

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

209347Orig1s000

**CLINICAL PHARMACOLOGY AND
BIOPHARMACEUTICS REVIEW(S)**

NDA	209347
Submission Type	505(b)(2)
Submission Date	04/19/2016
Generic Name	Ganciclovir Injection
Brand Name	(b) (4)
Indication	Treatment of cytomegalovirus (CMV) retinitis in immunocompromised adult patients, including patients with AIDS. Prevention of CMV disease in adult transplant recipients at risk for CMV disease.
Dosage Form/ Strength	500 mg/ 250 mL
Applicant	Exela Pharma Sciences
Review Team	Islam R. Younis, Ph.D.

Background

This 505(b)(2) application is based on a request to waive the requirement for in vivo relative bioavailability study. Per applicant, the proposed drug product (Ganciclovir Injection) has the same active ingredient, route of administration, and indications as CYTOVENE®-IV (ganciclovir sodium for injection). The applicant did not submit any new clinical or clinical pharmacology data in support of Ganciclovir Injection citing that the changes in the proposed product do not affect the safety or efficacy of the drug product which is supported by CMC data.

Recommendations

The application is recommended for approval from clinical pharmacology perspective.

Labeling Recommendations

The applicant was requested to submit the labeling in PLR format and editorial changes were made to the proposed labeling to make it complaint with current good labeling practices. The below table lists labeling changes made to clinical recommendations related to drug-drug interactions in Section 7. These clinical recommendations are similar to those in valganciclovir labeling.

Name of the Concomitant Drug	Applicant Initial Proposal	FDA Proposal
Didanosine	(b) (4)	Patients should be closely monitored for didanosine toxicity.
Zidovudine	(b) (4)	Dose reduction or interruption may be needed because both zidovudine and ganciclovir have the potential to cause neutropenia and anemia. Monitor with frequent tests of white blood cell counts with differential and hemoglobin levels.
Probenecid	(b) (4)	Ganciclovir dose may need to be reduced. Monitor for evidence of ganciclovir toxicity.
Imipenem-cilastatin	(b) (4)	Coadministration with imipenem-cilastatin is not recommended because generalized seizures have been reported in patients who received ganciclovir and imipenem-cilastatin.
Cyclosporine or	(b) (4)	Monitor renal function when GANCICLOVIR

amphotericin B	(b) (4)	INJECTION is co-administered with cyclosporine or amphotericin B because of potential increase in serum creatinine [see <i>Warnings and Precautions</i> (5.2)].

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/s/

ISLAM R YOUNIS
01/13/2017