

ND/CT/04/FF/2020/20654

Tele No.011-23236965
Fax.No.011-23236973

F. No. ND/CT20/000064
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:

5 OCT 2020

To,

M/s Sanzyme (P) Ltd.
Plot No.13, Sagar Society, Road No.2,
Banjara Hills, Hyderabad – 500034, India
Tel: 040-48589999

Subject:- Permission to conduct Phase III Clinical Trial vide Protocol No: SANZ-FSH/hCG-01, Version 1.0 dated 25 June 2020 using Study Drug: Endogen® HP, Pubergen® HP, Fostimon®, and Pregnyl®– regarding.

Sir,

With reference to your application No. ND/CT/04/FF/2020/20654 in CT04 dated 30.07.2020, please find enclosed herewith the permission in **Form CT-06, No. CT/ND/105/2020** to conduct the subject mentioned clinical trial under the provisions of **New Drugs and Clinical Trial Rules, 2019.**

This permission is subject to the conditions, as mentioned below.

Yours faithfully



(Dr. V. G. Somani)
Central Licensing Authority

Condition of permission

- (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;
- (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;
- (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 of the New Drugs and Clinical Trials Rules, 2019;
- (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 the Chapter VI of the said Rules 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 the 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 Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing 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) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.
 - (xix) Firm should include more Govt sites and the sites should be geographically distributed.**
 - (xx) Firm should ensure that FSH dose escalation criteria are clearly mentioned in the protocol.**
 - (xxi) The criteria for administration of GnRH agonist for prevention of OHSS should be clearly mentioned.**
 - (xxii) Firm should submit clear justification for sample size calculation.**
 - (xxiii) Firm should ensure that the protocol is followed uniformly by all the Investigators in all the sites.**
 - (xxiv) Accordingly, the revised protocol to be submitted to CDSCO.**

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 Licensing Authority hereby permits M/s Sanzyme (P) Ltd., Plot No.13, Sagar Society, Road No.2, Banjara Hills, Hyderabad, Telangana Hyderabad (India) – 500034, Telephone No.: 040-48589999 FAX: 040-48589999 to conduct clinical trial of the investigational new drug as per **Protocol No: SANZ-FSH/hCG-01; Version No.: 1.0; Date: 25.06.2020**.in the below mentioned clinical trials sites.

2. Details of new drug or investigational new drug and clinical trial site:-

Names of the new drug or investigational new drug:	Follicle- Stimulating Hormone (FSH) and Human Chorionic Gonadotropin (HCG)	
Therapeutic class:	Hormones and Antihormones	
Dosage form:	Injection	
Composition:	<ol style="list-style-type: none">Follicle- Stimulating Hormone (FSH) Injection 75 IU/ 2ml - Each vial / ampoule of sterile freeze dried product contains- Urofollitropin (FSH) B.P..... 75 IUChorionic Gonadotropin (HCG) for Injection USP 5000 IU/ 2ml- Each vial / ampoule of sterile freeze dried product contains- Human Chorionic Gonadotropin U.S.P.....5000 IU.	
Indications:	Product indicated for the treatment of female infertility in the following clinical situations: <ol style="list-style-type: none">Anovulation (including polycystic ovarian disease (PCOD) in women who have been unresponsive to treatment with clomiphene citrate.Controlled ovarian hyper stimulation to induce the development of multiple follicles for assisted reproductive technologies (ART) (e.g. in vitro fertilisation/ embryo transfer (IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI)).	
Details of clinical trial sites-		
Sr. No.	Name of Principal Investigator	Ethics Committee Name/ Registration Number
1.	Dr. Ratnabali Chkaravorty,	ECR/130/Inst/WB/2013/RR-19

	ILS Hospital, DD-6 Sector 1 , Salt Lake City Kolkata West Bengal - 700064	ILS Hospital Ethics Committee, ILS Hospital, Salt Lake, DD-6, 3 rd Ave, Near City Centre, Sector-1, Bidhan nagar, Kolkata, West Bengal- 700 064.
2.	Dr Hrishikesh Dattatraya Pai Lilavati Hospital and Research Center, Ethics Committee, Lilavati Hospital and Research Center, A-791, Bandra Reclamation, Bandra West, Mumbai Maharashtra - 400050	ECR/606/Inst/MH/2014/RR-17 Institutional Ethics Committee Lilavati Hospital and Research Center, Bandra West, Mumbai, Maharashtra - 400050
3.	Dr Vyshnavi Rao, Milann (A Unit of BACC Health Care Pvt. Ltd), No. 7 East Park Road, Kumara Park East, Bangalore, Karnataka - 560001	ECR/779/Inst/KA/2015 IIRRH-BACC Healthcare, Institutional Ethics Committee No. 7 East Park Road, Kumara Park East, Bangalore, Karnataka - 560001

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.

New Delhi

Date: 05 OCT 2020

(Dr. V. G. Somani)

Central Licensing Authority
Stamp

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002