CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210308Orig1s000

NON-CLINICAL REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PHARMACOLOGY/TOXICOLOGY NDA SUPPLEMENT REVIEW AND EVALUATION

Application number:	210308
Supporting document/s:	717
eCTD Sequence No.:	0000
Applicant's letter date:	5/19/2017
CDER stamp date:	5/19/2017
Product:	**Yonsa™ Abiraterone Acetate Tablets, 125 mg**
Indication:	In combination with methylprednisone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC)
Applicant:	Churchill Pharma; King of Prussia, PA
Review Division:	DHOT (DOP1)
Reviewer:	Kimberly Ringgold, PhD
Team Leader:	Tiffany Ricks, PhD (acting)
Division Director:	John Leighton, PhD, DABT (DHOT) Julia Beaver, MD (DOP1, acting)
Project Manager:	Kim Robertson

Yonsa™ (abiraterone acetate) is CYP17 inhibitor indicated for use in combination with methylprednisone for the treatment of patients with metastatic castration-resistant prostate cancer. This 505(b)(2) application was submitted on May 19, 2017 and relied on the Agency's previous findings of safety and effectiveness for the reference listed drug (RLD), Zytiga® 250 mg tablets for oral administration, as reflected in US FDA-approved labeling, for which Churchill Pharma does not own or have right of reference. As such, no new nonclinical studies were submitted to this supplement.

PPLR Changes to Label

Changes to most nonclinical sections in the label were made based on the recent updates to the Zytiga approved label where changes complied with the final rule on PLLR content and formatting (79 FR 72064) and recent practices. In sections 8.3 Females and Males of Reproductive Potential and 17 Patient Counseling Information, a recommendation was included to use effective contraception during treatment and for 3 weeks following the last dose of Yonsa™. This recommendation is based on the hypothetical risk of teratogenicity because of the presence of a pharmaceutical in the seminal fluid. The current approach in DHOT for drugs that are teratogenic or cause embryo-fetal death and are not genotoxic, like abiraterone, is 5 half-lives plus 3 weeks, to account for the residence time of unejaculated sperm. The half-life of abiraterone in humans is ~ 12 hours; therefore, 3 weeks is sufficient.

Recommendation:

There are no nonclinical issues to preclude the approval of this 505(b)(2) NDA application.

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/s/

KIMBERLY R RINGGOLD
03/19/2018

TIFFANY RICKS
03/19/2018