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JANSSEN-CILAG

Janssen-Cilag Pty. Ltd.
A.C.N. 000 129 975

00/388

Tuesday, 5 September 2000

SENT BY EXPRESS POST

EDG, Drug Safety and Evaluation Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

RE
08 SEP 2000
Drug Safety and Evaluation Branch

Dear Sir/Madam

Re: Clinical Trial Notification for Protocol RIS-AUS-9

I enclose a completed Clinical Trial Notification Form and TGA Credit Card Authorisation for $200.00 for the above mentioned trial. This is a single site study.

Please note that the original expected start date was 16/8/2000, the trial is now expected to start on the 14/9/2000

Should you require further information please contact me on (02) 8875 3218

I would appreciate formal TGA acknowledgment of the notification by fax on (02) 8875 3225.

Yours faithfully

Claire Methven

Claire Methven
Project Manager, Clinical Research

Enc: CTN Form
TGA Credit Card Authorisation

TGA BMD RECEIVED 08 SEP 2000

Telephone: (61 2) 8875 3333
Fax: (61 2) 8875 3500
Toll free: 1800 226 334

Locked Bag 2070, North Ryde NSW 1670, Australia
45 Khartoum Road, North Ryde NSW 2113, Australia

Therapeutic Goods Act 1989

00/388

TGA Therapeutic Goods Administration

Commonwealth Department of Health and Family Services

Clinical Trial of Drugs

DSEB 8.3 September 1997

Notification to the DRUG SAFETY AND EVALUATION BRANCH of an approval by a sponsor or other body or organisation to use a therapeutic good in a clinical trial:

- **under the Clinical Trial Notification (CTN) Scheme for Drugs; or**
- **at one or more additional sites for a Clinical Trial previously reported under the Clinical Trial Notification (CTN) Scheme for Drugs.**

Notification Type (Select One Only)

New CTN trial *(single site)*	X	Additional CTN site *(single)*	
New CTN trial *(multiple sites)*		Additional CTN sites *(multiple)*	

Use of Restricted Goods

Does this trial involve the use of any drug as an abortifacient or for "post-coital" or "emergency" contraception in women, or the use of a progesterone antagonist or a vaccine against human chorionic gonadotrophin for any purpose? Yes [ ] No [X]

Sponsor's Certification

I certify that all details contained within this form are true and accurate and that all required information and signatures have been included. The Sponsor named in Section 1 of this form is taking responsibility for the overall conduct of the trial.

Name (Print)	JANE VIERTEL	Position	CLINICAL RESEARCH MANAGER
Signature	6 / 7 / 00	Phone	(02) 8875 3336
		Fax	(02) 8875 3225

Office use only

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Commercial - in - Confidence

Clinical Trial of Drugs - Trial and Drug Details

Sponsor Details *(to be completed by sponsor)*

Sponsor's name: Janssen Cilag Pty Ltd

Enterprise ID code (If known):

2 Trial Details *(to be completed by sponsor)*

Protocol Number: RIS-AUS-9

If adding a Site - Clinical Trial Number:

Complete for a **New Trial** only: *(If notifying additional sites go to Section 4 "Site Details")*

Title and aim of Trial/Study: Second Generation Intervention Research in the Pre-Psychotic Phase of Illness in Schizophrenia and Related Psychoses. Version 26 July 2000

Trial Type: *(check one that is applicable or describe)*

Phase 1 [ ] Phase 2 [ ] Phase 3 [X] Bioavailability [ ] Other (describe) [ ]

This Trial: *(check any that are applicable)*

is placebo controlled [X]

involves gene therapy [ ]

is also being conducted in other countries [ ]

involves use of an unregistered device [ ]

Trial expected start: 16/08/2000

Trial expected completion: 01/ 01/2005

3 Drug Details *(to be completed by sponsor for a New Trial only) (list all drugs being trialled including all comparators)*

1 Active name: Risperidone

Trade name: Riperdal

Code name: R064766

Dosage form: Tablet

Strength: 0.5 - 2.0 mg

Biological origin [ ]

2 Active name:

Trade name:

Code name:

Dosage form:

Strength:

Biological origin [ ]

3 Active name:

Trade name:

Code name:

Dosage form:

Strength:

Biological origin [ ]

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Clinical Trial of Drugs - Trial and Drug Details

If there is more than one site, please complete a copy of this page for each site.

4 Trial Site Details *(to be completed by the sponsor)*

Site expected start: 14/09/2000 ~~16/ 08/2000~~

Site name: The PACE Clinic, Department of Psychiatry, University of Melbourne/MHSY

Site address: 35 Poplar Road, Parkville, Victoria

Postcode 3052

5 Ethics Committee Details *(to be completed by Ethics Committee responsible for monitoring trial)*

EC name: NORTH WESTERN MENTAL HEALTH BEHAVIOURAL & PSYCHIATRIC RESEARCH & ETHICS COMMITTEE

EC address: SUNSHINE HOSPITAL, 176-190 FURLONG RD. ST. ALBANS, VIC.

Postcode 3021

Ethics Committee Certification

I certify that the abovenamed Ethics Committee operates in accordance with the NH&MRC Statement on Human Experimentation and Supplementary Notes and has considered this clinical trial and provided advice to the body or organisation conducting the trial.

Name (Print): DR. TOM PEYTON

Position: CHAIRMAN

Signature: 01 09 00

Phone: 9365-1681

Fax: 9364-3792

6 Approving Authority Details *(to be completed by the body, organisation or institution approving the conduct of the trial at this site)*

Authority name: Professor Patrick McGorry

Authority address: PACE Clinic/MH-SKY, Locked Bag 10 Parkville 35 Poplar Rd Parkville Postcode 3052

Approving Authority Certification

I, the undersigned

- am authorised to represent the body, organisation or institution responsible for approving the conduct of the trial at the above named site;
- give approval in accordance with item 3 of Schedule 5A of the Therapeutic Goods Regulations for this trial to proceed; and
- undertake that the use of the drug will comply with all relevant Commonwealth and State or Territory legislation.

Name (Print): P.D. McGORRY

Position: Professor/Director

Signature: 14/9/00

Phone: 03 93422800

Fax: 03 93422941