Clinical Trial Details (PDF Generation Date :- Thu, 16 Sep 2021 20:00:03 GMT)

CTRI Number	CTRI/2012/11/003160 [Registered on: 30/11/2012] - **Trial Registered Prospectively**
Last Modified On	30/06/2016
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 Two-Part Study of Sativex Oromucosal Spray for Relieving Uncontrolled Persistent Pain at any site of cancer related pain in Patients With Advanced Cancer
Scientific Title of Study	A Two-part, Placebo-controlled, Study of the Safety and Efficacy of Sativex Oromucosal Spray (Sativex; Nabiximols) as Adjunctive Therapy in Relieving Uncontrolled Persistent Chronic Pain in Patients With Advanced Cancer, Who Have Inadequate Analgesia Even With Optimized Chronic Opioid Therapy.

Secondary IDs if Any

Secondary ID	Identifier
2010-022905-17	EudraCT
GWCA1103- Version 2, dated 16 May 2011	Protocol Number

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

Details of Principal Investigator	
Name	Tarun Pandotra
Designation	Director, Clinical Operations
Affiliation	PRA International
Address	B 402, Business Square, Andheri Kurla Road Chakala, Andheri (E) Mumbai (Suburban) MAHARASHTRA 400093 India
Phone	02240309578
Fax	02240309134
Email	PandotraTarun@praintl.com

Details Contact Person (Scientific Query)

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Name	Tarun Pandotra
Designation	Director, Clinical Operations
Affiliation	PRA International
Address	B 402, Business Square, Andheri Kurla Road Chakala, Andheri (E) Mumbai (Suburban) MAHARASHTRA 400093 India
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Email	PandotraTarun@praintl.com

Source of Monetary or Material Support

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> GW Pharmaceuticals Ltd PORTON DOWN SCIENCE PARK SALISBURY WILTSHIRE SP4 0JQ, United Kingdom
> Otsuka Pharmaceutical Development Commercialization Inc 2440 Research Blvd Rockville, MD 20850 USA

Primary Sponsor

Primary Sponsor Details	
Name	GW Pharmaceuticals Ltd
Address	PORTON DOWN SCIENCE PARK SALISBURY WILTSHIRE SP4 0JQ UK
Type of Sponsor	Pharmaceutical industry-Global

Details of Secondary Sponsor

Name	Address
Otsuka Pharmaceutical Development Commercialization Inc	2440 Research Blvd Rockville, MD 20850 USA
Pharmaceutical Research Associates India Pvt Ltd	B 402, Business Square, Andheri Kurla Road, Chakala, Mumbai - 400 093. India

Countries of Recruitment

List of Countries
Australia
India
Israel
Italy
Republic of Korea
Spain
Taiwan
United States of America

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Sushma Bhatnagar	AIIMS, New Delhi	AAIMS, Room No. 242, 2nd Floor, Dr. BRA, IRCH, New Delhi, Delhi, India New Delhi DELHI	919811326453 911126588227 shumob@yahoo.com
Dr Pushplata Gupta	Bhagwan Mahaveer Cancer Hospital & research Centre	Deaprtment of Oncology,JLN Marg, Mauriya Nagar, Jaipur-302017, Rajasthan, India Jaipur RAJASTHAN	919829098288 91412709716 pushp-anil@yahoo.co.in
Dr Rangaraju Rangarao	BLK Hospital, New Delhi	Pusa Road, New Delhi-110029 New Delhi DELHI	919811326453 rangaraor@airtel.blackberry.com
Dr Chetan Deshmukh	Deenanath Mangeshkar Hospital & Research Centre	department of Oncology, Erandawane, Near Mhatre Bridge, Pune-411004, Maharashtra, India Pune	919850811449 912066023025 drchetandeshmukh@gmail.com

		MAHARASHTRA	
Dr Anish Maru	Dharamshila Hospital & Research Center (DHRC), Delhi	Dharamshila Marg, Mayur Vihar Phase- I , Vasundhara Enclave, Delhi- 110096 East DELHI	919811254969 911122617770 anishmaru@yahoo.com
Dr Madhuri Lokapur	Jehangir Clinical Development Centre Pvt.Ltd., Pune	Jehangir Hospital Premices, 32 Sassoon Road, Pune- 411001 Pune MAHARASHTRA	919822097478 911122617770 anishmaru@yahoo.com
Dr Kirushna Kumar	Meenakshi Mission Hospital and Research Centre, Madurai	Lake Area, Melur Road, Madurai- 625107 Madurai TAMIL NADU	919787713004 914522586353 drkskk@yahoo.com
Dr Shoba Nair	Saint Johns Medical College and Hospital, Bangalora	Dept. of Paina and Palliative Care, Sarjapur Road, Koramgala, Bangalore-560034, Karnataka Bangalore KARNATAKA	919743107123 nair.shoba@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethical Review Board – Meenakshi Mission Hospital and Research Centre, Madurai.	Approved	10/11/2012	No
Ethics Committee – BLK Superspeciality Hospital, New Delhi.	Approved	18/09/2012	No
Ethics Committee – Dharamshila Hospital & Research Centre, Delhi.	Submittted/Under Review	No Date Specified	No
Ethics Committee, Bhagwan Mahaveer Cancer Hospital & Research Centre, Jaipur	Approved	06/03/2012	No
Institution Ethics Committee, AIIMS, New Delhi	Approved	28/02/2012	No
Institutional Ethical Review Board, St. Johns Medical College Hospital, Bangalore.	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, Deenanath Mangeshkar Hospital & Research Centre, Pune	Submittted/Under Review	No Date Specified	No
Jehangir Clinical Development Centre Institutional Review Board, Pune	Approved	28/07/2012	No

Regulatory Clearance Status from DCGI

Status	Date

Approved/Obtained	10/01/2012

Health Condition / Problems Studied

Health Type	Condition
Patients	patients with advanced cancer, who have inadequate analgesia even with optimized chronic opioid therapy

Intervention / Comparator Agent

Type	Name	Details
Comparator Agent	GA0034 (Placebo)	Oromucosal spray, containing ethanol:propylene glycol:50) excipients, with peppermint 0.05%) flavoring and colorings FD&C Yellow No.5 (E102 tartrazine)(0.0260%), FD&C Yellow No.6 (E110 sunset yellow) (0.0038%),FD&C Red No. 40 (E129 Allura red AC)0.00330%) and FD&C Blue No.1 (E133 Brilliant blue FCF)(0.00058%). All study arm patients would be receiving standard pain therapy as well as prescribed by the investigator. Total duration of therapy for patients that complete the study will be 7 weeks
Intervention	Sativex oromucosal spray	Oromucosal spray, containing THC (27 mg/mL): CBD (25 mg/mL), in ethanol: propylene glycol (50:50) excipients, with peppermint oil (0.05%) flavoring. Each actuation delivers THC 2.7 mg and CBD 2.5 mg. All study arm patients would be receiving standard pain therapy as well as prescribed by the investigator. Total duration of therapy for patients that complete the study will be 7 weeks.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. The patient has advanced cancer for which there is no known curative therapy. 2. The patient has a clinical diagnosis of cancer related pain, which is not alleviated with their current optimized opioid treatment 3. The patient is receiving an optimized maintenance dose of Step III opioid therapy, preferably with a sustained release preparation, but also allowing a regular maintenance dose of around the clock use of immediate release preparations 4. The patient is receiving a daily maintenance dose Step III opioid therapy of less than or equal to a total daily opioid dose of 500 mg/day of morphine equivalence (including maintenance and break-through opioids) 5. The patient is using no more than one type of break-through opioid analgesia

Exclusion Criteria

Exclusion Criteria	
Details	1. Have any planned clinical interventions that would affect their pain (e.g., chemotherapy or radiation therapy where, in the clinical

	judgment of the investigator, these would be expected to affect pain) 2. The patient is currently using or has used cannabis or cannabinoid based medications within 30 days of study entry and is unwilling to abstain for the duration of the study 3. Has experienced myocardial infarction or clinically significant cardiac dysfunction within the last 12 months or has a cardiac disorder that, in the opinion of the investigator would put the patient at risk of a clinically significant arrhythmia or myocardial infarction 4.Has significantly impaired renal function 5. Has significantly impaired hepatic function 6. Female patients of child-bearing potential and male patients whose partner is of child-bearing potential, unless willing to ensure that they or their partner use effective contraception, for example, oral contraception, double barrier, intra-uterine device, during the study and for three months thereafter (however, a male condom should not be used in conjunction with a female condom as this may not prove effective)

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints
Mean 11-point NRS average pain score over the last four days of the Part B treatment period (end of treatment) taken from the IVRS	Mean 11-point NRS average pain score over the last four days of the Part B treatment period (end of treatment) taken from the IVRS

Secondary Outcome

Outcome	Timepoints
Percentage improvement in NRS average pain score from baseline to the end of treatment	Time Frame: 7 weeks
Mean 11-point NRS worst pain score from baseline to the end of treatment	Time Frame: 7 weeks
Mean sleep disruption NRS score from baseline to the end of treatment	Time Frame: 7 weeks

Target Sample Size	**Total Sample Size=**540 **Sample Size from India=**162 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 3
Date of First Enrollment (India)	17/12/2012
Date of First Enrollment (Global)	31/08/2012
Estimated Duration of Trial	**Years=**3 **Months=**11 **Days=**0
Recruitment Status of Trial (Global)	Open to Recruitment
Recruitment Status of Trial (India)	Other (Terminated)
Publication Details	
Brief Summary	Clinical study GWCA1103 is a Phase III therapeutic confirmatory study, of up to 11 weeks duration, to be carried out in patients with advanced cancer and who are

experiencing cancer-related pain that is not fully alleviated by their current opioid therapy. They are patients who are likely to have a limited life expectancy. GWCA1103 is a two-part (Part A and B), placebo-controlled, study of the safety and efficacy of Sativex oromucosal spray (Sativex; Nabiximols). The study's primary objective is to evaluate the efficacy of Sativex, compared with placebo, when used as an adjunctive measure, in relieving uncontrolled persistent chronic pain (not breakthrough pain) in patients with advanced cancer, who have inadequate analgesia even with optimized chronic opioid therapy.

In India thousands of cases related to cancer pain are reported every year. This molecule has been studied previously and there are no concerns with respect to the safety profile of the molecule. The conduct of this study in India will help generate data on safety & efficacy of Sativex. The data will support the use of Sativex oromucosal spray (Sativex; Nabiximols) as adjunctive therapy in relieving uncontrolled persistent chronic pain in patients with advanced cancer who have inadequate analgesia even with optimized chronic opioid therapy.

This trial is likely to benefit about 162 patients that will participate in the study and further may provide a new treatment to patients with cancer pain if the molecule is found to be successful.