



ST. THERESA'S HOSPITAL

(A Unit of St. Theresa's Convent Society

PAN : AAATS7437D)

SANATHNAGAR, HYDERABAD - 500 018.

TELANGANA, Phone : 040 - 23704411, 23701013

Date _____

Date: 20-May-2018

From,

The Member Secretary,
Ethics Committee,
St Theresa's Hospital
Hyderabad-5000 18

To,

Dr. Bharat Vaswani,
Yashoda Cancer Institute,
Behind Hari hara kala bhavan
SP Road, Secunderabad-500003

Ref: Protocol No: AKY/2019/01

Protocol title: "An observational study to evaluate safety and effectiveness of Akynzeo®, an oral fixed dose combination of Netupitant and Palonosetron in the management of CINV".

Sub: Approval of the Study & Study related documents

After reviewing the Study documents submitted by you, during the meeting held on **18-May-2019** at 17:00 hrs in the St. Theresa's Hospital Library the Ethics Committee is satisfied with the ethical considerations of the study.

Further we have also reviewed and approved the following trial related documents submitted by you:

S.no	Documents
1	Covering letter addressed to chairperson / Member secretary
2	Principal Investigator's CV and MRC
3	Study booklet comprising of protocol. Antiemesis assessment tool
4	CTA for Dr. Bharat vaswani, Dr Bharat Patodiya and Dr. Dattatreya
5	List of Investigators

Study: AKY/2019/01



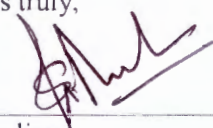
The constitution of this Ethics Committee who reviewed the above documents is as follows:

S.NO	EC MEMBER NAME	DESIGNATION	QUALIFICATION	VOTING	AFFILIATION TO THE INSTITUTION	GENDER
01	Dr.S.C.Parakh	Chairman	MD.LLM	YES	NO	MALE
02	Ms.N.Pauline	Member Secretary	M.B.A	YES	YES	FEMALE
03	Dr.K.Lalitha	Clinician	MBBS, DNB	YES	YES	FEMALE
04	Dr.B.Raghuveer	Basic Medical Scientist	MBBS, MD, Pharmacology	YES	NO	MALE
05	Ms.Thomasamma	Scientific Member	BPT	NO	YES	FEMALE
06	Mr. Bobba Tambi Jojibabu	Lay person	B.COM, MBA	YES	NO	MALE
07	Ms. Aukapelly Nirmala	Social Scientist	BSC (MSW)	YES	NO	FEMALE
08	Mr.Nagothu Vijaya Bhaskara Rao	Legal Expert	MA, LLB	YES	No	MALE

We confirm that the Ethics Committee constitution and operation is as per ICH-GCP guidelines and Schedule Y.

The Ethics committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report.

Yours truly,


 Sr.Pauline
 Member Secretary
 Ethics Committee
 St.Theresa's Hospital
 Sanathnagar
 Hyderabad -5000 18



Date: 20/may/2019