BLA 761363/S-010

SUPPLEMENT APPROVAL

Merck Sharp and Dohme LLC
Attention: Dr. Elizabeth Shang
Director, Global Regulatory Affairs
1700 Rockville Pike
Suite 252
Rockville, MD 20852

Dear Dr. Shang:

Please refer to your supplemental biologics license application (sBLA) received September 23, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for Winrevair (sotatercept-csrk) for injection.

This Prior Approval sBLA provides for an update to the approved labeling to include the term “pericardial effusion” to the Adverse Reactions (6.2) section.

APPROVAL

We have completed our review of this sBLA, as amended. This supplement is approved.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,[1] that is identical to the enclosed labeling (text for the Prescribing Information,) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements.

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

ENHANCED PHARMACOVIGILANCE

We request you conduct enhanced pharmacovigilance for 3 years from the date of this letter, to monitor for new onset or worsening pericardial effusion. We request that you provide a narrative summary including analysis of all cases that indicate new onset or worsening pericardial effusion in your periodic safety reports [e.g., periodic adverse drug experience report (PADER) as required under 21 CFR 600.80(c)(2)], quarterly through March 25, 2027, and annually thereafter through March 29, 2029.The evaluation should give particular attention to serious cases requiring medical intervention or those associated with cardiac decompensation. Your summary analyses should include interval and cumulative data from clinical trials, postmarketing reports, and the published literature, relative to the date of approval of Winrevair. Furthermore, your evaluation should include a detailed causality assessment, analyzing factors such as the temporal association between drug exposure and the event, duration of therapy, associated signs and symptoms, relevant laboratory values, diagnostic test results (e.g., echocardiogram, pericardial fluid analysis and/or pericardial pathology reports if applicable), concomitant medications (e.g., antithrombotic agents, prostacyclin analogs), potential confounders, underlying patient risk factors, treatment given for the event, event outcome, and dechallenge/rechallenge.

If you have any questions, contact Lori Anne Wachter, RN, BSN, RAC – Drugs (US), Regulatory Project Manager for Safety, at 301 796-3975 or lori.wachter@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Selena DeConti, PharmD, MPH
Deputy Director for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hematology, Endocrinology and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information

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.

/s/

SELENA D DECONTI
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