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Study No.: AVA100468
Title: An open-label extension to study AVA100193, to assess the long-term safety and efficacy of rosiglitazone (extended release tablets) in subjects with mild to moderate Alzheimer's disease
Rationale: Rosiglitazone maleate (RSG) is a member of the thiazolidinedione class of anti-diabetic drugs, which improve glycaemic control in Type II diabetic subjects by reducing insulin resistance. RSG also inhibits the release of cytokines interleukin-1 (IL-1), interleukin-6 (IL-6) and tumour necrosis factor- α (TNF- α) from monocytes or microglia, which have been stimulated by phorbol esters, okadaic acid, or beta amyloid peptide. Because both altered glucose regulation and inflammation appear to play roles in the pathogenesis of Alzheimer's disease (AD), peroxisome proliferator-activated receptor-gamma (PPAR γ) agonists such as RSG may be useful in AD treatment.
Phase: Phase IIb
Study Period: 21 July 2004 to 12 May 2006
Study Design: Multi-centre, open-label, single group study in male and female outpatients with mild to moderate AD, who had completed 24 weeks of treatment in Study AVA100193.
Centres: 40 sites in Europe and 2 sites in New Zealand.
Indication: Treatment of subjects with mild to moderate Alzheimer's disease
Treatment: Subjects took one tablet of study medication daily in the morning, either with or without food. All subjects received one 4mg tablet once daily for the first 4 weeks of treatment. From Visit 3 (Week 4) onwards, subjects were to receive one 8mg tablet once daily for the remaining 44 weeks of treatment. On the day of visits in the fasting state (Visits 6 and 9), the daily dose of study medication was not to be taken until fasting blood samples were collected.
Objectives: The primary objective of this study was to evaluate the long-term safety and tolerability of RSG XR in subjects with mild to moderate Alzheimer's disease who had completed 24 weeks of treatment in the AVA100193 study. The secondary objective of this study was to evaluate further the long-term efficacy of RSG XR in terms of cognitive function, overall clinical response, measures of behaviour and activities of daily living.
Primary Outcome/Efficacy Variable: Primary Safety Endpoint: Frequency of adverse events.
<p>Secondary Outcome/Efficacy Variable(s): Secondary Safety Endpoints: Frequency of serious adverse events; Percentage of subjects with adverse event of oedema; Change from baseline in vital signs. Frequency of vital signs of clinical concern; Change from baseline (both AVA100193 and AVA100468 baselines) in weight; Change from baseline (AVA100193 baseline) in measures of lipid metabolism (total cholesterol, HDL, LDL, VLDL, triglycerides, free fatty acids) and lipoproteins (Apo A1, Apo B); Frequency of clinical chemistry (including lipids) and haematology parameters of clinical concern; Change from baseline (both AVA100193 and AVA100468 baselines) in fasting insulin; Change from baseline (both AVA100193 and AVA100468 baselines) in fasting plasma glucose; Change from baseline (both AVA100193 and AVA100468 baselines) in HbA1c; Change from baseline (both AVA100193 and AVA100468 baselines) in homeostasis model assessment (HOMA) estimate of insulin resistance.</p> <p>Efficacy Endpoints: Change from baseline (both AVA100193 and AVA100468 baselines) in Alzheimer's Disease Assessment Scale – cognitive (ADAS-cog) total score; Clinician's Interview-Based Impression of Change – plus (CIBIC+) score (from AVA100193 baseline); Change from baseline (both AVA100193 and AVA100468 baselines) in Neuropsychiatric Inventory (NPI) total score; Change from baseline (both AVA100193 and AVA100468 baselines) in Disability Assessment for Dementia (DAD) total score; Change from baseline (AVA100193 baselines) in Mini Mental State Examination (MMSE) total score.</p> <p>Additional efficacy endpoints added following the results of the double-blind AVA100193 study: Change from baseline (both AVA100193 and AVA100468 baselines) in ADAS-cog score by APOE4 genotype; CIBIC+ score (from AVA100193 baseline) by APOE4 genotype</p>
Statistical Methods: This was an open-label extension study with only one treatment group so there were no treatment comparisons to be made between AVA100468 treatment groups. For exploratory purposes, efficacy data were summarized by treatment groups assigned in the previous AVA100193 study. No formal statistical analysis was performed on these data since the study population was self-selected and not randomized.

The primary objective of this study was to evaluate the long-term safety of the study. Therefore the primary endpoint was a safety endpoint, the frequency of adverse events. Treatment emergent AEs, clinical laboratory evaluations, vital signs and ECG data were summarized.

Three populations were used to summarise the AVA100468 study data. These were the "All Subjects" population which contained all subjects who received at least one dose in the extension study. A second population was the "Re-consented Pharmacogenetics" population which included all subjects who had consented to pharmacogenetic testing in study AVA100193, who had APOE genotype data available and re-consented to the use of their APOE genetic data in the analysis of the AVA100468 study results. A third population was the "Full Pharmacogenetics" population which included all subjects who had consented to pharmacogenetic testing in the AVA100193 study, had APOE genotype data available, but had not specifically re-consented for the use of their APOE genotype data in the analysis of the AVA100468 study results.

Study Population: Male or female subjects who had successfully completed Visit 8 of AVA100193 (24 weeks of treatment) without tolerability issues, where in the opinion of the subject and of the investigator, it was beneficial to continue treatment with RSG XR.

	Placebo	RSG 2mg	RSG 4mg	RSG 8mg	Total
Number of Subjects:					
Planned, N	106	109	114	113	422
Randomised, N	80	80	89	88	337
Completed, n (%)					276 (82)
Total Number Subjects Withdrawn, N (%)					61 (18)
Withdrawn due to Adverse Events n (%)					23 (7)
Withdrawn due to Lack of Efficacy n (%)					0
Withdrawn for other reasons n (%)					38 (11)
Demographics	Placebo	RSG 2mg	RSG 4mg	RSG 8mg	Total
N (All Subjects Population)	80	80	89	88	337
Females: Males	48:32	46:34	46:43	57:31	197:140
Mean Age, years (SD)	71.5 (9.07)	70.5 (8.25)	68.9 (9.56)	70.4 (8.60)	70.3 (8.91)
Race, n (%)	80 (100)	80 (100)	89 (100)	88 (100)	337 (100)

Efficacy Results:

Visit labels refer to Week number from start of the AVA100193 Study. Week 24 AVA100193 is the baseline for the AVA100468 Study.

Summary of Change From AVA100193 Baseline for ADAS-cog Score by Visit (All Subjects Population)

Note: A negative value of change from baseline represents clinical improvement, whereas a positive value represents clinical decline

Subject visit		Placebo N=80	RSG 2mg N=80	RSG 4mg N=89	RSG 8mg N=88
Week 24	n	79	80	88	87
	Mean (SD)	-0.6 (6.22)	-0.5 (6.45)	-1.4 (6.03)	-1.4 (5.59)
	Median	0.0	0.0	-1.0	-2.0
	Range	-25 - +12	-19 - +18	-25 - +15	-23 - +10
Week 48	n	69	72	80	78
	Mean (SD)	0.2 (7.69)	-0.4 (7.11)	0.3 (7.94)	0.2 (7.98)
	Median	0.0	-1.0	0.0	-0.5
	Range	-18 - +17	-20 - +17	-24 - +22	-25 - +29
Week 72	n	64	66	75	69
	Mean (SD)	3.3 (8.05)	1.1 (8.15)	2.3 (9.86)	1.5 (10.16)
	Median	1.5	2.0	1.0	0.0
	Range	-9 - +29	-22 - +22	-25 - +34	-30 - +39

Summary of Change From AVA100193 Baseline for ADAS-cog Score by Visit and APOE4 Carriage (Re-consented Pharmacogenetics Population)					
Subject visit		APOE4 Carriage			
		No (N=53)		Yes (N=53)	
Week 24	n	53		53	
	Mean (SD)	-2.2 (6.21)		-0.1 (4.96)	
	Median	-4.0		1.0	
	Range	-17 - +12		-11 - +10	
Week 48	n	49		52	
	Mean (SD)	-2.3 (7.43)		0.7 (6.19)	
	Median	-3.0		0.0	
	Range	-19 - +15		-18 - +17	
Week 72	n	46		48	
	Mean (SD)	-1.1 (8.71)		3.4 (6.74)	
	Median	-2.0		3.0	
	Range	-18 - +24		-10 - +21	
Summary of Change From AVA100193 Baseline for ADAS-cog Score – RSG vs Placebo by APOE4 Carriage (Full Pharmacogenetics Population)					
Subject visit		APOE4 Carriage			
		No		Yes	
		Placebo (N=49)	RSG (N=167)	Placebo (N=49)	RSG (N=167)
Week 48	n	22	87	20	60
	Mean (SD)	-0.1 (4.30)	0.9 (4.56)	1.0 (5.64)	1.3 (5.89)
	Median	0.0	1.0	0.5	0.5
	Range	-8 - +7	-11 - +12	-10 - +11	-7 - +31
Week 72	n	21	80	18	54
	Mean (SD)	3.1 (5.13)	2.3 (5.95)	3.2 (5.18)	2.7 (7.20)
	Median	2.0	1.0	2.0	1.0
	Range	-8 - +18	-10 - +23	-4 - +17	-7 - +37
Summary of CIBIC+ (All Subjects Population)					
Note: A CIBIC+ score below 4 (e.g. 3.5) represents clinical improvement, whereas a CIBIC+ score above 4 (e.g. 4.5) represents clinical decline					
Subject visit		Placebo N=80	RSG 2mg N=80	RSG 4mg N=89	RSG 8mg N=88
Week 24	n	79	80	88	88
	Mean (SD)	3.8 (1.04)	3.6 (1.20)	3.5 (1.15)	3.5 (1.19)
	Median	4.0	4.0	4.0	3.0
	Range	2-6	1-6	1-7	1-7
Week 48	n	71	71	80	80
	Mean (SD)	4.1 (1.26)	3.9 (1.13)	3.9 (1.14)	3.9 (1.23)
	Median	4.0	4.0	4.0	4.0
	Range	1-7	1-7	1-7	1-7
Week 72	n	64	66	74	70
	Mean (SD)	4.3 (1.31)	4.1 (1.26)	4.1 (1.28)	3.9 (1.36)
	Median	4.0	4.0	4.0	4.0
	Range	1-7	1-7	1-7	1-7

Summary of CIBIC+ by APOE4 Carriage (Re-consented Pharmacogenetics Population)					
Subject visit		APOE4 Carriage			
		No (N=53)		Yes (N=53)	
Week 24	n	53		53	
	Mean (SD)	3.3 (1.15)		4.0 (1.16)	
	Median	3.0		4.0	
	Range	1-6		2-6	
Week 48	n	49		52	
	Mean (SD)	3.6 (1.15)		4.4 (1.16)	
	Median	4.0		4.0	
	Range	1-6		1-7	
Week 72	n	46		48	
	Mean (SD)	3.6 (1.22)		4.7 (1.35)	
	Median	4.0		5.0	
	Range	1-7		2-7	
Summary of Change From AVA100193 Baseline for NPI by Visit (All Subjects Population)					
Note: A negative value of change from baseline represents clinical improvement, whereas a positive value represents clinical decline					
Subject visit		Placebo N=80	RSG 2mg N=80	RSG 4mg N=89	RSG 8mg N=88
Week 24	n	80	80	89	88
	Mean (SD)	-1.5 (7.17)	-2.5 (7.36)	-1.9 (5.56)	-2.6 (6.69)
	Median	-1.0	-2.0	-1.0	-1.0
	Range	-28 - +29	-22 - +24	-15 - +18	-21 - +19
Week 48	n	71	72	81	80
	Mean (SD)	-1.6 (9.47)	-2.4 (6.42)	-0.7 (7.92)	-2.6 (8.25)
	Median	-1.0	-2.0	-1.0	-1.0
	Range	-38 - +29	-21 - +14	-16 - +46	-35 - +31
Week 72	n	64	66	75	70
	Mean (SD)	0.8 (11.10)	-1.4 (7.28)	-0.0 (8.93)	-1.0 (8.47)
	Median	0.0	-1.0	0.0	-1.0
	Range	-28 - +54	-20 - +20	-16 - +49	-22 - +34
Summary of Change From AVA100193 Baseline for DAD by Visit (All Subjects Population)					
Note: A positive value of change from baseline represents clinical improvement, whereas a negative value represents clinical decline					
Subject visit		Placebo N=80	RSG 2mg N=80	RSG 4mg N=89	RSG 8mg N=88
Week 24	n	80	80	89	88
	Mean (SD)	1.8 (5.98)	2.2 (4.97)	1.3 (4.29)	0.8 (5.75)
	Median	2.0	2.0	1.0	0.0
	Range	-12 - +18	-16 - +15	-10 - +13	-29 - +16
Week 48	n	71	72	81	80
	Mean (SD)	-0.2 (7.28)	0.1 (6.84)	0.2 (6.25)	-0.6 (6.76)
	Median	1.0	0.0	0.0	0.0
	Range	-19 - +17	-33 - +12	-15 - +23	-33 - +12
Week 72	n	64	66	75	70
	Mean (SD)	-1.0 (7.40)	-0.5 (6.95)	-1.1 (7.32)	-1.2 (8.09)
	Median	-0.5	-0.5	0.0	0.5
	Range	-19 - +14	-14 - +18	-30 - +13	-37 - +12

Summary of Change From Screening MMSE by Visit (All Subjects Population)					
Note: A positive value of change from baseline represents clinical improvement, whereas a negative value represents clinical decline					
Subject visit		Placebo N=80	RSG 2mg N=80	RSG 4mg N=89	RSG 8mg N=88
Week 24	n	80	80	89	88
	Mean (SD)	0.6 (3.73)	1.0 (3.55)	0.8 (2.83)	-0.0 (3.18)
	Median	1.0	1.0	0.0	0.0
	Range	-10 - +7	-9 - +12	-6 - +9	-10 - +7
Week 48	n	71	72	81	80
	Mean (SD)	-0.4 (4.61)	0.6 (3.84)	-0.1 (3.55)	-0.9 (4.52)
	Median	-1.0	1.0	0.0	0.0
	Range	-14 - +11	-10 - +9	-11 - +8	-16 - +10
Week 72	n	64	66	75	70
	Mean (SD)	-0.9 (4.07)	-0.7 (4.90)	-0.9 (4.71)	-1.4 (5.51)
	Median	-1.0	0.0	-1.0	-1.0
	Range	-11 - +7	-16 - +12	-17 - +10	-17 - +12

Summary of Change From AVA100193 Baseline for Fasting Insulin, Fasting Plasma Glucose, HbA1c and HOMA IR at Week 72					
Subject visit		Placebo N=80	RSG 2mg N=80	RSG 4mg N=89	RSG 8mg N=88
Fasting insulin (pmol/L)					
Baseline	n	80	80	89	88
	Mean (SD)	99.78 (146.628)	83.00 (93.061)	82.48 (71.280)	81.36 (77.445)
	Median	75.80	65.00	65.00	57.70
	Range	21.7 – 1212.5	14.4 – 815.5	14.4 – 469.1	21.7 – 360.9
Week 72	n	52	51	57	55
	Mean (SD)	-13.32 (70.802)	-29.86 (97.366)	-28.62 (83.241)	-25.98 (67.341)
	Median	-21.65	-14.50	-14.50	-14.40
	Range	-158.8 - +216.5	-663.9 - +79.4	-389.7 - +173.2	-288.6 - +230.9
Fasting plasma glucose (mmol/L)					
Baseline	n	77	76	82	84
	Mean (SD)	5.60 (0.720)	5.51 (0.560)	5.42 (0.538)	5.54 (0.643)
	Median	5.50	5.45	5.35	5.40
	Range	4.5 – 9.4	4.1 – 7.1	4.3 – 6.7	4.1 – 7.5
Week 72	n	55	54	63	61
	Mean (SD)	-0.28 (0.731)	-0.22 (0.675)	-0.25 (0.728)	-0.36 (0.640)
	Median	-0.40	-0.25	-0.20	-0.30
	Range	-1.9 - +2.8	-1.8 – +1.2	-3.7 - +1.5	-1.8 - +1.3
HbA1c (% of total Hb)					
Baseline	n	80	80	89	88
	Mean (SD)	5.65 (0.350)	5.69 (0.374)	5.60 (0.425)	5.65 (0.365)
	Median	5.70	5.65	5.60	5.60
	Range	4.9 – 6.3	4.5 – 6.7	4.9 – 7.0	4.8 – 6.6
Week 72	n	62	64	73	67
	Mean (SD)	0.28 (0.332)	0.27 (0.333)	0.23 (0.315)	0.22 (0.392)
	Median	0.30	0.30	0.30	0.20
	Range	-0.9 - +1.2	-0.6 - +1.1	-0.9 - +0.9	-1.1 – +1.7
HOMA IR					
Baseline	n	77	75	81	84
	Mean (SD)	3.93 (8.240)	2.91 (3.368)	2.65 (2.218)	2.81 (2.801)
	Median	2.46	2.34	2.13	1.95
	Range	0.6 – 70.6	0.4 – 27.8	0.4 – 16.0	0.7 – 14.3
Week 72	n	52	50	56	54
	Mean (SD)	-0.46 (2.870)	-1.08 (3.398)	-1.23 (3.444)	-1.25 (2.442)
	Median	-0.74	-0.68	-0.81	-0.62
	Range	-5.5 - +13.1	-22.8 - +4.0	-18.9 - +5.1	-13.1 - +0.8
1. Calculation of HOMA: Insulin Resistance (HOMA IR) = [Fasting insulin (uU/mL) X fasting plasma glucose (mmol/L) / 22.5]					

Safety Results: An on-therapy adverse event (AE) was defined as an AE with onset on or after study entry and up to 30 days after the last dose of study medication.

An on-therapy serious adverse event (SAE) was defined as an SAE with onset on or after the date when informed consent was given and up to 30 days after the last dose of study medication.

The Safety results presented are from the AVA100468 study. Results for the change in lipid metabolism, lipoproteins and weight are presented from the AVA100193 baseline. For the Safety results from the AVA100193 study, please refer to the CTR summary for the AVA100193 study.

	RSG 8mg; N=337
Most Frequent Adverse Events – On-Therapy	n (%)
Subjects with any AE(s), n(%)	163 (48)
Oedema peripheral	19 (6)
Nasopharyngitis	17 (5)
Anaemia	11 (3)
Headache	11 (3)
Muscle spasm	10 (3)
Urinary incontinence	10 (3)
Fatigue	9 (3)
Back pain	8 (2)
Dizziness	7 (2)
Influenza	7 (2)
Osteoarthritis	7 (2)
	RSG 8mg; N=337
	n (%)
Percentage of subjects with the AE of oedema – On-Therapy	5 (1)

Serious Adverse Events - On-Therapy n (%) [n considered by the investigator to be related to study medication]	
Subjects with non-fatal SAEs, n (%)	RSG 8mg; N=337
	n (%) [related]
Any subject with non-fatal SAE	26 (8) [1]
Femur fracture	2 (1) [0]
Anaemia	1 (<1) [0]
Angina pectoris	1 (<1) [0]
Ankle fracture	1 (<1) [0]
Arrhythmia	1 (<1) [0]
Back pain	1 (<1) [0]
Breast cancer	1 (<1) [0]
Cardiac failure	1 (<1) [1]
Cardiac pacemaker malfunction	1 (<1) [0]
Chest pain	1 (<1) [0]
Circulatory collapse	1 (<1) [0]
Convulsion	1 (<1) [0]
Coronary artery disease	1 (<1) [0]
Dementia Alzheimer's type	1 (<1) [0]
Dislocation of joint prosthesis	1 (<1) [0]
Duodenal ulcer	1 (<1) [0]
Dysphagia	1 (<1) [0]
Faecal incontinence	1 (<1) [0]
Febrile infection	1 (<1) [0]
Fracture of the skull base	1 (<1) [0]
Gastrointestinal neoplasm	1 (<1) [0]
Hip fracture	1 (<1) [0]
Hypokalaemia	1 (<1) [0]
Incontinence	1 (<1) [0]
Mental impairment	1 (<1) [0]
Oedema	1 (<1) [1]
Pelvic fracture	1 (<1) [0]
Psychotic disorder	1 (<1) [0]
Rectal cancer	1 (<1) [0]
Rib fracture	1 (<1) [0]
Skin laceration	1 (<1) [0]
Syncope	1 (<1) [0]
Transient ischaemic attack	1 (<1) [0]
Tumour haemorrhage	1 (<1) [0]
Urinary tract infection	1 (<1) [0]
Subjects with fatal SAEs, n (%)	
	n (%) [related]
Total number of subject deaths	4 (1) [1]
Fatal SAE leading to death during or up to 30 days after study participation	2 (1) [0]
Death NOS (not otherwise specified)	1 (<1) [0]
Possible bacterial pneumonia	1 (<1) [0]
Fatal SAE leading to death more than 30 days after stopping study medication	2 (1) [1]
Hepatic function abnormal	1 (<1) [0]
Ischaemic stroke	1 (<1) [1]

Change from baseline (AVA100193 baseline) of potential clinical concern (PCC) for measures of lipid metabolism and lipoproteins (All Subjects Population)		
Parameter – Any visit post-baseline	Range	RSG 8mg N=337 n (%)
LDL cholesterol (mmol/L)	High	242 (80)
Cholesterol (mmol/L)	High	59 (19)
HDL cholesterol (mmol/L)	Low	21 (7)
VLDL cholesterol calculation (mmol/L)	High	20 (7)
Triglycerides	High	0
Apolipoprotein A1	High	0
Apolipoprotein B	High	0
Free fatty acids	High	ND
LDL cholesterol - low density lipoprotein cholesterol; HDL cholesterol – high density lipoprotein cholesterol VLDL cholesterol – very low density lipoprotein cholesterol; ND – not determined		

Summary of Change in Subject Weight From the AVA100193 Baseline to Week 72 (Week 48 in AVA100468) (Safety Population in AVA100193 and All Subjects Population in AVA100468)					
Subject Visit in AVA100193	n and change in body weight ¹	Placebo (N=124) n (%)	RSG 2mg (N=128) n (%)	RSG 4mg (N=131) n (%)	RSG 8mg (N=135) n (%)
Baseline	n	124	128	131	135
	High	0	0	0	0
	Low	0	0	0	0
Week 2	n	119	127	129	133
	High	0	2 (2)	1 (<1)	1 (<1)
	Low	1 (<1)	0	2 (2)	0
Week 8	n	118	125	125	127
	High	0	2 (2)	0	3 (2)
	Low	2 (2)	0	1 (<1)	0
Week 16	n	109	114	119	120
	High	1 (<1)	5 (4)	7 (6)	6 (5)
	Low	2 (2)	1 (<1)	5 (4)	2 (2)
Week 24	n	106	110	114	113
	High	4 (4)	7 (6)	7 (6)	16 (14)
	Low	1 (<1)	2 (2)	7 (6)	3 (3)
Any AVA100193 visit post baseline and up to Week 24	n	123	128	131	135
	High	4 (3)	15 (12)	9 (7)	21 (16)
	Low	7 (6)	2 (2)	11 (8)	4 (3)
Weeks of Treatment (Subject Visit in AVA100468)	n and change in body weight ¹	RSG 8mg N=337 n (%)			
Week 32 (Week 8)	n	323			
	High	10 (3)			
	Low	2 (<1)			
Week 40 (Week 16)	n	316			
	High	15 (5)			
	Low	3 (<1)			
Week 48 (Week 24)	n	304			
	High	17 (6)			
	Low	7 (2)			
Week 56 (Week 32)	n	293			
	High	17 (6)			
	Low	11 (4)			
Week 64 (Week 40)	n	282			
	High	27 (10)			
	Low	13 (5)			
Week 72 (Week 48)	n	275			
	High	29 (11)			
	Low	14 (5)			
Any AVA100193 visit post baseline and up to Week 72	n	335			
	High	49 (15)			
	Low	39 (12)			
1. High – Subjects with ≥7% increase in body weight; Low – Subjects with ≥7% decrease in body weight					

Conclusion: Due to the non-randomized study design, these results are exploratory and can only be hypothesis generating. They should be interpreted with caution, and are not intended to guide clinical management of patients with Alzheimer's disease. The Re-consented Pharmacogenetics population in this study was also only 50% of those who consented in AVA100193.

A total of 163 subjects (48%) experienced any non-serious AE and the most frequent AEs were oedema peripheral, nasopharyngitis, anaemia and headache. A total of 26 subjects (8%) experienced any non-fatal SAE and the only SAE reported by more than one subject was femur fracture (2 subjects; 1%). Four subjects (1%) experienced a single fatal SAE which was either: Death Nos; Hepatic function abnormal; Ischaemic stroke or Possible bacterial pneumonia.

Publications: The efficacy and safety results of the first 24 weeks of treatment in the AVA100193 study are summarised in the following publication:

Risner ME, Saunders AM, Altman JFB, Ormandy GC, Craft S, Foley IM, Zvartau-Hind ME, Hosford DA, Roses AD. Efficacy of rosiglitazone in a genetically defined population with mild-to-moderate Alzheimer's disease. The Pharmacogenomics Journal 2006; 6: 246-254.

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