

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### ***APPLICATION NUMBER:***

**211284Orig1s000**

***Trade Name:*** Temixys Tablets, 300 mg / 300 mg

***Generic or Established:*** Lamivudine and tenofovir disoproxil fumarate

***Sponsor:*** ELC Group s.r.o.

***Approval Date:*** November 16, 2018

***Indication:*** For the use of TEMIXYSTM (lamivudine and tenofovir disoproxil fumarate) tablets, 300 mg/300 mg in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg.

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## 211284Orig1s000

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*APPLICATION NUMBER:*

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**APPROVAL LETTER**



NDA 211284

**NDA APPROVAL**

ELC Group s.r.o.  
U.S. Agent for Celltrion Inc., Korea  
Attention: Jinny Han, Project Manager, Regulatory Affairs  
1500 Market Street  
12<sup>th</sup> Floor, East Tower  
Philadelphia, PA 19102

Dear Ms. Han:

Please refer to your New Drug Application (NDA) dated January 15, 2018, received January 16, 2018 and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TEMIXYS<sup>TM</sup> (lamivudine and tenofovir disoproxil fumarate) tablets, 300 mg/300 mg.

This new drug application provides for the use of TEMIXYS<sup>TM</sup> (lamivudine and tenofovir disoproxil fumarate) tablets, 300 mg/300 mg in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg.

### **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 text. Based on the data provided, the expiration dating period is 24 months for TEMIXYS<sup>TM</sup> (lamivudine and tenofovir disoproxil fumarate) tablets, 300 mg/300 mg in bottles when stored below 30°C (86°F).

In addition to the bottles containing 30 tablets, this application provides for bottles containing 60 and 100 tablets for PEPFAR (President's Emergency Plan for AIDS Relief) use.

### **WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS**

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of

labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert) as well as annual reportable changes not included in the enclosed labeling. 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*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible via publicly available labeling repositories.

### **CONTAINER LABELING**

Submit final printed container labeling that is identical to the enclosed container labeling submitted on October 22, 2018 as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2018, Revision 5)*. For administrative purposes, designate this submission “**Final Printed Container Labeling for approved NDA 211284.**” Approval of this submission by FDA is not required before the labeling is used.

### **MARKET PACKAGE**

Please submit one market package of the drug product when it is available to the following address:

Kyong Hyon  
Food and Drug Administration  
Center for Drug Evaluation and Research  
White Oak Building 22, Room: 6134  
10903 New Hampshire Avenue  
Silver Spring, Maryland  
*Use zip code **20903** if shipping via United States Postal Service (USPS).*  
*Use zip code **20993** if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for patients less than 35 kg because the product

does not represent a meaningful therapeutic benefit over existing therapies.

### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the Prescribing Information, Medication Guide, and Patient Package Insert (as applicable) to:

OPDP Regulatory Project Manager  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf> ).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kyong Hyon, Safety Regulatory Project Manager, at 301-796-0734.

Sincerely,

*{See appended electronic signature page}*

Jeffrey Murray, M.D., M.P.H.  
Deputy Director  
Division of Antiviral Products

Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling  
Prescribing Information  
Patient Package Insert  
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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JEFFREY S MURRAY  
11/16/2018

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