



Today's Discoveries . . . Tomorrow's Medicines

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The Sunshine Project
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To whom this may concern:

As the newly appointed Institutional Biosafety Committee chairman and contact person, the issue of response to the Sunshine Project request for meeting minutes is my responsibility. I am attaching meeting minutes for 2003 and 2005, the last two formal meetings of the NewLink Genetics Institutional Biosafety Committee. No meetings were held in 2004 and 2006 since the only IBC business would have been annual renewals of previously approved, and unamended, research and such renewals were approved without full committee review.

As can be seen from the meeting minutes, the approved projects typically examined effects of cellular vaccines (incorporating a single genetic insertion) in animal models. During the period from 2003-2006 NewLink Genetics did have additional research projects (all research involving animals) that were conducted in various facilities of the Iowa State University of Ames, IA. All such experiments conducted on the ISU campus were done under the authority of the ISU IBC and underwent mandatory approval and annual renewal procedures as determined by the ISU IBC. The Sunshine Project has requested and was issued copies of those ISU IBC meeting minutes.

I am unaware if the Sunshine Project would have additional requests for information regarding NewLink Genetics' IBC but any such inquiries, if directed to me, will receive the required response in a more timely manner.

Sincerely,

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IBC Meeting October 21, 2003

Medical Oncology and Hematology Associates
1221 Pleasant Street, Suite 490
4th floor of John Stoddard Cancer Center

Application for Use of Recombinant DNA, Infectious Agents or Toxins

Project Title:

A phase I/II study of an antitumor vaccination using α (1,3) galactosyltransferase expressing allogenic tumor cells in patients with relapsed or refractory breast cancer.

Review of clinical protocol NLG-0102

Members present: Julie Ballard, Jane Bradley, Ann Herring, Carma Herring, Dean Hoganson, Isabelle Lutziger, Tatiana Seregina and Robert Unfer

Guest speaker: Lucy Tennant

Members Missing: Dawn Bertrand

- 4:05pm Welcome by Tatiana Seregina
Invites everybody to visit NewLink Genetics
Invites members to recruit for interims and graduate students to work at NewLink Genetics
- 4:10pm Tatiana Seregina introduces the company:
- the founders
 - the goal: to become a vertically integrated pharmaceutical company
 - main focus: Cancer
 - 1st drug: HyperAcute Vaccine
 -
 - introduces Genomavir
- 4:15pm IBC:
- talks about IBC
 - voluntary compliance with NIH Guidelines for Research Involving Recombinant DNA Molecules
- 4:20pm
- 1st employee got hired in April 2000, right now there are 33 employees
 - trained in universal precautions
 - need sketches/CV from all members to be mailed to Isabelle Lutziger
 - announces provisional chair: Jane Bradley
 - chair will be elected once the members got to know each other
 - Tatiana Seregina and Isabelle Lutziger will never be voting

- 4:25pm
- Talk about first drug:
 -
 - xenotransplantation: patients were given mouse cells
 - > strong immuno-response
 - take pig heart into baboon -> heart destroyed in 20 minutes
 - all higher primates lost alpha-gal gene
 - but alpha-gal consists of about 1% of total antibodies in human
 - this is why heart pigs get rejected: hyperacute reaction
- 4:30pm
- Lab animal experiments
 - knockout-mice (without alpha-gal)
 - RRBC immunization
 - Hyperacute results
 - Hyperacute Vaccine
 - Make human cancer cells which look like mouse cells
 - Irradiated cells
- Lead Product:
- applicable to most cancers
 - potent response: cell mediated tumor response
 - highest circulating antibodies in humans
 - low toxicity expected (toxicity studies in animal performed)
 - tailored to group of cancers
 - potential as adjuvant therapy
- 4:45pm
- Question by Jane Bradley:
- Control group?
- Answer: No control group, not possible (phase IV stage cancer patients)
- 4:45pm-
4:55pm
- Safety Program at NewLink Genetics (9 slides) presented by Isabelle Lutziger
- 4:55pm
- Tatiana Seregina introduces Lucy Tennant
Lucy Tennant presents:
Summary of protocol:
- Eligibility
 - Vaccine given intradermally
 - Injection 4 times, once every 4 weeks
 - Lethally irradiated cells
- Biosafety Training for Clinical Research Staff:
- all personnel
 - universal precautions
 - sharps disposal; biohazard waste in biohazard bags
 - expectations: work safely, follow NLG-1-2 protocol, practice universal precautions, proper disposal of vaccine
- Clinical Considerations:

- internal medical exposure control procedures would be followed in case of accidental needle stick occurrence

5pm:

Question by Carma Herring: Volume of vaccine?

Answer by Tatiana Seregina: always 1 ml, different concentrations

Consent: need good trained nurses or doctors for intradermal injections.

5:05pm

Question by Carma Herring: What exactly are we voting about?

Answer by Tatiana Seregina: About safety of product.

Occlusive Bandage: Biosafety concern, maybe better no bandage, otherwise biosafety at home of patient needed.

Question by Julie Ballard: How effective is irradiation?

Answer by Tatiana Seregina: guaranteed 100%, all cells are killed, all virus and everything is killed.

Question by Julie Ballard: where the cells come from?

Answer by Tatiana Seregina: Established cell lines,
tested for HIV, Hepatitis B, C and are negative

which are

Question by Jane Bradley: Done in lots?

Tatiana: inject with virus -> sort for alpha-gal positive cells

→ master cell bank 1×10^9 in 100 vials

→ working cell bank

→ production lots

Both master cell bank and production lots are extensively tested

5:15pm

Jane Bradley counts the votes: 6 yes, 0 no

5:16pm

Tatiana Seregina thanks and reinvites everybody to visit NewLink Genetics

Institutional Biosafety Committee Meeting Minutes

NewLink Genetics Corporation

January 13, 2005

Present:

Dawn Bertrand, IBC Committee Administrator, NLG Biosafety Officer, IBC Animal Expert
 Tatiana Seregina, Ph.D., D. Sci., V.P. for Clinical and Regulatory Affairs, NLG IBC Human Gene Transfer Expert
 Jane Bradley, IBC Chair
 Dean Hoganson, Scientific Member

Robert Unfer, Scientific Member
 Ann Herring, Scientific Member

Not Present:

Julie Ballard, IBC Community Member

Time Called to Order: 2 p.m.

Time Adjourned: ~ 3:00 p.m.

Location: Conference Room, Medical Oncology and Hematology Associates, 1221 Pleasant Street, Suite 490, 4th Floor, John Stoddard Cancer Center

Prepared By: Dawn Bertrand

AGENDA ITEM	DISCUSSION	ISSUE/ACTION/MOTION	NEXT FOLLOW-UP DEADLINE & WHO
Approval of October 21, 2003 Meeting Minutes	Minutes from the Biosafety meeting held on October 21, 2003 were distributed for review.	Approved as written	Minutes from prior meetings will be presented and approved at the beginning of every meeting
IBC Membership and terms of appointment/Introduction to new Biosafety Officer/IBC Administrator	Tatiana summarized and reconfirmed the terms of commitment for Committee members and then introduced Committee members to Dawn Bertrand, who is presently serving as the NewLink Genetics Biosafety Officer/ IBC Administrator	Committee members will inform the IBC Coordinator if they can no longer serve.	None
Overview of NLG Clinical Trials	Tatiana gave an overview of the progress of Phase I clinical trials currently being conducted in the cancer vaccine trials for Lung, Breast, Melanoma, Prostate and Pancreatic cancer. She stated that since patients have so many standard treatment options recruitment and subsequent eligibility can be very difficult. This has presented some patient recruitment challenges but she was optimistic for the new year of 2005.	None	Overviews and updates will be provided at each IBC meeting.

AGENDA ITEM	DISCUSSION	ISSUE/ACTION/ MOTION	NEXT FOLLOW-UP DEADLINE & WHO
IBC Annual Report	Dawn Bertrand reviewed NewLink's Annual IBC Report that was received and approved by the NIH Office of Biotechnology Activities.		Annual reports will be updated and submitted to NIH each year
Safety Program at NLG	Dawn Bertrand presented NewLink's present safety training program which consisted of lectures and video viewing. All training obligations have been completed.	Dawn is looking at updating the training program by adding a module on animal allergens and animal related safety issues	Safety program updates will be summarized and presented to the Committee each year
Review/Discussion of Applications for Use of Recombinant DNA, Transgenic Animals	The following applications were reviewed and discussed during the session:		
Annual Renewal	"HyperAcute Breast Cancer Vaccine Trial" by Roscoe Morton, M.D.	Approve as written	An annual renewal application will be filed each year
New Application	"Breeding Colony Protocol for Alpha 1,3 –Galactosyltransferase Knockout Mice" by Gabriela Rossi, Ph.D.	Approval was suspended pending the revision of the application to reflect an "NA" option for the question asking whether foreign gene expression will be attempted and what proteins, if any, will be produced.	The application will be revised and this project will be resubmitted.
New Application	"Study for the Efficiency of Vaccination and Toxicity Using Alpha Gal Expressing Vaccines in Murine Models for Human Cancers" by Gabriela Rossi, Ph.D.	Approval was suspended pending the revision of the application to reflect an "NA" option for the question asking whether foreign gene expression will be attempted and what proteins, if any, will be produced.	The application will be revised and this project will be resubmitted
New Application	"General Safety Testing of Production Lots of Allogeneic Vaccines For Clinical Use" by Henry Lejukole, Ph.D.	Approval was suspended pending clarification of the site away from the animal lab where contaminated materials will be decontaminated. The Committee has also requested copies of QC validation records from the lab autoclave and SOP's for Biohazardous waste disposal.	This project has been suspended until Spring 2006
New Application	"Study on the Tumorigenicity of Human Cancer Cell Lines in the Xenotransplanted Athymic Nude Mouse Model" by Henry Lejukole, Ph.D.	Approved as written	An annual renewal application will be filed each year
New Application	"In Vivo Test for the presence of Inapparent Viruses in Human Cell Lines" by Henry Lejukole, Ph.D.	Approved as written	An annual renewal application will be filed each year
New Application	"In Vivo Tests for the Presence of Inapparent Viruses" by Chilly Chung, Research Associate	Approval suspended pending clarification of liquid waste disposal by submission of waste disposal SOP's and description of availability of vaccines to personnel.	

New Application	"Functional Proteomics (Genomavir)" by Won Bin Young, Ph.D.	Approved as written	An annual renewal application will be filed each year
New Application	"Cancer Vaccine" and "Anti-Virus Vaccine" by Won-Bin Young, Ph.D.	Approved as written	An annual renewal application will be filed each year
New Application	"Development of an HIV-1 Vaccine" by Mario Mautino, Ph.D.	Approval suspended pending clarification of the term "BL3 safety practices" for a BL2 rated project and a better description of the bleach decontamination procedure and validation procedures post solution treatment	
New Application	"Use of HIV-1 Derived Vectors for Gene Transfer and gene Expression" by Mario Mautino, Ph.D.	Approval suspended pending clarification of the term "BL3 safety practices" for a BL2 rated project and a better description of the bleach decontamination procedure and validation procedures post solution treatment	
New Application	"Use of Recombinant Adenoviral Vectors to Express Proteins at High Levels" by W. Jay Ramsey, M.D., Ph.D.	Approval suspended pending clarification of waste disposal SOP's.	
Open Forum/ Meeting Conclusion	There were no further discussions. The meeting was adjourned ~3:00pm.		