideline clarifies that indication specific guidance not fully applicable**
- **It covers all section points described in other product/class specific guidance:**
  - nonclinical
  - PK and PD
  - clinical efficacy and safety

No additional guidance required