# Cross-Discipline Team Leader (CDTL) Review

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| Date | 3/11/25 |
| From | Theodore Carver, Ph.D.<br>Senior Pharmaceutical Quality Assessor<br>CDER/OPQ/OPQA1/DPQAII |
| Through | Mary Ross Southworth, PharmD.<br>Deputy Division Director for Safety<br>Division of Cardiology and Nephrology<br>CDER/OND/OCHEN/DCN |
| Submission Type/Number | NDA 218772 Resubmission, SD 24 |
| Type of Application | 505(b)(2) |
| Applicant | Scienture, Inc. |
| Date of Receipt | September 17, 2024 |
| PDUFA Goal Date | March 17, 2025 |
| Established/Proper Name | Losartan Potassium |
| Strength | 10 mg/mL |
| Route of Administration | oral |
| Proposed Indication(s) | • Treatment of hypertension, to lower blood pressure in adults and children greater than 6 years old. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.<br>• Reduction of the risk of stroke in patients with hypertension and left ventricular hypertrophy. There is evidence that this benefit does not apply to Black patients.<br>• Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes and a history of hypertension. |
| Regulatory Action | Approval |

This CDTL review is based on the primary reviews, memos, and documented review input, as listed below:

| Material Reviewed/Consulted | Review Team |
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| Integrated Quality Review, Office of Pharmaceutical Quality (OPQ); DARRTS, | Ali Mohamadi, Theodore Carver, Upasana Sahu, Sateesh Kumar Sathigari |

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| dated 3/7/2025. | |
| Pharmacology/Toxicology NDA Review and Evaluation Memorandum, Division of Pharm/Tox for Cardiology, Hematology, Endocrinology, and Nephrology (DPT-CHEN); DARRTS, dated 2/5/2025. | Narendranath Reddy Chintagari and Sree Rayavarapu |
| Label and Labeling Reviews, Division of Medication Error Prevention and Analysis 2 (DMEPA 2); DARRTS, dated 2/18/2025 and 3/3/2025. | Julie Neshiewat and Nicole Iverson |
| Memorandum with labeling comments, Office of Prescription Drug Promotion (OPDP), Office of Medical Policy; DARRTS, dated 2/7/2025. | Meena Savani and Sapna Shah |
| Memorandum to File, Postmarketing Requirement, Division of Cardiology and Nephrology (DCN); DARRTS, dated 2/10/2025. | Soukehal Sabry |

1. Background

The Applicant, Scienture, Inc., has submitted New Drug Application (NDA) 218772 for marketing approval of Losartan Potassium Oral Suspension, 10 mg/mL, according to Section 505(b)(2) of the Federal, Food, Drug, and Cosmetic Act. NDA 218772 makes reference to the Listed Drug COZAAR® (losartan potassium) tablets, 100 mg, for which the applicant is Organon, LLC and which was approved under NDA 20386. The Applicant proposes the same dose and dosing regimen for the oral suspension of losartan as approved for COZAAR. A Complete Response was issued by FDA for this NDA on August 19, 2024 due to product quality deficiencies identified for the assays and stability studies submitted in the original NDA. The NDA resubmission was reviewed with respect to resolution of product quality deficiencies and the product labeling.

2. Product Quality

Review of response to product quality deficiencies.

The drug product is a white, translucent suspension with a peppermint odor that is filled into 6 oz. white high-density polyethylene (HDPE) bottles and packaged in cartons. (b) (4) The original NDA review identified deficiencies in the information provided for the particle size and content assay methods and inadequate investigations of OOS and OOT results during stability studies, including a failure to adequately follow up on results of investigations documented in reports. The Applicant provided additional information in the resubmission that was deemed adequate to address the product quality deficiencies. In addition, the method for measuring particle size was verified by FDA. The NDA remains adequate with

respect to all other OPQ review disciplines. A shelf life of 18 months is granted for the drug product when stored at 20ºC to 25ºC. See also the Integrated Quality Assessment dated August 8, 2024.

Quality Labeling

The quality aspects of the product labeling were reviewed and found to be adequate after Applicant's revisions.

3. Non-Clinical Pharmacology/Toxicology

The Nonclinical review team reviewed the information provided in the resubmission concerning the (b) (4) and concluded that there are no expected safety concerns.

4. Clinical Pharmacology

See previous Division Director/ CDTL review dated August 14, 2024.

5. Statistical-Evaluation

See previous Division Director/ CDTL review dated August 14, 2024.

6. Clinical Studies/Financial Certification Disclosure

See previous Division Director/ CDTL review dated August 14, 2024.

7. Advisory Committee Meeting

N/A.

8. Pediatrics, and Other Relevant Regulatory Issues

The Applicant agreed to a postmarketing requirement to conduct a safety and pharmacokinetic study in pediatric patients two to less than six years of age. See also previous Division Director/ CDTL review dated August 14, 2024.

9. Labeling

The labeling reviews from DMEPA and OPDP concluded that all recommended changes have been implemented and there are no outstanding deficiencies.

10. Recommended Regulatory Action

NDA 218772 is recommended for approval, because all deficiencies identified during review of the original NDA have been addressed. I agree with this assessment and recommend approval of this NDA.

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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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