



Government of India  
Central Drugs Standard Control Organisation (Headquarter)  
(Directorate General of Health Services)  
FDA Bhavan, ITO, Kotla Road  
New Delhi - 110002 (Delhi)  
Phone No.: 91-11-23216367  
Fax No.: 91-11-23236973  
E-Mail: dci@nic.in

File No. BIO/CT/21/000067

Dated 23.05.2022

To,  
M/s Synchron Research Services Pvt. Ltd.,  
Synchron House B/H Mondeal Park,  
Nr. Gurudwara Ahmedabad – 380059,  
Gujarat, India

Subject: Application for grant of permission to conduct Phase I (pivotal single dose PK/PD and immunogenicity study) clinical trial entitled – “A randomized, double blind, three-arm, parallel group, single dose comparative PK, PD, safety and immunogenicity study comparing ADL-018 with US-licensed Xolair and EU-approved Xolair administered through subcutaneous route in healthy adult subjects” as per Protocol No.: OMA/2019/1692, Version 5.0 Date: 26.03.2022- regarding

Ref.: Your Application No. BIO/CT04/FF/2021/25522 dated 06-May-2021

Sir,

With reference to your Application No.: BIO/CT04/FF/2021/25522 dated 06-May-2021, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

- i. Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licensing Authority under rule 8;
- ii. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall

be located within the same city or within a radius of 50 kms of the clinical trial site;

- iii. In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;
- iv. The Central Licensing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;
- v. Clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;
- vi. Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;
- vii. Status of enrolment of the trial subjects shall be submitted to the Central Licensing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
- viii. Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority electronically in the SUGAM portal;
- ix. In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing Authority within thirty working days of such termination;
- x. Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licensing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI;
- xi. In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing Authority in accordance with the provisions of the said Chapter;
- xii. In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing Authority in accordance with the provisions of the said Chapter;
- xiii. The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorised by the Central Licensing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to

inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;

- xiv. Where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licensing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;
- xv. The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;
- xvi. The Central Licensing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;
- xvii. The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- xviii. For subject cited clinical trial, firm shall constitute an independent DSMB for trial monitoring and submit the DSMB constitution details to this office before initiating the said trial.
- xix. Any major change made in the protocol shall be duly notified and got approved from this office before implementation.

Yours faithfully,

**VENUGOPAL G SOMANI**  
(Dy. G. Somani)  
Drugs Controller General (India)  
Central Licensing Authority

Digitally signed by VENUGOPAL G SOMANI  
DN: c=IN, o=CENTRAL DRUGS STANDARD  
CONTROL ORGANIZATION, ou=DRUGS  
CONTROLLER GENERAL (INDIA),  
\*pseudonym=112046a34e2177bacb25574  
8732c456d249073a55e952d9cb5b58748e  
63102, postalCode=110002, st=DELHI,  
serialNumber=e97f241aa0c0bba41522525  
44400000000000000000000000000000  
eaf5d, cn=VENUGOPAL G SOMANI  
Date: 2022.05.23 15:37:24 +05'30'

## FORM CT-06

(See rules 22, 25, 26, 29 and 30)

### PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits **M/s Synchron Research Services Pvt. Ltd.**, Synchron House, Behind Mondeal Park, Near Gurudwara, S.G. Highway, Ahmedabad –380059, Gujarat, India, to conduct clinical trial of the new drug or investigational new drug study titled “A randomized, double blind, three-arm, parallel group, single dose comparative PK, PD, safety and immunogenicity study comparing ADL-018 with US-licensed Xolair and EU-approved Xolair administered through subcutaneous route in healthy adult subjects” as per Protocol No.: OMA/2019/1692, Version 5.0 Date: 26.03.2022 in the below mentioned clinical trial sites.

2. Details of new drug and clinical trial site [as per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi

Date: 23.05.2022

**VENUGOPAL G SOMANI**

Digitally signed by VENUGOPAL G SOMANI  
DN: c=IN, o=CENTRAL DRUGS STANDARD  
CONTROL ORGANIZATION, ou=DRUGS  
CONTROLLING GENERAL (India),  
pseudonym=112046a34e21727bacb2557  
af75c2b0a0e349c3195b58748  
ee3113c, postalCode=110002, st=DELHI,  
serialNumber=747143411522525  
ffca0705074b4997e6b2f4b5c8d81cf282ad  
eaf5d, cn=VENUGOPAL G SOMANI  
Date: 2022.05.23 15:37:36 +05'30'

**Annexure:****Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug	Omalizumab (r-DNA origin) injection 150 mg/ml														
Therapeutic class	Monoclonal antibodies														
Dosage form:	Subcutaneous injection (1 mL of PFS) (single-dose prefilled syringe)														
Composition:	<table border="1"> <thead> <tr> <th>Name of Ingredient</th><th>Quantity/ mL</th></tr> </thead> <tbody> <tr> <td>Omalizumab (r-DNA Origin) (ADL-018)... In-house</td><td>150 mg/mL</td></tr> <tr> <td>Sodium phosphate monobasic monohydrate.... USP</td><td>2.07 mg/mL</td></tr> <tr> <td>Sodium phosphate dibasic heptahydrate...USP</td><td>1.34 mg/mL</td></tr> <tr> <td>L-Arginine Hydrochloride... FCC (Food Chemicals Codex)</td><td>42.13 mg/mL</td></tr> <tr> <td>Poloxamer 188 (w/v).....NF</td><td>0.4 mg/mL</td></tr> <tr> <td>Water for injection....in-house</td><td>q.s to 1.0 mL</td></tr> </tbody> </table>	Name of Ingredient	Quantity/ mL	Omalizumab (r-DNA Origin) (ADL-018)... In-house	150 mg/mL	Sodium phosphate monobasic monohydrate.... USP	2.07 mg/mL	Sodium phosphate dibasic heptahydrate...USP	1.34 mg/mL	L-Arginine Hydrochloride... FCC (Food Chemicals Codex)	42.13 mg/mL	Poloxamer 188 (w/v).....NF	0.4 mg/mL	Water for injection....in-house	q.s to 1.0 mL
Name of Ingredient	Quantity/ mL														
Omalizumab (r-DNA Origin) (ADL-018)... In-house	150 mg/mL														
Sodium phosphate monobasic monohydrate.... USP	2.07 mg/mL														
Sodium phosphate dibasic heptahydrate...USP	1.34 mg/mL														
L-Arginine Hydrochloride... FCC (Food Chemicals Codex)	42.13 mg/mL														
Poloxamer 188 (w/v).....NF	0.4 mg/mL														
Water for injection....in-house	q.s to 1.0 mL														
Indications:	<p>Moderate to severe persistent asthma in adults and pediatric patients of 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.</p> <p>Nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as an add-on maintenance treatment.</p> <p>Chronic idiopathic urticaria in adults and adolescents 12 years of age and older with who remain symptomatic despite H1 antihistamine treatment.</p>														

**Details of clinical trial site:**

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	Synchron Research Services Pvt. Ltd., 1 <sup>st</sup> and 2 <sup>nd</sup> Floor, Swagat Plaza II, Iscon-Bopal Road, Ambli, Ahmedabad-380056, Gujarat, India Telephone: +91-2717	Sangini Hospital Ethics Committee C/o Sangini Hospital, 1 <sup>st</sup> Floor, Santorini Square, B/h Abhishree Complex, Opp. Star Bazar, Nr. Jodhpur Cross Roads, Satellite, Ahmedabad-380015, Gujarat, India Telephone: 07940056171	Dr. Rajesh Bhayani

	-235282, 235283 Fax: +91-2717- 230919	<u>EC Reg. No.</u> ECR/147/Inst/GJ/2013/RR-19	
--	---	--	--

