

?Basic information

JapicCTI-No.	JapicCTI-101246
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?Title of the study

Title of the study	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Cardiovascular Outcomes Following Treatment With Alogliptin in Addition to Standard of Care in Subjects With Type 2 Diabetes and Acute Coronary Syndrome
Public title of the study	Cardiovascular Outcomes Study of Alogliptin in Subjects With Type 2 Diabetes and Acute Coronary Syndrome (EXAMINE)
Primary sponsor	Takeda Global Research & Development Center, Inc.,*
Secondary sponsor	
Study Type	interventional (drug)
Summary	The purpose of this study is to evaluate the cardiovascular outcomes of alogliptin, once daily (QD), compared with placebo, in addition to standard of care, in subjects with type 2 diabetes mellitus and acute coronary syndrome.

?Details of the study

Disease or condition	Diabetes Mellitus, Type 2 and Acute Coronary Syndrome	
Intervention	Intervention name	Alogliptin (SYR-322, SYR110322)
	INN of the intervention	Alogliptin
	Classification name(code) of the intervention	396 (antidiabetic agents)
	Dosage And administration of the intervention	Alogliptin (25 mg, 12.5mg, 6.25mg) tablets, orally, once daily for up to 4.75 years for patients with normal or mildly impaired renal function as defined by estimated glomerular filtration rate.
	Control intervention name(code)/td>	Placebo
	INN of the control intervention	-
	Classification name(code) of the control intervention	--- (other)
	Dosage And administration of the control intervention	Alogliptin placebo matching tablets, orally, once daily for up to 4.75 years.
Objectives of the study	Treatment	
Study phase	Phase 3	
Study design	Randomized, Parallel Assignment, Double Blind, Safety Study	
Target sample size	5400	
Inclusion Criteria	<p>1)Diagnosis of type 2 diabetes mellitus 2)Subject is receiving monotherapy or combination antidiabetic therapy with a glycosylated hemoglobin level between 6.5% and 11.0%, inclusive, at Screening (between 7.0 and 9.0%, inclusive, if the subject's antidiabetic regimen includes insulin) 3)Diagnosis of acute coronary syndrome within 15 to 90 days prior to randomization</p> <p>Age : 18years old or more Sex : Both</p>	
Exclusion Criteria	<p>1)Signs of type 1 diabetes mellitus 2)Currently receiving a glucagon-like peptide-1 analogue for glycemic control of type 2 diabetes mellitus at Screening 3)Received a dipeptidyl peptidase-4 inhibitor for either more than 14 days total or within the 3 months prior to Screening</p>	

Outcome	Primary Outcome	Time from randomization to the occurrence of the Primary Major Adverse Cardiac Events, defined as a composite of cardiovascular death, nonfatal myocardial infarction and nonfatal stroke.
	Timepoints	Time Frame: At first occurrence (up to 4.75 years).
	Secondary Outcome	Time from randomization to the occurrence of the Secondary Major Adverse Cardiac Events defined as a composite of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke and urgent revascularization due to unstable angina.
	Timepoints	Time Frame: At first occurrence (up to 4.75 years).
Institutions		
Duration of the study	2009-9-1 ~ 2014-12-1	
Study status	On-going	
recruitment status	Recruiting	
Region	Argentina; Austria; Australia; Belgium; Brazil; Bulgaria; Canada; Chile; Costa Rica; Czech Republic; Denmark; European Union; Finland; France; Germany; Guatemala; Hong Kong; Hungary; India; Israel; Italy; Japan, Korea; Latvia; Lithuania; Malaysia; Mexico; Netherlands; New Zealand; Peru; Philippines; Poland; Portugal; Romania; Russia; Serbia; Slovakia; South Africa; South Korea; Spain; Sweden; Thailand; Turkey; Ukraine; United Kingdom; United States	

?Secondary ID

Related ID Name	Clinicaltrials.gov Registry ID
Related ID number	NCT00968708
Related ID Name	Takeda ID
Related ID number	SYR-322_402
Related ID Name	Universal Trial Number
Related ID number	U1111-1111-6825
Related ID Name	EudraCT Registry ID
Related ID number	2009-011222-34
Related ID Name	CTRI Registry ID
Related ID number	CTRI/2010/091/000046
Related ID Name	SANCTR Registry ID
Related ID number	DOH-27-0310-3047
Related ID Name	NRES Registry ID
Related ID number	09/H0709/63

?Related information

Name of URL	
URL address	
Description of URL	

?Contact information

Organization	Takeda Pharmaceutical Company Limited
Division	Contact for Clinical Trial Information
Contact person or e-mail	

address etc.	https://www.takeda.co.jp/contact/form/en/form/
Organization (Scientific)	Takeda Global Research & Development Center
Division (Scientific)	Clinical Science
Contact person or e-mail address etc. (Scientific)	Study Director: VP, Clinical Science Takeda Global Research & Development Center, e-mail: medicalinformation@tpna.com

?Other

Source funded	
Name of research funds	
Other	*Takeda Global Research & Development Centre (Europe) Ltd., Takeda Pharmaceutical Company Limited

?History

History	2010/8/17 application date
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