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A phase II, dose ranging, multi-centre study to evaluate the safety and efficacy of combretastatin A4 phosphate for treating subfoveal choroidal neovascularization in subjects with pathologic myopia

Submission date 07/12/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 19/12/2006	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 08/08/2008	**Condition category** Eye Diseases	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.oxigene.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MMD-213

Study information

Scientific Title

Study objectives
To evaluate the safety and efficacy of three dose groups (27, 36 and 45 mg/m^2) of Combretastatin A4 Phosphate for the treatment of subfoveal Choroidal NeoVascularization (CNV) in subjects with pathologic myopia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Western Institutional Review Board, Local Institutional Review Boards, and the Food and Drugs Adminstration (FDA).

Study design
A phase II, dose ranging, multi-centre study

Primary study design
Interventional

Secondary study design
Multi-centre

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pathologic myopia; mypoic macular degeneration

Interventions
Combretastatin A4 Phosphate (CA4P) versus placebo

Intervention Type
Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)
Combretastatin A4 Phosphate

Primary outcome measure
Best corrected ETDRS visual function (visual acuity) as evaluated by a masked grader.

Secondary outcome measures
1. Fluorescein angiography as evaluated by a masked grader;
2. Optical Coherence Tomography (OCT) as evaluated by a masked grader.

Overall study start date
11/01/2004

Completion date
03/01/2007

Eligibility

Key inclusion criteria
1. Provide written informed consent
2. Be able and willing to follow instructions
3. Age 18 to 50 years old (inclusive)
4. Have area of choroidal neovascularization within 50 µm or under the geometric center of the foveal avascular zone
5. Have greatest linear dimension of lesion 5,400 µm or less, with more than or equal to 50% of the lesion composed of CNV (features which obscure the boundaries of the CNV such as blood, serous pigment epithelial detachment or blocked fluorescence must occupy less than 50%) as confirmed by Doheny Image Reading Center
6. Have best corrected distance visual acuity (Early Treatment Diabetic Retinopathy Study [ETDRS] chart) of 20/20 to 20/200 (LogMAR +0.0 to 1.0), inclusive in the qualifying eye(s)
7. Have pathologic myopia presenting 6.0 diopters or more correction required OR an axial length of the eye more than or equal to 26.5 mm
8. Be able and willing to avoid any medication that the Investigator feels may interfere with the study
9. If female and of childbearing potential; agree to submit a sample for pregnancy testing and have a negative pregnancy test within 1 day prior to each treatment. Females are considered of childbearing potential unless they are surgically sterile or post-menopausal for 12 months. Females of childbearing potential must agree to an approved form of contraception for the duration of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
23

Key exclusion criteria
1. Have contraindications, allergies or sensitivity to the use of the study medications
2. Have clinical signs or symptoms, in the opinion of the investigator, that may interfere with the study
3. Features of any condition other than pathologic myopia associated with Choroidal NeoVascularization (CNV), such as Age-related Macular Degeneration (AMD)
4. Have a tear of the retinal pigment epithelium
5. Have undergone ocular therapy/surgery or major surgery in the last three months or have any surgeries planned during the study period
6. Have any significant illness or condition, ocular or systemic that could, in the opinion of the investigator, be expected to interfere with the study
7. Have angina (stable or severe, even if controlled with medications), six months s/p myocardial infarction, Congestive Heart Failure (CHF), history of or presence of any clinical significant supraventricular or ventricular arrhythmias or syncope episodes
8. Have Electrocardiogram (ECG) with QTc more than 450 msec or other clinically significant abnormalities such as left bundle branch block, left ventricular hypertrophy, etc.
9. Have uncontrolled QTc prolongation
10. Take any drugs(s) known to prolong the QTc interval however subject can remain eligible if a non-QTc substitute can be administered
11. Have uncontrolled hypertension (defined as blood pressure consistently greater than 150 /100 mmHg irrespective of medication)
12. Uncontrolled hypokalemia and/or hypomagnesemia
13. Have symptomatic peripheral vascular disease or cerebrovascular disease
14. Have psychiatric disorders or other conditions rendering subjects incapable of complying with the requirements of the protocol
15. Be receiving concurrent hormonal therapy with exception of GnRH agonists in subjects with hormone refractory prostate cancer, Hormone Replacement Therapy (HRT), oral contraceptive, and megestrol acetate used for anorexia/cachexia
16. Be receiving anticoagulation with warfarin, heparin or low molecular weight heparin other than low dose (1 mg) warfarin for maintenance of Hickman line patency
17. Be a woman who is currently pregnant, nursing, or planning a pregnancy; or woman who has a positive pregnancy test
18. Have participated in an investigational drug or device trial within 30 days of entering the study

Date of first enrolment
11/01/2004

Date of final enrolment
03/01/2007

Locations

Countries of recruitment

Canada

Russian Federation

Taiwan

United States of America

Study participating centre
Vitreoretinal Consultants
Houston
United States of America
77030

Sponsor information

Organisation
Oxigene (USA)

Sponsor details
230 Third Avenue
Waltham
United States of America
02451

Sponsor type
Industry

ROR
https://ror.org/00cj7p033

Funder(s)

Funder type
Industry

Funder Name
Oxigene (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration