ZYTIGA® (abiraterone acetate) and Abiraterone Acetate Authorized Generic Bioequivalence

SUMMARY

- Abiraterone acetate, distributed by Patriot Pharmaceuticals, LLC, was an authorized generic of ZYTIGA.[1]
  - In 2020, Patriot Pharmaceuticals, LLC, a subsidiary of Janssen Pharmaceuticals, discontinued abiraterone acetate 250 mg authorized generic.
  - The authorized generic was both bioequivalent and clinically equivalent to ZYTIGA; therefore, the product was substitutable. Branded ZYTIGA will continue to be distributed on behalf of Janssen Biotech, Inc. in the United States.
- The term "authorized generic" is most commonly used to describe an approved brand name drug that is marketed as a generic product without the brand name on its label.[2]
- Brand name companies (or their licensees) may market authorized generics under the company's originally approved New Drug Application (NDA).[2]
  - Patriot Pharmaceuticals, LLC did not submit an Abbreviated New Drug Application (ANDA), rather it filed under the ZYTIGA NDA as another distributor.
- As the authorized generic of ZYTIGA, bioequivalence testing and rating was not required by the Food and Drug Administration (FDA) for abiraterone acetate distributed by Patriot Pharmaceuticals, LLC.
- Since authorized generics are marketed under the brand name's NDA, they are not listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book). However, an authorized generic is considered to be therapeutically equivalent to its brand-name drug because it is the same drug.[2]

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) was conducted on 19 October 2022. The summary in this response pertains to the authorized generic and excludes bioequivalence data from other generic formulations of abiraterone acetate.

REFERENCES

1. ZYTIGA (abiraterone acetate) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ZYTIGA-pi.pdf.
2. *FDA list of authorized generic drugs*. U.S. Food and Drug Administration; July 1, 2022. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm126389.htm. Accessed July 8, 2022.