U.S. FOOD & DRUG ADMINISTRATION

NDA 220258

**TENTATIVE APPROVAL**

Azurity Pharmaceuticals, Inc.
Attention: Mahesh Vangara
Senior Manager- Regulatory Affairs
8 Cabot Road
Suite 2000
Woburn, MA 01801

Dear Mahesh Vangara:

Please refer to your new drug application (NDA) dated December 27, 2024, received December 27, 2024, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for RESNIBEN (cabozantinib) tablets.

This NDA proposes the use of RESNIBEN (cabozantinib) tablets for:

(b) (4)

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105(a); therefore, this application is not approved and will not be approved until the FDA issues an approval letter after any necessary additional review of the application. Enclosed are the tentatively approved labeling (text for the Prescribing Information, Patient Package Insert, and carton and container labeling). This tentative approval determination is based upon information available to the FDA at this time, (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

Final approval of your application is subject to expiration of the 30-month period provided for in section 505(c)(3)(C) of the FD&C Act, and subject to expiration of a period of patent protection and/or exclusivity. Therefore, final approval of your application may not be granted at this time.

A listed drug(s) upon which your application relies is subject to a period of patent protection, and your application contains a certification(s) to one or more patents under

section 505(b)(2)(A)(iv) of the FD&C Act stating that the patent(s) is/are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("paragraph IV certification").

Section 505(c)(3)(C) of the FD&C Act provides that approval of a new drug application submitted pursuant to section 505(b)(2) of the FD&C Act that includes a paragraph IV certification shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of a paragraph IV certification. If such a patent infringement action is brought prior to the expiration of 45 days from the later of the date the notice provided under section 505(b)(3) is received by the patent owner or approved application holder, then your application would be subject to a 30-month stay of approval, unless other conditions are met. You notified us that you complied with the requirements of section 505(b)(3) of the FD&C Act.

In addition, you have notified the FDA that the patent owner and/or approved application holder has initiated a patent infringement suit against you with respect to U.S. Patents 8,877,776; 11,091,439; 11,091,440; 11,098,015; 11,298,349; and 12,128,039 in the United States District Court for the District of Delaware (1:25-cv-00478-UNA). With respect to the patent infringement suit, final approval cannot be granted until:

1)
   - Expiration of the 30-month period provided for in section 505(c)(3)(C) beginning on the later of the date of receipt by any owner of the listed patent or application holder of the notice required under section 505(b)(3), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or
   - The date the court decides that the patent(s) is/are invalid or not infringed as described in section 505(c)(3)(C)(i), (ii), (iii), or (iv) of the FD&C Act, or,
   - The date the court disposes of the patent litigation as described in 21 CFR 314.107(b)(3)(viii),
   - The listed patent(s) has/have expired, and
2) We are assured there is no new information that would affect whether final approval should be granted.

To obtain final approval of this application, submit an amendment two or six months prior to the date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If

there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not approved and cannot be legally marketed, and the use of the enclosed tentatively approved labeling is not permitted for marketing this drug product. If you believe that there are grounds for issuing the final approval letter before the expiration of the patent(s) and/or exclusivity protection, you should amend your application accordingly.

If you have any questions, contact Kim J. Robertson, Senior Regulatory Health Project Manager, at (301) 796-1441, or kim.robertson@fda.hhs.gov.

Sincerely,

*{See appended electronic signature page}*

Christy Osgood, MD
Supervisory Associate Director
Division of Oncology 1
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURES: (tentatively approved)

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/
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CHRISTY L OSGOOD
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