CoCensys

PROTOCOL 1042-0112

INCLUSION CRITERIA
VISIT 1 - SCREENING

SITE NUMBER: 0 1

SUBJECT INITIALS: J A C

BIRTH DATE: 6 2 (year) 0 6 (month) 1 8 (day)

FORM: I/E

INCLUSION CRITERIA: *If any answer to questions 1-11 is NO, the subject must be excluded from the clinical investigation.*

		YES	NO
1.	Subject is a pre-menopausal female between 18 and 55 years of age (inclusive).	☑	☐
2.	Subject is medically stable and in good health as determined by medical history, physical examination, vital signs, 12-lead ECG, and laboratory evaluation.	☑	☐
3.	Subject has had a neurologic examination that is considered to be within normal limits, and Subject is without a defined neurologic disorder other than migraine headaches.	☑	☐
4.	Subject is either practicing effective birth control (using the same method for the past 3 months), or is surgically sterilized; if a hysterectomy has been performed, Subject's ovaries remain intact.	☑	☐
5.	Subject has had a negative urine pregnancy test, and is currently not lactating. (Note: a negative *serum* pregnancy test is also required, and results must be obtained prior to randomization.)	☑	☐
6.	Subject has a measured supine diastolic blood pressure (after being supine for 5 minutes) of less than 95 mm Hg, but greater than or equal to 65 mm Hg.	☑	☐
7.	Subject's body weight is within 15 % of normal for sex, height, and body frame, as specified by the Metropolitan Life Insurance table *Ideal Body Weight Nomogram* (see Protocol, Appendix 11.9).	☑	☐
8.	Subject is able to communicate effectively with the study personnel, and is able to follow protocol procedures.	☑	☐
9.	Subject is properly informed of the nature and risks of the clinical investigation, and has given informed consent in writing prior to entering the clinical investigation.	☑	☐
10.	Subject is able to devote the necessary time to comply with all of the visit schedules for this study, to complete all tests related to safety and efficacy, and participate for the full term of the clinical investigation.	☑	☐
11.	Subject is asymptomatic at Screening, but has a 6-month or greater history of 1-8 moderate to severe migraine headaches per month, with or without an aura, as defined by the International Headache Society diagnostic criteria (see Protocol, Appendix 11.2).	☑	☐

Complete the following calculation, excluding the number of mild migraines:

Average number of each migraine type *per month*

mild	moderate	+ severe	= total
0.0	0.1	+ 0.2	= 0.3

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EXCLUSION CRITERIA

VISIT 1 - SCREENING

SITE NUMBER: 0 1

SUBJECT INITIALS: J A C

BIRTH DATE: 0 6 (year) 0 6 (month) 1 8 (day)

FORM: I/E

EXCLUSION CRITERIA: *If any answer to questions 1-14 is YES, the subject must be excluded from the clinical investigation.*

		YES	NO
1.	Subject requires the use of valproate, dihydroergotamine, or ergot preparations as a prophylactic agent (see Protocol for acceptable migraine prophylactic therapies).	☐	☑
2.	Subject is known to abuse drugs for the treatment of migraine headaches (i.e., Subject takes medication for acute migraine headache on more than 10 days per month).	☐	☑
3.	Subject presents with frequent chronic tension-type headaches (≥ 15 days/month) or is not able to distinguish between tension-type headaches and migraine attacks.	☐	☑
4.	Subject has a history of renal dysfunction, cardiovascular disease, or pulmonary disease.	☐	☑
5.	Subject is a known or suspected alcohol abuser or illicit drug user (at present or at any time within the past year); or Subject has had a positive urine drug screen.	☐	☑
6.	Subject has a history of liver disease, the diagnosis of cirrhosis by liver biopsy, or three of the following clinical signs of cirrhosis: • spider angiomata • palpable spleen or ascites • abnormal collateral veins on the abdomen • palmar erythema • firm, non-tender liver (with a nodular or irregular edge)	☐	☑
7.	Subject has previously tested positive for hepatitis, or has a history of hepatitis.	☐	☑
8.	Subject has either a history of a positive blood test for HIV, a history of risk factors associated with HIV infection, or is suspected of having an HIV infection.	☐	☑
9.	Subject is pregnant or lactating, or is of childbearing potential and fails to use adequate contraception or is judged to be unreliable in her use of contraception.	☐	☑
10.	Subject anticipates undergoing the implantation of a contraceptive device under the skin (e.g., Norplant), or a contraceptive injection (e.g., Depo-Provera) within 1 week prior to investigational product administration.	☐	☑
11.	Subject has exhibited AST, ALT, gGGT, Alkaline Phosphatase, or LDH values that are outside of the clinical laboratory reference range, and that are considered clinically significant by the Investigator.	☐	☑
12.	Subject has donated blood within 1 month prior to investigational product administration.	☐	☑
13.	Subject has used an investigational drug within the past month.	☐	☑
14.	Subject has previously participated in this clinical investigation.	☐	☑

INFORMED CONSENT OBTAINED: 1 9 9 7 (year) 0 3 (month) 1 0 (day)

PRINCIPAL INVESTIGATOR'S SIGNATURE — 1 9 9 7 (year) 0 3 (month) 1 3 (day)

C570812 G1 C1 S1 L3713

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LABORATORY REPORT
ACCESSION NO. C570812

INVESTIGATOR: (L3713)
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PROTOCOL: 1042-0112
INVESTIGATOR: 01
SUBJECT NUMBER: 0101 3/16/97
PATIENT INITIALS: JAC
VISIT: SCRN
Screening
COLLECTION TIME: 15:30 DATE: 10-Mar-97
DATE RECEIVED IN LABORATORY: 11-Mar-97
DATE REPORTED BY LABORATORY: 11-Mar-97
SEX: F BIRTHDATE: 18-Jun-62 AGE: 34

304 3267 071

				Clinical Significance No	Clinical Significance Yes	*Comments
CHEMISTRY						
Total Bili	0.5		0.2-1.2 mg/dL			
Alk Phos	65		31-110 U/L			
ALT (SGPT)	25		6-34 U/L			
AST (SGOT)	20		9-34 U/L			
Urea Nitr	9		4-24 mg/dL			
Creatinine	0.7		0.4-1.1 mg/dL			
Glucose	124	H	70-115 mg/dL	[✓]	[ ]	
Calcium	9.0		8.4-10.3 mg/dL			
Phosphorus	3.2		2.2-5.1 mg/dL			
Total Prot	7.0		6.1-8.4 g/dL			
Albumin	4.0		3.3-4.9 g/dL			
Cholest	231		140-261 mg/dL			
Triglycer	173		44-213 mg/dL			
LDH	189		53-234 U/L			
Sodium	143		132-147 mEq/L			
Potassium	3.8		3.4-5.4 mEq/L			
Chloride	112		94-112 mEq/L			
Bicarb	20.8		17.0-30.6 mEq/L			

*If Clinically significant, please comment.

Investigator's Signature: _____ Date 3/13/97

d="delta" significant change (+ or -) from patient's baseline
H(High) or L(Low)=Values above or below SciCor reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

L3713

(INV)

TESTING COMPLETE PROTOCOL: 1042-0112 INVESTIGATOR: 01
VISIT: SCRN