10.0 RESULTS

Table 1A
Occurrence of tumours in test article and negative control mice

Test article mouse	Tumour	Euthansia d.p.i.
Animal # 1	^	^0
Animal # 2	none observed	84
Animal # 3	none observed	84
Animal # 4	none observed	84
Animal # 5	none observed	84
Animal # 6	none observed	84
Animal # 7	none observed	84
Animal # 8	none observed	84
Animal # 9	none observed	84
Animal # 10	none observed	84

^ Mouse died during the inoculation procedure.

Negative Control mouse	Tumour	Euthanasia d.p.i.
Animal # 1	none observed	84
Animal # 2	none observed	84

d.p.i. = days post inoculation

Table 1B
Histopathological examination of negative control mice [A]

Negative Control Mice	Tissues	Observations
Animal # 1	Lungs and muscle from inoculation site	No tumours detected
Animal # 2	Muscle from inoculation site	No tumours detected
	Lung	No tumours detected Focus of pigmented macrophages

[A] Based on non-audited histopathological results

Table 1C
Histopathological examination of test article mice [A]

Test article mouse	Tissues	Observations
Animal # 1	^	^
Animal # 2	Lungs and muscle from inoculation site	No tumours detected
Animal # 3	Lungs	No tumours detected Chronic active perivasculitis with associated alveolar macrophage accumulation *
	Muscle from inoculation site	No tumours detected Mild multifocal perivasculitis *
Animal # 4	Lungs and muscle from inoculation site	No tumours detected
Animal # 5	Lungs and muscle from inoculation site	No tumours detected
Animal # 6	Lungs and muscle from inoculation site	No tumours detected
Animal # 7	Lungs and muscle from inoculation site	No tumours detected
Animal # 8	Lungs and muscle from inoculation site	No tumours detected
Animal # 9	Lungs and muscle from inoculation site	No tumours detected
Animal # 10	Lungs and muscle from inoculation site	No tumours detected

[A] Based on non-audited histopathological results
^ Mouse died during the inoculation procedure.
*The findings in animal # 3 were considered within the normal range of spontaneous lesions seen in mice of this age and strain.

Table 2A
Occurrence of tumours in positive control mice

Positive control mouse	Tumour	Euthanasia d.p.i.
Animal # 1	none observed	84
Animal # 2	observed	84
Animal # 3	none observed	84
Animal # 4	observed	84
Animal # 5	observed	84
Animal # 6	observed	84
Animal # 7	observed	84
Animal # 8	observed	84
Animal # 9	observed	84
Animal # 10	observed	84

d.p.i. = days post inoculation

Table 2B
Histopathological examination of positive control mice [A]

Positive control mouse	Tissue	Observations
Animal # 4	Site of inoculation	Carcinomas consistent with those induced by administration of HeLa cells.
	Lung	No abnormalities detected
Animal # 6	Site of inoculation	Carcinomas consistent with those induced by administration of HeLa cells.
	Lung	No abnormalities detected
Animal # 7	Site of inoculation	Carcinomas consistent with those induced by administration of HeLa cells.
	Lung	No abnormalities detected

[A] Based on non-audited histopathological results

11.0 STUDY DIRECTOR STATEMENT

This study was conducted in accordance with the Principles of Good Laboratory Practice, as described in Good Laboratory Practice Regulations 1999 (Statutory Instrument 1999 No. 3106). These regulations are in conformance with European Directives 87/18/EEC, 88/320/EEC, 90/18/EEC, 99/11/EC, 99/12/EC and subsequent amendments.

The study was conducted in accordance with the principles of the United States Federal Register, Title 21 Code of Federal Regulations Part 58, and subsequent amendments, issued by the Food and Drug Administration. The reported results completely and accurately reflect the raw data of the study.

The phase of the studies delegated to Principal Investigators were as follows:

Preparation of wax blocks and slides from these wax blocks was performed by Colin Russell, CCRM Biotech Ltd.

Histopathological examination of slides was performed by, Alys Bradley, Charles River Laboratories.

P L Rooney

Paul Rooney, Study Director

28 FEB 06

Date

12.0 QUALITY ASSURANCE STATEMENT

The execution of this type of short-term study is not individually inspected. The procedures involved are inspected at intervals according to a pre-determined schedule. This report has been audited by Quality Assurance and has been found to accurately reflect the methods and procedures used in the study. The reported results accurately reflect the raw data of the study.

AM 27 Feb 06

Quality Assurance Date

As part of the predetermined schedule the following audits were performed.

Audit date	Step	Report date
15 Dec 05 - 19 Dec 05	Test system preparation.	19 Dec 05
15 Dec 05 - 19 Dec 05	Administration of test article to test system.	19 Dec05
24 Jan 06 - 30 Jan 06	Manipulation of test system.	30 Jan 06
15 Dec 05 - 19 Dec 05	Observation of test system	19 Dec 05

During the course of this study the following audits were performed.

27 Jul 05	Protocol approval	27 Jul 05
22 Feb 06- 23 Feb 06	Draft report and raw data audit	28 Feb 06

13.0 RECORD MAINTENANCE

All protocols, raw data and a copy of the Final Report are retained for BioReliance by:

Iron Mountain
260 Helen Street
Glasgow
G51 3LJ
Scotland

Responsibility for maintaining samples of the test article rests solely with the sponsor.

14.0 TESTING FACILITY

Responsibility for maintaining samples of the test article rests solely with the sponsor.

The *in* vivo testing facility and address of the Study Director is:

BioReliance
Pentlands Science Park
Bush Loan
Penicuik
Edinburgh
EH26 0PZ
Scotland

15.0 TEST SITES

The test site and address of the Principal Investigator for the delegated phase, preparation of wax blocks and subsequent preparation of slides was:

CCRM Biotech Ltd
Unit 16
Cromarty Campus
Rosyth Europak
Rosyth
Fife
KY11 2WX
Scotland

The test site and address for the Principal Investigator for the delegated phase, histopathological examination was:

Charles River Laboratories
Preclinical Services Edinburgh Ltd.
Elphinstone Research Centre
Tranent
EH33 2NE
Scotland, UK

研究成果の刊行に関する一覧表

発表者氏名	論文タイトル名	発表誌名	巻号	頁	出版年
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