ISRCTN81721411 https://doi.org/10.1186/ISRCTN81721411

A Phase II, open-label study to evaluate the safety, tolerability, and pharmacokinetic profile of Proxinium™ in patients with recurrent squamous cell carcinoma of the head and neck who have received at least one prior anti-cancer treatment regimen for recurrent disease

Submission date
06/04/2006

Recruitment status
Stopped

Registration date
17/08/2006

Overall study status
Stopped

Last Edited
28/01/2019

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00272181

Protocol serial number
VB4-845-01-IIA

Study information

Scientific Title
A Phase II, open-label study to evaluate the safety, tolerability, and pharmacokinetic profile of Proxinium™ in patients with recurrent squamous cell carcinoma of the head and neck who have received at least one prior anti-cancer treatment regimen for recurrent disease

Study objectives
To evaluate the safety, tolerability and pharmacokinetic profile of Proxinium™ in patients with recurrent Squamous Cell Carcinoma of the Head and Neck (SCCHN).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Institutional Review Boards at various Universities, Hospitals and Clinics in North America, also approved by the Food and Drug Administration on 17/11/2005 (reference number: 12610).

Study design
Multicenter open-label safety study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Squamous Cell Carcinoma of the Head and Neck

Interventions
Proxinium™ injected intratumorally weekly.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Proxinium¿

Primary outcome(s)
Determine safety, tolerability and pharmacokinetic profile of Proxinium™ in SCCHN patients.

Key secondary outcome(s)

1. Tumour response rates
2. Time to progression
3. Overall Survival
4. Progression free survival associated with intratumoral injection of Proxinium™

Completion date
30/11/2006

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. The patient must have histologically confirmed SCCHN
2. The patient must have immunohistochemically confirmed Epithelial Cell Adhesion Molecule (Ep-CAM)positive SCCHN
3. The patient must have received therapy for their primary disease (i.e., SCCHN) consisting of radiotherapy with or without surgery and with or without chemotherapy
4. Patients must have progressed on or after receiving at least one prior anti-cancer treatment regimen containing one or more anti-cancer agents (e.g., chemotherapy, biologic therapy, or photodynamic therapy) for their recurrent disease
5. The patient must have fully recovered or reached a stable state of symptomatology from any previous treatment-related toxicity
6. The patient must have at least one accessible target tumor without direct carotid artery involvement (ie, a distance of less than 5 mm between a tumor and carotid) and must be likely to retain study drug

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. The patient has known brain tumor or brain metastases
2. The patient has nasopharyngeal SCCHN
3. The patient has concurrent or documented history of any one of the following:
a. Human Immunodeficiency Virus (HIV)
b. Hepatitis C virus
c. Hepatitis B surface antigen
4. The patient has uncontrolled bleeding from any target tumor(s) that are being considered for Proxinium™ treatment
5. The patient has a history of tumor hemorrhage that has required medical intervention (other

than direct compression)
6. The patient is a candidate for surgical tumor resection of their target tumor(s)
7. The patient is pregnant or lactating
8.The patient has clinically significant renal or hepatic disease
9. The patient requires regular use of aspirin, full-dose warfarin, or heparin. Use of low-dose agents to maintain patency of vascular catheters is allowed

Date of first enrolment
16/12/2005

Date of final enrolment
30/11/2006

Locations

Countries of recruitment
Canada

United States of America

Study participating centre
4009 Banister Lane
Austin
United States of America
78704

Sponsor information

Organisation
Viventia Biotech Inc (Canada)

ROR
https://ror.org/0440s3562

Funder(s)

Funder type
Industry

Funder Name
Viventia Biotech Inc (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration