NAVINTA LLC

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August 28, 2013

2013 AUG 29 A 10: 35

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: ANDA Suitability Petition – Ganciclovir Injection, 500 mg/10 ml (50mg/mL)

Dear Food and Drug Administration:

Please find enclosed herewith a Suitability Petition request for Ganciclovir Injection, 500 mg/10 ml (50mg/mL) (in duplicate). Please do not hesitate to contact me if you have any question or need any more information.

Yours sincerely

M. Patel.

Dr. Mahendra Patel Ph.D.
Chief Executive Officer
Navinta LLC

FDA-2013-P-1061

2013-7259
CP

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Re: ANDA Suitability Petition – Ganciclovir Injection, 500 mg/10 ml (50mg/mL)

Dear Food and Drug Administration:

The undersigned submits this petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FDC Act), and in accordance with 21 C.F.R. § 314.93 and § 10.30, requesting the Food and Drug Administration (FDA) to find that the proposed drug product Ganciclovir Injection, 500 mg/10 ml (50mg/mL), solution, is suitable for consideration in an abbreviated new drug application (ANDA).

A. ACTION REQUESTED

This petition seeks to change in dosage form from the reference listed drug (RLD) from lyophilized powder to solution. We request that FDA find the Ganciclovir Injection, 500 mg/10 ml (50mg/mL) Solution, is suitable for submission as an ANDA. The reference listed drug (RLD) upon which this petition is based is Cytovene® (ganciclovir sodium for injection, 500 mg/vial, in lyophilized powder form). The NDA N019661 for Cytovene®, held by Roche was approved on June 23, 1989 (listing from the current electronic Orange Book) and there are no patents nor exclusivities remain for this product.

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B. STATEMENT OF GROUNDS

Under Section 505(j)(2)(C) of the FDC Act, a petition may be filed with the agency, seeking permission to file an ANDA for a new drug that differs from a "listed" drug in dosage form. The FDC Act provides that such a petition shall be approved by the agency, unless the agency finds that investigations are needed to demonstrate the safety and effectiveness of the proposed drug product. For the reasons discussed below, FDA should approve this ANDA suitability petition, as investigations will not be needed to demonstrate the safety and effectiveness of the proposed drug product.

1. In General

The Reference Listed Drug (RLD) in Orange Book, Cytovene®, is a lyophilized powder containing 500 mg of ganciclovir sodium (expressed as ganciclovir) in a 10-cc sterile, single-use vial. The proposed drug product Ganciclovir Injection, 500 mg/10 ml (50mg/mL) would be a ready-to-use (RTU) aqueous injectable dosage form, at a concentration of 50 mg/mL ganciclovir, containing a total of drug content of 500 mg per vial (10 ml/vial). The proposed drug would offer convenience for practitioners by avoiding the reconstitution step when preparing the drug for administration.

As required by 21 C.F.R § 314.93(d)(1) and (2), the active ingredient of the proposed drug product is of the same pharmacological and therapeutic class as that of RLD, and the proposed drug product can be expected to have the same therapeutic effect as the RLD when administered to patients for each condition of use in the RLD's labeling.

Specifically, the proposed drug product would use the same active ingredient at the same concentration as that of the reconstituted RLD, and would be intended for administration by

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intravenous infusion, same as the reconstituted RLD. There are no inactive ingredients in the RLD as well as the proposed drug product.

Upon reconstitution with 10 mL of Sterile Water for Injection, USP, the lyophilized RLD product, Cytovene®, yields a solution with pH 11 and a ganciclovir concentration of approximately 50 mg/mL. The composition of the proposed ready-to-use (RTU) ganciclovir sodium injection, 500 mg/10 mL, has ganciclovir concentration of approximately 50 mg/mL and is at pH 11.

Thus, the proposed RTU solution product is identical in Q1/Q2 to the existing lyophilized product (upon reconstitution).

The proposed changes in the labeling would be limited to the change in the dosage form and the directions for use. The reconstitution step would be omitted. The uses, indications, warnings, precautions, and directions for use after reconstitution would remain the same as that of the RLD, Cytovene®.

There are examples of conversion of dosage forms from lyophilized product to ready-to-use solution products through an ANDA route in the past by the FDA (approved suitability petitions). One such example is:

1) Paraplatin® (carboplatin for injection), 50 mg/vial, 150 mg/vial, and 450 mg/vial, in lyophilized form to carboplatin injection, 10 mg/mL, 5 mL, 15 mL, and 45 mL (Docket number: 01P-0036/CP1).

If this suitability petition is approved, the ANDA for the proposed drug product would establish that the proposed product is bioequivalent to the RLD, or be eligible for a waiver of the in vivo bioequivalency, in accordance with 21 C.F.R. Part 320 and FDA's usual policies.

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C. **Pediatric Use Information**

As the package insert of Cytovene® 500 mg contains adequate dosing and administration information for the pediatric population, no additional pediatric studies are required as a result of this suitability petition.

D. **Environmental Impact**

An environmental assessment report on the action requested in this petition is not required under 21 CFR § 25.31

E. **Economic Impact**

The petitioner does not believe that this is applicable in this case, but will agree to provide such analysis if requested by the agency.

F. **Certification**

The under signed certifies that to the best of his knowledge, the petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Yours sincerely

M.R.Patel

Dr. Mahendra Patel,
Chief Executive Officer
Navinta LLC

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DR. MAHENDRA PATEL
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