Clinical Trial Details (PDF Generation Date :- Sun, 27 Nov 2022 10:18:15 GMT)

CTRI Number	CTRI/2018/01/011109 [Registered on: 02/01/2018] - **Trial Registered Prospectively**
Last Modified On	23/06/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	A study to evaluate safety and efficacy of GRC 27864 in patients with hip / knee osteoarthritis pain
Scientific Title of Study	A Phase 2, dose- range finding, 12-week, double-blind, randomized, parallel group study to evaluate safety and efficacy of GRC 27864 in patients with moderate osteoarthritis pain

Secondary IDs if Any

Secondary ID	Identifier
GRC 27864-201, Version No. 3.0, dated 31 Oct 2017	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	
Designation	
Affiliation	
Address	
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
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Primary Sponsor

Primary Sponsor Details	
Name	Glenmark Pharmaceuticals SA
Address	Glenmark Pharmaceuticals S.A. Chemin de la Combeta 5 La Chaux-de-Fonds SWITZERLAND
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Amena Khatun Hospital Ethics Committee	Approved	09/03/2019	No
BhaktiVedanta Hospital Ethics Committee	Approved	26/02/2018	No
Dhwani Ethics Committee, VIROC Hospital	Approved	03/09/2018	No
Ethics Commiittee, Unique Hospital-Multispeciality and Research Institute	Approved	17/12/2018	No
Ethics Committee, St. Theresa Hospital	Approved	31/12/2017	No
Ethics Committee-Care Institute Of Medical Sciences (CIMS)	Approved	13/08/2018	No
Father Muller Institutional Ethics Committee	Approved	27/03/2018	No
Instituitional Ethics Committee-Human Research, LTM Medical College	Approved	26/02/2018	No
Institutional Ethics Committee - YAMER	Approved	14/05/2018	No
Institutional Ethics Committee - AMAI Charitable Trust's ACE Hospital	Approved	14/04/2018	No
Institutional Ethics Committee - ChanRe Rheumatology	Approved	06/02/2018	No
Institutional Ethics Committee - Clinical Studies	Approved	06/05/2019	No
Institutional Ethics	Approved	18/01/2018	No

Committee - Clinical Studies, Apollo Hospital			
Institutional Ethics Committee - Gleneagles Global Hospitals	Approved	09/03/2018	No
Institutional Ethics Committee - GMC, Nagpur	Approved	04/08/2018	No
Institutional Ethics Committee - GMERS Medical College	Approved	16/04/2018	No
Institutional Ethics Committee - Grant Medical College	Approved	27/02/2018	No
Institutional Ethics Committee - Malpani Multispeciality Hospital	Approved	13/02/2018	No
Institutional Ethics Committee for Human Research - Sir Sayajirao General Hospital	Approved	02/02/2018	No
Institutional Ethics Committee, King George Hospital	Approved	10/02/2018	No
Institutional Ethics Committee, KLE Academy of Higher Education and Research	Approved	08/04/2019	No
Institutional Ethics Committee, Kokilaben Dhirubhai Ambani Hospital	Approved	01/03/2018	No
Institutional Ethics Committee, MV Hospital	Approved	25/03/2018	No
Institutional Ethics Committee- Deenanath Mangeshkar Hospital and Research Centre	Approved	29/10/2018	No
Institutional Ethics Committee- Dr Jivraj Mehta Smarak Health Foundation Bakeri medical research center	Approved	15/04/2019	No
Institutional Ethics Committee- GCS Medical College	Approved	10/05/2019	No
Institutional Ethics Committee- Noble Hospital Pvt. Ltd	Approved	06/04/2018	No
Institutional Ethics Committee-Government Medical College and Government General	Approved	31/05/2019	No

Hospital			
Intuitional Ethics Committee-Kempegowda Institute of Medical Sciences, Bangalore	Approved	25/04/2018	No
KIMS Ethics Committee, Telangana	Approved	18/07/2018	No
Lifepoint Research Ethics Committee	Approved	26/03/2018	No
Magna Care Ethics Committee, Chopda Medicare	Approved	24/12/2017	No
MAHE Ethics Committee	Approved	10/07/2018	No
Narayana Health Medical Ethics Committee	Approved	19/03/2019	No
NKP Salve Institutional Ethics Committee	Approved	30/12/2017	No
O &P Institutional Ethics Committee	Approved	09/02/2018	No
O and P institutional Ethics Committee	Approved	19/03/2019	No
Omega Ethical Committee	Approved	27/01/2018	No
Pentamed Ethics Committee, Medipoint Hospital	Approved	03/01/2018	No
Rathi Ethics Committee	Approved	16/04/2018	No
Sanjivani Hospital Ethics Committee	Approved	03/01/2018	No
Saviour Hospital Ethics Committee	Approved	11/01/2019	No
Shivam Ethics Committee	Approved	16/04/2019	No
Shree Hospital Ethics Committee	Approved	05/03/2018	No
Supe Hospital Ethics Committee	Approved	31/01/2018	No
Swastic Ethics Committee, Sri Nidan Hospital	Approved	26/12/2017	No
Yash Societys Sujata Birla Hospital Ethics Committee	Approved	16/01/2018	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	07/12/2017

Health Condition / Problems Studied

Health Type	Condition
Patients	Unilateral primary osteoarthritisof knee

Intervention / Comparator Agent

Type	Name	Details
Intervention	GRC 27864	10 mg QD orally for 12 weeks
Intervention	GRC 27864	25 mg QD orally for 12 weeks
Intervention	GRC 27864	75 mg QD orally for 12 weeks

Comparator Agent	Placebo	QD orally for 12 weeks

Inclusion Criteria

Inclusion Criteria	
Age From	40.00 Year(s)
Age To	70.00 Year(s)
Gender	Both
Details	1. Male and female subjects aged 40 years to 70 years (both inclusive) at the time of signing the ICF 2. Subjects diagnosed with primary osteoarthritis of the hip or knee for at least 3 months in accordance with American College of Rheumatology (ACR) clinical and radiological criteria 3. Subjects who may or may not have received an NSAID or other oral analgesic therapy and report moderate pain intensity on 0-100 Visual Analogue Scale

Exclusion Criteria

Exclusion Criteria	
Details	1. Subjects experiencing severe pain, on 0-100 Visual Analogue Scale in most severely affected joint 2. Subjects who have history or presence of signs/symptoms suggestive active peptic ulcer disease and gastrointestinal (GI) bleeding 3. Subjects with known aspirin allergy, allergic reaction to non-steroidal anti-inflammatory drugs (NSAIDs) including asthma and urticaria 4. Use of NSAIDs, COX-2 inhibitors or aspirin (except aspirin up to 100 mg daily for cardio-protection) within previous 7 days of randomization 5. Use of oral, intra-articular or intramuscular corticosteroid or intra-articular hyaluronic acid within 12 weeks before randomization 6. Subjects with a history of myocardial infarction, coronary artery bypass grafting/ percutaneous coronary intervention, unstable angina, stroke or transient ischemic attack, congestive heart failure (CHF) with symptoms at rest or with minimal activity 7. Subjects with inherited or acquired disorders in platelet function, bleeding or coagulation or requiring anti-coagulation (except low dose aspirin for cardioprotection) 8. Presence of any clinically significant illness or disease; any condition that, in the opinion of the Investigator, would interfere with evaluation of the study drug or interpretation of subject safety or study results 9. Positive serology for Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV) and Hepatitis C virus (HCV) at screening 10. Females who are pregnant or breastfeeding

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Double Blind Double Dummy

Primary Outcome

Outcome	Timepoints
Mean change from baseline in the Western	12 weeks

Ontario and McMaster's University Osteoarthritis Index 3.1 pain subscale (WOMAC-PS) at the end of treatment	

Secondary Outcome

Outcome	Timepoints
Mean change from baseline in the Patient Global Assessment of Response to Therapy (PGART) using 0-4 point Likert scale	2, 4, 8 and 12 weeks of treatment and at follow up (14 weeks)
Mean change from baseline in the Investigator Global Assessment of Response to Therapy (IGART) using 0-4 point Likert scale	2, 4, 8 and 12 weeks of treatment and at follow up (14 weeks)
Proportion of subjects meeting OMERACT-OARSI responder criteria	4 and 12 weeks
Incidence of TEAEs and SAEs	Throughout study duration
PK and PD assessment	Day 1 and Day 85
Biomarker assessment	Day 85

Target Sample Size	**Total Sample Size=**624 **Sample Size from India=**624 **Final Enrollment numbers achieved (Total)=**624 **Final Enrollment numbers achieved (India)=**624
Phase of Trial	Phase 2
Date of First Enrollment (India)	25/01/2018
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**2 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	This is a randomized, double-blind, parallel group, placebo-controlled study. A total of 624 (156 per arm) subjects will be enrolled in the study to receive GRC 27864 orally once daily doses of 10 mg, 25 mg, 75 mg and placebo for 12-weeks. The primary outcome measures will be the efficacy of GRC 27864 given orally at daily doses of 10 mg, 25 mg and 75 mg for 12-weeks compared to placebo assessed by WOMAC-PS in patients with moderate osteoarthritis pain. The secondary outcomes will be safety and tolerability of GRC 27864. Any adverse event (AE), either clinical/laboratory, will be recorded and assessed for severity, seriousness and causality.