PUMCH Approval Number: KS2021303

Ethics Committee Approval for Expedited Review from the Drug Clinical Trial Ethics Committee of Peking Union Medical College Hospital, Chinese Academy of Medical Sciences

Project Number: 002401

Drug/Medical Device Name	REGEND001 Autologous Therapy Product	Registration Category	Biological Products Class 1
Applicant	Regend Therapeutics XLotus (Jiangxi) Co, Ltd.	Task Source	NMPA
Professional Group	Department of Respiratory Medicine	Application Matter	Domestic Drug Registration
Approval Number	CXSL1900019	Principal Investigator	Zuojun Xu
Chairperson	Liying Cui	Vice Chairpersons	Xiaomei Zhai, Hua Bai
Protocol Title	Protocol for An Open-Label Clinical Study to Explore the Safety, Tolerability, and Preliminary Efficacy of REGEND001 Autologous Therapy Product for Treatment of Idiopathic Pulmonary Fibrosis (IPF)		
Protocol Number	XHYX-IND-IPF-P1		

This research project was approved by the Drug Clinical Trial Ethics Committee of Peking Union Medical College Hospital, Chinese Academy of Medical Sciences on January 28, 2021. Approval number: KS2021039. Approval Comment: Approved.

Review Comment:

☑ Approved ☐ Requires Committee Review ☐ Disapproved

Frequency of Follow-Up Review:

☑ 3 months ☐ 6 months ☐ 1 year ☐ None ☐ Other

Signature of the Chairperson/Vice Chairperson of the Ethics Committee: Liying Cui

Date: 2021-06-07

*The materials for this approval are attached.

Attachment:

1. Protocol (Version No.: 4.0; Version Date: May 18, 2021)
2. Informed Consent Form (Version No.: 2.0; Version Date: May 19, 2021)
3. Recruitment Advertisement (Version No.: 2.0; Version Date: May 19, 2021)
4. eCRF (Version No.: 1.0; Version Date: April 30, 2021)
5. eCRF (Version No.: 1.1; Version Date: May 27, 2021)
6. Document Amendment Instructions (Protocol, Informed Consent, Recruitment Advertisement, eCRF)
7. Interim Diagnosis Form (Version No.: A/0)
8. Subject Inclusion/Exclusion Criteria Determination Form (Version No.: A/0)
9. 6-Minute Walking Distance Test Record Form (Version No.: A/0)
10. Medical Research Council Dyspnea Scale (Version No.: A/0)
11. Saint George's Respiratory Questionnaire (Version No.: A/0)
12. Bronchial Basal Cell Collection Record Form (Version No.: A/0)
13. Bronchial Basal Cell Transportation Receipt Form (Version No.: A/0)
14. Cell Preparation Distribution Application Form (Version No.: A/0)
15. Cell Preparation Transportation Receipt Form (Version No.: A/0)
16. Cell Preparation Infusion Record Form (Version No.: A/0)
17. Cell Preparation Return Registration Form (Version No.: A/0)
18. Document Amendment Instructions (Procedural Forms)

1. This Ethics Committee is independent and complies with ICH GCP, China GCP, and relevant local regulations. All attending members are within their valid term of office.

2. This Ethics Committee will keep the clinical research materials and related content confidential. Additionally, there is no conflict of interest with this research project.

3. The approval is valid for one year. Please report the clinical trial status in a timely manner according to the corresponding follow-up review frequency.

4. Address of the Ethics Committee: 41 Damucang Hutong, Xicheng District, Beijing. Contact person: Jiali Tian, Phone number: 010-6915839

Drug Clinical Trial Ethics Committee of Peking Union Medical College Hospital, Chinese Academy of Medical Sciences