



Clinical Trial Details (PDF Generation Date :- Fri, 27 Jan 2023 19:23:15 GMT)

<b>CTRI Number</b>	CTRI/2011/04/001684 [Registered on: 20/04/2011] - <b>Trial Registered Retrospectively</b>		
<b>Last Modified On</b>	23/10/2015		
<b>Post Graduate Thesis</b>	No		
<b>Type of Trial</b>	Interventional		
<b>Type of Study</b>	Drug		
<b>Study Design</b>	Randomized, Parallel Group, Placebo Controlled Trial		
<b>Public Title of Study</b>	A phase I clinical study to evaluate effects of ZYD1 in healthy people		
<b>Scientific Title of Study</b>	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		
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>	
	ZYD1/1001	Protocol Number	
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>		
	<b>Name</b>	Dr Tanvi Shah	
	<b>Designation</b>	Ass. Rsrch Sntst	
	<b>Affiliation</b>		
	<b>Address</b>	Clinical Research Department, Zydus Research Centre Sarkhej-Bavla N. H. No. 8 A, Moraiya Ahmadabad GUJARAT 382 213 India	
	<b>Phone</b>	912717250801	
	<b>Fax</b>		
	<b>Email</b>	tanvishah@zyduscadila.com	
	<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>	
		<b>Name</b>	Dr Rajendra H Jani
<b>Designation</b>		Sr V P	
<b>Affiliation</b>		Cadila Healthcare Limited	
<b>Address</b>		Zydus Cadila House Plot No. 360, TPS 5 Service Road Vile Parle (East) Mumbai MAHARASHTRA 400057 India	
<b>Phone</b>		912226186057	
<b>Fax</b>		912226151735	
<b>Email</b>		rhjani@zyduscadila.com	
<b>Details Contact Person (Public Query)</b>	<b>Details Contact Person (Public Query)</b>		
	<b>Name</b>	Dr. Rajendra H. Jani	
	<b>Designation</b>		
	<b>Affiliation</b>		
	<b>Address</b>	Zydus Cadila House Plot No. 360, TPS 5, Service Road, Vile Parle (East) Mumbai MAHARASHTRA 400057 India	



	<b>Phone</b>	91-22-26186057		
	<b>Fax</b>	91-22-26151735		
	<b>Email</b>	rhjani@zyduscadila.com		
<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Cadila Healthcare Limited, Ahmedabad			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
	<b>Name</b>	Cadila Healthcare Limited Zydus Tower Satellite Road Ahmedabad Gujarat		
	<b>Address</b>	Cadila Healthcare Ltd. Satelite Road Ahmedabad, gujarat		
	<b>Type of Sponsor</b>	Pharmaceutical industry-Indian		
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	NII			
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
	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
<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	Independent Ethics Committee - Aditya	Approved	21/01/2011	Yes
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Approved/Obtained		17/09/2010	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Healthy Human Volunteers		Treatment of Type 2 Diabetes Mellitus	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	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)	
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>			
	<b>Age From</b>	18.00 Year(s)		
	<b>Age To</b>	45.00 Year(s)		
	<b>Gender</b>	Both		
	<b>Details</b>	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.					
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>					
<b>Details</b>	<p>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 &gt;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.</p>					
<b>Method of Generating Random Sequence</b>	Computer generated randomization					
<b>Method of Concealment</b>	Pre-numbered or coded identical Containers					
<b>Blinding/Masking</b>	Participant, Investigator and Outcome Assessor Blinded					
<b>Primary Outcome</b>	<table border="1" style="width: 100%;"> <thead> <tr> <th style="text-align: center;">Outcome</th> <th style="text-align: center;">Timepoints</th> </tr> </thead> <tbody> <tr> <td>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.</td> <td>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</td> </tr> </tbody> </table>	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	
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<b>Secondary Outcome</b>	<table border="1" style="width: 100%;"> <thead> <tr> <th style="text-align: center;">Outcome</th> <th style="text-align: center;">Timepoints</th> </tr> </thead> <tbody> <tr> <td>NIL</td> <td>NIL</td> </tr> </tbody> </table>	Outcome	Timepoints	NIL	NIL	
Outcome	Timepoints					
NIL	NIL					



<b>Target Sample Size</b>	<b>Total Sample Size=112</b> <b>Sample Size from India=112</b> <b>Final Enrollment numbers achieved (Total)=</b> <b>Final Enrollment numbers achieved (India)=</b>
<b>Phase of Trial</b>	Phase 1
<b>Date of First Enrollment (India)</b>	28/02/2011
<b>Date of First Enrollment (Global)</b>	No Date Specified
<b>Estimated Duration of Trial</b>	<b>Years=1</b> <b>Months=0</b> <b>Days=0</b>
<b>Recruitment Status of Trial (Global)</b>	Not Applicable
<b>Recruitment Status of Trial (India)</b>	Completed
<b>Publication Details</b>	
<b>Brief Summary</b>	<p>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</p> <ol style="list-style-type: none"> <li>1. Safety and tolerability</li> <li>2. Pharmacokinetics (PK) after single and multiple subcutaneous administrations in healthy adult male volunteers</li> <li>3. Pharmacodynamic (PD) effect after single and multiple subcutaneous dose administrations in healthy adult male volunteers</li> <li>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</li> </ol>