



Lymphotoec, Inc.



Lymphotec, Inc.

Career summary of the president Teruaki Sekine

1967 - 1999 : Service at National Cancer Center

1972 - 1978 : Research on HB virus

1977 : Acquisition of Doctor of Medicine degree
at Tokyo University

1978 - 1980 : Study abroad to the immunology
laboratory at William Beaumont Hospital
in Michigan, U.S.A.

1981 - 1986 : Research on monoclonal antibody

1986 : Assumption of the chief of common
laboratory at National Cancer center

1987 - : Research on activated autolymphocyte therapy

Apr. 1998 - : Part-time lecturer at Faculty of Medicine,
Tokyo Medical and Dental University

Spt. 1998 - : Representative director of Research
Association for infectious disease cell
therapy

Mar. 1999 - : Compulsory retirement from National
Cancer Center

Till Mar. 1999 - : Director of Kitasato Institute (part-time)

Apr. 1999 : Establishment of Lymphotec, Inc.

Apr. 1999 - : Visiting professor at Nihon University
School of Medicine

Oct. 1999 - : Visiting professor at
Tokyo women's Medical University

Oct. 1999 : Winning of Tamiya Award (presented by
Foundation for Promotion of Cancer
Research)



Lymphotec, Inc.

Company Overview

Established	: April 26, 1999
President	: Teruaki Sekine
Capital	: ¥300 million
Employees	: 36 (as of March 2012)
Head Office	: 18-4 Fuyuki, Koto-ku, Tokyo, Japan
Stockholders	: Teruaki Sekine, Toyo Seikan Kaisha, Ltd. , Olympus Corporation, Wako Pure Chemical Industries, Ltd.
Area of Business	: Support of activated autolymphocyte therapy, out-licensing to overseas, development of cellular drugs, research reagents, sales of equipment, lymphocyte storage
Clients	: 52 medical institutions including: Hakusan-Dori Clinic, Tokyo Medical & Dental University Hospital, and Tokyo Women's Medical University Medical center East. INNOCELL Corporation (in South Korea)



Lymphotec, Inc.

History

- Apr. 1999 : Establishment of Lymphotec, Inc.
- May. 2000 : Adoption of commissioned development agenda from Japan Science and Technology Corporation (acquisition of development budget)
- Aug. 2000 : Research achievements on preventing liver cancer recurrence after surgery posted on “The Lancet”
- Apr. 2003 : Conclusion of joint research agreement on activated T cells with Tokyo Medical and Dental University
- Apr. 2005 : Conclusion of out-licensing agreement on activated lymphocyte culture with **INNOCELL Corp. in south Korea**
- Jan. 2006 : Obtainment of ISO 9001 certification, Quality Management Standard
- Aug. 2007 : INNOCELL’s clinical trial on activated lymphocyte against liver cancer approved by Ministry of Health and Welfare in South Korea
- Apr. 2011 : **Commencement of joint research with Toyo Seikan Kaisha, Ltd.**
- Apr. 2011 : **Submission of application for confirmation to the Ministry of Health, Labour and Welfare “Activated autolymphocyte preparations as a drug of preventing Glioblastoma recurrence”**
 - Sep.2011 : The above application for confirmation switched to **regulatory strategy consultation**



Specialized medical facility owned by Lymphotec, Inc.



Hakusan-Dori Clinic

Activated autolympocyte therapy hospital,
designated as the associated facility
of Tokyo Women's Medical University Medical Center East

Doctors / Kenji Ogawa, M.D., Ph.D.
Professor emeritus at Tokyo Women's Medical center East.
Tetsuro Kajiwara, M.D.
Professor at Tokyo Women's Medical center East.
Munetetsu Tei, M.D., Ph.D.
Professor at Nihon Pharmaceutical University.
Takeshi Shimakawa, M.D.
Department of Surgery, Tokyo Women's Medical Center East.

Cancer Treatment using activated autolymphocyte therapy

What is activated autolymphocyte (activated ALT) therapy?

Activated ALT is a form of immunotherapy that involves removal of lymphocytes from blood, stimulation of their growth and injection back into the body.

Activated ALT developed by
the President Teruaki Sekine, M.D., Ph.D.

① Blood withdrawal



② Cell culture



1000x lymphocytes

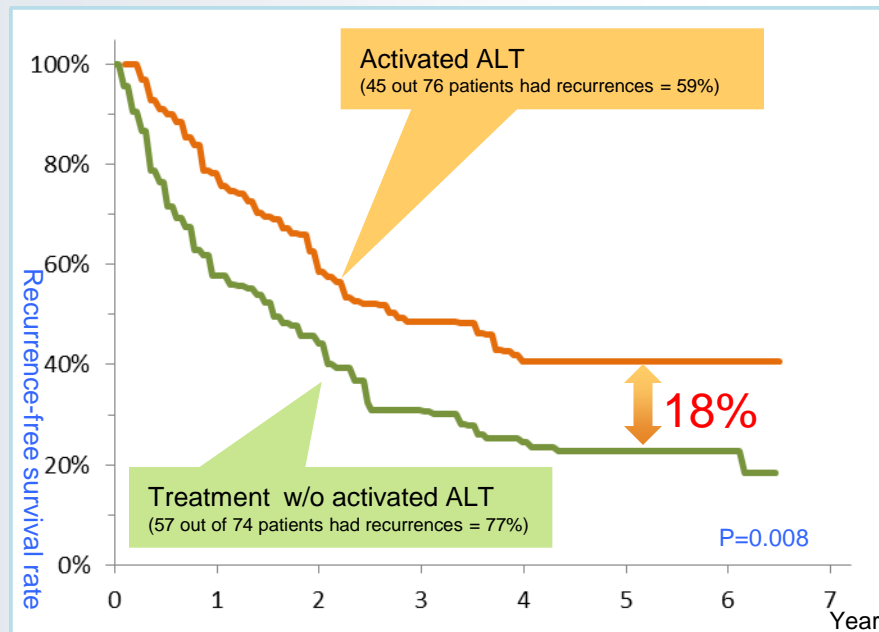
③ Drip



Activated autolymphocyte therapy -1-

Prevention of recurrence (1)

Recurrence-free survival rate/Result of clinical trial conducted at Miyagi Cancer Center in Japan.



Endpoints	Recurrence rate Rate of liver cancer recurrence after surgery	Time to recurrence Time to liver cancer recurrence after surgery
Activated ALT	59%	2.8 yrs.
Treatment w/o activated ALT	77%	1.6 yrs.
Comparison	18% decrease	+1.2 yrs.

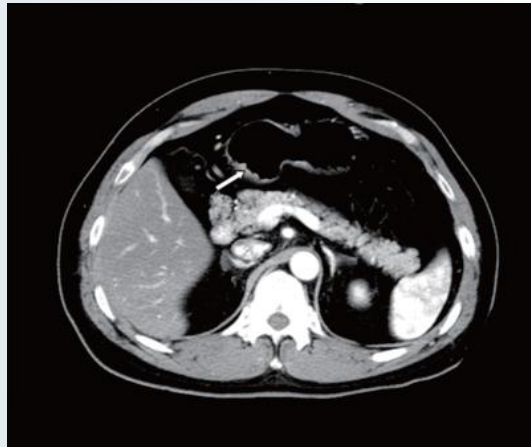
Appeared in the Lancet
356, 802-807 (2000)

Activated autolymphocyte therapy -1-

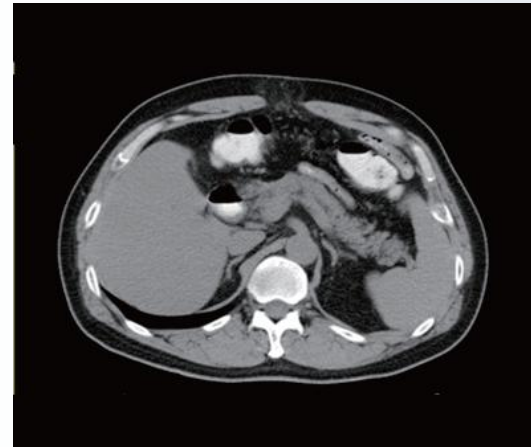
Prevention of recurrence (2)

Prevention of scirrhous gastric cancer recurrence

Before surgery (Feb. 2008)



After surgery (Oct. 2009)



Patient: Male, 44 years old, [scirrhous gastric cancer stage III with lymph node metastasis](#)
Began activated ALT right after surgery and continued it once a week for the earliest stage and once or twice a month currently. Chemotherapy underwent for a few months along the way.

Activated autolymphocyte therapy -2-

Infectious disease therapy

Virus infectious disease

Persistent herpes simplex and Epstein-Barr viruses infection
(Wiskott-Aldrich syndrome)



Before activated ALT



After four injections,
three weeks later

- Disease involving thrombocytopenia, eczema and immune deficiency.
- Immune deficiency syndrome with X-linked recessive inheritance.
- The causal gene is located on the short arm of the X chromosome.

Activated autolymphocyte therapy

Mechanism






Four key points of activated ALT

- Effective against cancers that grow slowly.
- Very minimal side effects.
- More effective when combined with other therapies.
- Memory T cells play a starring role.

Clinical trials

Clinical trials conducted in Japan

Five patients received activated ALT after removal of tumors (Glioblastoma) and observed catamnesis.

	Age / Sex	Catamnesis
	1. 38 / Female	13 yrs. 6 mo. / Survived
	2. 29 / Female	13 yrs. 9 mo. / Survived
	3. 49 / Male	3 yrs. 9 mo. / Died
	4. 58 / Male	3 yrs. 8 mo. / Died
	5. 40 / Male	6 yrs. 7 mo. / Survived

As of Dec.31, 2007, Miyagi Cancer Center

Three-year survival rate among patients suffered from highly-malignant brain is

23.8%

Due to activated ALT, three out of five patients were able to

inhibit recurrence equal to or more than five years.

Activated ALT is likely to be effective in inhibiting recurrence of brain tumors.

Clinical trials

Clinical trials conducted in South Korea

As Ministry of Health and Welfare in South Korea approved clinical trials in August 2007, INNOCELL Corp. began the trials.

Subjects: Liver cancer (ph III): 230 patients
Brain tumor (ph III): 180 patients

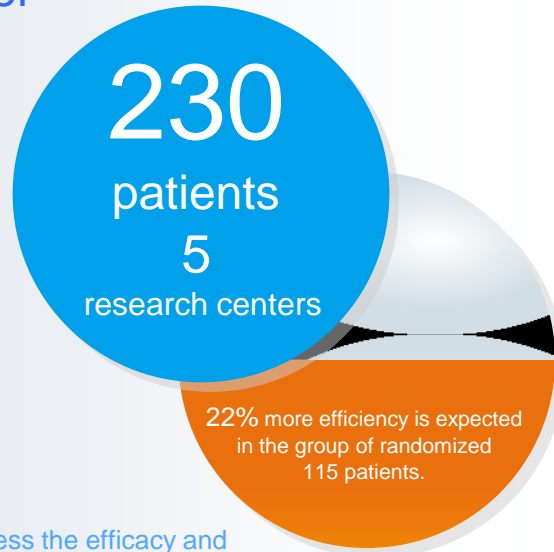
Period: July 2011 through December 2012

Expected to receive drug approval in December 2013.

Clinical trials

Clinical trials conducted by INOCELL Corp. in South Korea

Liver cancer



Clinic trial to assess the efficacy and safety of "INOCELL Immuncell-LC" in hepatocellular carcinoma patients



Seoul University Hospital
Samsung Seoul Hospital
Seoul Asan Medical Center
Korea University Guro/Ansan Hospital

Brain tumor



Clinical trial to assess the efficacy and safety of "INOCELL Immuncell-LC" with Temozolomide in glioblastoma patients



Yonsei Severance Hospital
Samsung Seoul Hospital
Seoul Asan Medical Center
Korea University Anam Hospital
Kyung Hee University Hospital
Konkuk University Hospital
Hanyang University Guri Hospital

Current anti-cancer drug therapy survival rate is at 10-20%
only one FDA Approved anti-cancer drug for Liver Cancer
(Nexavar- Bayer Schering)

Current average survival for glioblastoma is 14weeks
5 year survival rate is less than 2%

Thank you.