Clinical Trial Details (PDF Generation Date :- Fri, 16 Apr 2021 19:24:39 GMT)

CTRI Number	CTRI/2011/04/001684 [Registered on: 20/04/2011] - **Trial Registered Retrospectively**
Last Modified On	23/10/2015
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 phase I clinical study to evaluate effects of ZYD1 in healthy people
Scientific Title of Study	A randomized, double blind, placebo controlled Phase I clinical study to evaluate the safety, tolerability and pharmacokinetics of ZYD1, a selective GLP-1 agonist, following the subcutaneous administrations in healthy volunteers

Secondary IDs if Any

Secondary ID	Identifier
ZYD1/1001	Protocol Number

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

Details of Principal Investigator	
Name	Dr Tanvi Shah
Designation	Ass. Rsrch Sntst
Affiliation	
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Details Contact Person (Public Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Cadila Healthcare Limited, Ahmedabad

Primary Sponsor

Primary Sponsor Details	
Name	Cadila Healthcare Limited Zydus Tower Satellite Road Ahmedabad Gujarat
Address	Cadila Healthcare Ltd. Satelite Road Ahmedabad, gujarat
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIl	

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Tanvi Shah	Zydus Research Centre	Clinical Research Department,Sarkhej-Bavla N. H. No. 8 A, Moraiya-382 213 Ahmadabad GUJARAT	91-2717-250801-5 tanvishah@zyduscadila.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Independent Ethics Committee - Aditya	Approved	21/01/2011	Yes

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	17/09/2010

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Treatment of Type 2 Diabetes Mellitus

Intervention / Comparator Agent

Type	Name	Details
Intervention	ZYD1	5 to 50 mg subcutaneously OD or BID depending upon the pharmacokinetic profile obtained in Plan I (Single dose study)
Comparator Agent	Placebo	5 to 50 mg subcutaneously OD or BID depending upon the pharmacokinetic profile obtained in Plan I (Single dose study)

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	45.00 Year(s)
Gender	Both
Details	1. Age: 18-45 years 2. Mentally, physically and legally eligible to give informed consent. 3. Male and female volunteers weighing between 50-75kg and 45-75kg respectively. 4. Ability to communicate effectively with the study personnel. 5. Willingness to adhere to the protocol requirements. 6. For

	gender effect study, only females with history of sterility or at least one year menopause or use of long acting non-hormonal contraceptive measures (e.g., Intra uterine device) will be recruited.

Exclusion Criteria

Exclusion Criteria	
Details	1. Presence or history of hypersensitivity to any of the active or inactive ingredients of ZYD1 formulation. 2. Presence or history of Pancreatitis at any time (Serum Amylase/Serum Lipase more than UNL) 3. Presence or history of Severe Gastrointestinal disease in the last six months. 4. Presence or history of Renal insufficiency at any time (serum creatinine >1.5mg/dL). 5. Active liver disease and/or liver transaminases greater than 1.5 X upper limit of normal (UNL). 6. History or presence of other systemic disorders or diseases (e.g., respiratory, gastrointestinal, endocrine, immunological,dermatological, neurological, psychiatric disease or any other body system involvement). 7. Abnormal BT, CT, PT and APTT tests on the day of check in. 8. History or presence of any medication in the last 14 days. 9. History or presence of significant alcoholism or drug abuse within the past one year. 10. History or presence of significant smoking (more than 10 cigarettes per day) or consumption of tobacco products (more than 10 times per day). 11. Difficulty with donating blood. 12. Systolic blood pressure more than 140mmHg and less than 100mmHg and diastolic blood pressure more than 90mmHg and less than 60mmHg. 13. Pulse rate less than 60/minute and more than 100/minute. 14. Any clinically significant abnormal X-ray or laboratory findings during screening. 15. History or presence of any clinically significant ECG abnormalities during screening. 16. Major illness and/or Major surgery in last 3 months. 17. Volunteers who have participated in any drug research study other than the present trial within past 3 months. 18. Volunteers who have donated one unit (350ml) of blood in the past 3 months. 19. For gender effect study, female volunteers with following criteria will not be recruited: - History of pregnancy or lactation in the past 3 months - Fertile female volunteers not protected against pregnancy by adequate long-term anti- fertility device or history of less than one year of menopause - Using hormonal contraceptives - Using hormone replacement therapy - Unable to give assurance for protection against pregnancy for 3 months after the participation in this trial - Positive urine pregnancy test on the day of check-in.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Participant, Investigator and Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
1. Safety and tolerability 2. Pharmacokinetics (PK) after single and multiple subcutaneous administrations in healthy adult male volunteers 3. Pharmacodynamic (PD) effect after single and multiple subcutaneous dose administrations in healthy adult male volunteers. 4. Gender effects: Pharmacokinetics, Pharmacodynamic effect and safety parameters in female volunteers at pre-selected single dose will be compared with the results of single dose study in male volunteers.	1. For single dose and gender effect study - The venous blood samples will be withdrawn at pre-dose (before dosing), 0.5, 1, 2, 3, 4, 6 ,8, 10, 12, 24, 48, 72 and 120 hrs post dose 2. Multiple dose study - Day 01 - Pre-dose, 1, 2, 3, 4 and 8 hours following first dosing. Day 02 to 06 - Pre-dose of each . Day 07 - Pre-dose, 1, 2, 3, 4 , 8, 12, 24, 36, 48, 72 and 120 hrs post dose

Secondary Outcome

Outcome	Timepoints
NIL	NIL

Target Sample Size	**Total Sample Size=**112 **Sample Size from India=**112 **Final Enrollment numbers achieved (Total)=** **Final Enrollment numbers achieved (India)=**
Phase of Trial	Phase 1
Date of First Enrollment (India)	28/02/2011
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	
Brief Summary	A randomized, double-blind, placebo-controlled Phase I clinical study to evaluate the safety, tolerability, and pharmacokinetics of ZYD1, a selective GLP-1 agonist, following subcutaneous administration in healthy volunteers. Objectives of this study are 1. Safety and tolerability 2. Pharmacokinetics (PK) after single and multiple subcutaneous administrations in healthy adult male volunteers 3. Pharmacodynamic (PD) effect after single and multiple subcutaneous dose administrations in healthy adult male volunteers 4. Gender effects: Pharmacokinetics, pharmacodynamic effect and safety parameters in female volunteers at preselected single dose will be compared with the results of single-dose study in male volunteers