Demonstration of Equivalence between Glatopa™ and Copaxone® 20 mg

James Anderson, Tammy Ganjily, Ish Capila, Christine Bell, Jim Prescott, Jon Lansing, Joe Gajcha, Rick Schlieben, Mani Iyer, John Bishop, and Ganesh Kaundinya
Momenta Pharmaceuticals, Inc., Cambridge, MA

INTRODUCTION AND PURPOSE

Glatopa™ (glatiramer acetate, injection, Sodium—MRL) is a biologic product marketed as a generic version of Copaxone® 20 mg (glatiramer acetate, injection, Teva Pharmaceuticals Industries Ltd.) for the treatment of relapsing forms of multiple sclerosis. In the United States, a generic drug is approved under the Abbreviated New Drug Application (ANDA) (505b(g)) pathway. Clinical data are generally required to support approval. We have demonstrated bioequivalence and shown that the drug is equivalent to the innovator drug.

RESULTS AND DISCUSSION

Equivalence of Starting Materials

- Various lots were used (up to 50 for some products).
- Equivalence of starting materials, process signatures, physicochemical properties, and biological and immunological attributes were studied over several years.

Equivalence of Structural Signatures

- A rigorous scientific approach enabled determination of equivalence for Glatopa™ and Copaxone® 20 mg.
- Active ingredient samples were demonstrated using four-point criteria framework. These criteria included equivalence of starting materials, process parameters, physicochemical properties, biological, and immunological attributes.

Equivalence of Biological and Immunological Properties

- A detailed understanding of the biological functions of GA were essential in order to demonstrate the equivalence of Glatopa and Copaxone in biological functional analyses as well as in the key aspects of Glatopa described in the literature (see Poster P647).

Four-Point Criteria for Demonstration of Equivalence of Glatopa and Copaxone 20 mg

1. Equivalence of starting materials and basic chemistry.
2. Equivalence of structural signatures for polymerization, depolymerization, and purification.
3. Equivalence of biological and immunological properties.

REFERENCES


CONCLUSIONS

- The methods and data presented here represent a small portion of the comprehensive set of physicochemical (structural and biological) functional assays that were conducted. The differences were observed in a structure function between Glatopa and Copaxone (20 mg), and numerous other (100 physicochemical and immunological measures) that were used to demonstrate equivalence of our product to the innovator drug.

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