EMA Workshop on Biosimilar Monoclonal Antibodies, 24 October 2011

Session 3.1: Clinical Issues

«Is product/indication specific guidance necessary and meaningful »

Innovator Industry Presentation

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Topic: Indication/Product Specific Guidance

EBE recommends additional specific guidance to improve transparency and benefit development of certain categories of products/product classes

- EBE considered several classification approaches including:
  - By class or target (TNF, b-cell, IL-6…)
  - Broadly by therapeutic area (cytotoxic, immunomodulatory)
    - Cytotoxic agents can be further segmented into mAbs with and without receptor modulation
  - By construct (chimeric, humanized, fully human, fusion, fragment)
  - By indication (Rheumatoid arthritis, NHL, CRC…)

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EBE Recommendation

- Specific guidance may be beneficial for classes of products based on target
  - TNF blocking agents, b-cell, VEGF…
- The rationale for this suggestion is that specific comparability experiments may be warranted for different classes of molecules and this guidance could be pre-specified to provide consistency in development programmes
- In addition, specific guidance can be provided for certain classes as new information is accumulated on biosimilar development programmes
  - Information could be added as annexes for specific drug classes

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Class Specific Guidance

B-cell targeted antibody represents one example of a product class needing specific guidance

- The molecule has multiple mechanisms of action, such as ADCC, CDC, and apoptotic pathways
  - Different MOAs in different clinical settings may require different evidence necessary for establishing biosimilarity
- Host and disease factors may contribute to mode of action for example:
  - Intact effector mechanisms (complement, NK cells)
  - CD20 receptor number and density (CLL)
  - Concomitant medication (steroids, chemotherapy)

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What Should Class Specific Guidelines Include?

AS warranted:

- Requirements for analytic assessments including effector function testing (regardless of their role in MOA)
- PK or PK/PD requirements specific to distinct indicated populations and molecular class
- Guidance on immunogenicity studies in populations expected to exhibit different propensities for ADA formation
- Specific requirements for clinical trials to demonstate similar efficacy and safety

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