



सत्यमेव जयते

**GOVERNMENT OF INDIA**  
**CENTRAL DRUGS STANDARD CONTROL**  
**ORGANISATION (Headquarter)**  
(Directorate General of Health Services)  
Ministry of Health & Family Welfare  
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. CT/19/000071**

To,

M/s. Novartis Healthcare Private Limited,  
Inspire BKC, Part of 601 & 701, Bandra Kurla Complex,  
Bandra (East), Mumbai (India) – 400051, Maharashtra.

Sir,

With reference to your application No GCT/CT04/FF/2019/16086 (GCT/69/19) dated 09-08-2019, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A multicenter, randomized, double-blind, placebo-controlled phase 2b dose-finding study to investigate the efficacy and safety of ligelizumab (QGE031) in adolescent patients with Chronic Spontaneous Urticaria (CSU)” Protocol number CQGE031C2202 Version No. 00 (Original Protocol) dated 18/January/2018** under the provisions of New Drugs and Clinical Trial Rules, 2019

The permission granted by the Central Licensing Authority to conduct clinical trial 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 Licencing 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 Licencing 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;

**File No. CT/69/19-DCG(I)**

- (vii) status of enrolment of the trial subjects shall be submitted to the Central Licencing 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 Licencing 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 Licencing 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 Licencing 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 Licencing Authority within thirty working days of the receipt of order issued by Central Licencing 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 Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing 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 Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing 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 Licencing 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
- (xvi) the Central Licencing 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) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

(Dr. V. G. Somani)  
Drugs Controller General (India)  
Central Licencing Authority  
Stamp

## FORM CT-06

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

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

1. The Central Licensing Authority hereby permits **M/s. Novartis Healthcare Private Limited, Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai (India) – 400051** to conduct clinical trial of the new drug or investigational new drug as per **Protocol number CQGE031C2202 Version No. 00 (Original Protocol) dated 18/January/2018** in the below mentioned clinical trial sites [As per Annexure].-

2. Details of new drug or investigational 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 ct, 1940.

Place: New Delhi

Date \_\_\_\_\_

(Dr. V. G. Somani)  
Drugs Controller General (India)  
Central Licensing Authority  
Stamp

**Note:** The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

**Annexure:**

Details of new drug or investigational new drug:

<b>Names of the new drug or investigational new drug</b>	QGE031 (Ligelizumab)			
<b>Therapeutic class:</b>	Monoclonal Antibody			
<b>Dosage form:</b>	Solution for Injection			
<b>Composition:</b>	<b>Ingredient</b>	<b>Theoretical Amount per vial (mg)<sup>1)</sup></b>	<b>Function</b>	<b>Reference to standards</b>
	QGE031 drug substance	120.0 mg	Drug substance	Novartis monograph
	L-Histidine	0.282 mg <sup>2)</sup>	Buffering agent	Ph. Eur., USP/NF
	L-Histidine Hydrochloride monohydrate	3.811 mg <sup>2)</sup>	Buffering agent	Ph. Eur.

**File No. CT/69/19-DCG(I)**

	Trehalose dihydrate	94.575 mg	Stabilizer/Tonicity Adjuster	Ph. Eur., USP/NF
	Polysorbate 20	0.200 mg	Surfactant	Ph. Eur., USP/NF
	Water for injection	q.s up to 1.068g	Solvent	Ph. Eur., USP/NF
	<p>1) The overfill (20%), which allows the withdrawal of the labeled amount of the drug product from the vial, is not included in this table</p> <p>2) A define ration of L-histidine &amp; L-histidine hydrochloride monohydrate is used to target pH at 5.0</p> <p>The overall buffer concentration is at 20 mM.  q.s. = quantity sufficient  Ph. Eur: European Pharmacopeia; USP: United States Pharmacopeia;  NF: National Formulary</p>			
<b>Indications:</b>	Adolescent patients with Chronic Spontaneous Urticaria (CSU)			

<b>Names of the new drug or investigational new drug</b>	QGE031 Placebo 1ml			
<b>Therapeutic class:</b>	Placebo			
<b>Dosage form:</b>	Solution for Injection			
<b>Composition:</b>	<b>Ingredient</b>	<b>Theoretical Amount per vial (mg)<sup>1)</sup></b>	<b>Function</b>	<b>Reference to standards</b>
	L-Histidine	3.103 mg	Buffering agent	Ph. Eur./USP
	Trehalose dihydrate	102.149 mg	Tonicity	Ph. Eur./USP
	Polysorbate 20	0.200 mg	Surfactant	Ph. Eur./USP
	25 % Hydrochloric acid added as a 1N solution	up to pH 5.0	pH adjusting agent	Ph.Helv.
	Water for injection	up to 1.036g	Solvent	Ph. Eur./USP
<p>1) The 20% overfill which permits withdrawal of the labeled volume from the vial is not included in this table</p>				
<b>Indications:</b>	Not Applicable			

Details of clinical trial site:

<b>Names and address of clinical trial site</b>	<b>Ethics committee details</b>	<b>Name of investigator</b>
Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi-110060, India	Sir Ganga Ram Hospital Ethics Committee, Room No. 1496, 4 <sup>th</sup> Floor, Old Building, Old Rajinder Nagar, New Delhi-110060, India  ECR/20/Inst/DL/2013/RR-16	Dr. Rohit Batra

**File No. CT/69/19-DCG(I)**

Dept. Of Dermatology, S.P. Medical College & A.G. Hospitals, Bikaner- 334003 (Raj.), India	Ethics Committee, C/o Principal, S.P. Medical College & A.G. Hospitals, Bikaner-334003 (RAJ.), India  ECR/27/SP/Inst/RJ/2013/RR-16	Dr. Rajesh Dutt Mehta
OPD-54, 1 <sup>st</sup> Floor, Dr. D.Y. Patil Hospital and Research Centre, Sector-5, Nerul, Navi Mumbai-400706	Institutional Ethics Committee, Dr. D.Y. Patil Medical College And Research Centre, Sector-5, Nerul, Navi Mumbai, 400706  ECR/195/Inst/MH/2013/RR-16	Dr. Kiran Godse
3 <sup>rd</sup> ,Floor Clinical Research Department, Sujata Birla Hospital and Medical Research Center, Opposite to Bytco College, Nashik Pune Highway, Nashik Road, 422101, Maharashtra, India	Yash Society's Sujata Birla Hospital Ethics Committee, C/O Sujata Birla Hospital and Medical Research Centre, 1 <sup>st</sup> Floor, EC Office, Opposite to Bytco College, Nashik Pune Highway, Nashik Road, 422101, Maharashtra, India  ECR/98/Inst/MH/2013/RR-16	Dr. Suneel Chandrakant Vartak