September 29, 2010

#### Eisai and Anaeropharma Science Conclude Agreements Concerning the Novel Anticancer Agent APS001 and a Drug Delivery System Using *Bifidobacterium Longum*

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") and Shinshu University venture company Anaeropharma Science, Inc. (Headquarters: Tokyo, President & CEO: Tetsuya Mishima, "Anaeropharma Science") today announced that they have concluded an option agreement concerning APS001, a novel anticancer agent currently under development at Anaeropharma Science that utilizes characteristic features of *Bifidobacterium longum*, as well as an agreement concerning the discovery of novel anticancer agents that utilize *Bifidobacterium* as a drug delivery system. The two contracts cover the development of drugs that utilize obligate anaerobes and nonpathogenic bacteria, traits which are characteristic of *Bifidobacterium*, a human intestinal tract bacterium. An overview of the two contracts follows.

### 1) An option agreement concerning APS001, a novel anticancer agent that utilizes the characteristic features of *Bifidobacterium*

Under the terms of the agreement, Eisai acquires the right of first review concerning the results of the Phase I clinical trials for the novel anticancer agent APS001, which are scheduled to be conducted in the United States by Anaeropharma Science, and the right of first refusal concerning the licensing of the compound under development. Eisai shall compensate Anaeropharma Science for these two priority rights.

## 2) A joint research agreement concerning the discovery of novel anticancer agent candidates that utilize characteristic features of *Bifidobacterium* as a drug delivery system

Under the terms of the agreement, the two companies shall conduct joint research regarding specific substances in order to discover novel anticancer agent candidates that utilize *Bifidobacterium* as a drug delivery system. Eisai shall bear the research expenses for the joint research and shall acquire the right of first refusal regarding the exclusive licensing necessary for commercialization based on the results of this joint research. Furthermore, regarding research that is not covered by this agreement, the agreement shall not constrain any research into delivery systems using *Bifidobacterium* that Anaeropharma Science conducts independently.

The purpose of these two agreements is to offer new treatment options to cancer patients and their families by establishing a new drug delivery system that utilizes characteristic features of *Bifidobacterium* and by researching new therapeutic treatments to succeed low-molecular compounds and biologics.

Eisai and Anaeropharma Science position oncology as a therapeutic area of focus and are committed to the development of novel anticancer agents and pharmaceuticals for supportive care. Through these efforts, the two companies seek to make further contributions to satisfying the diverse needs of patients, their families, and healthcare professionals while increasing the benefits provided to them.

# [Please see the following notes for further information on APS001, the *Bifidobacterium* drug delivery system, Anaeropharma Science and Eisai]

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#### **Notes to Editors**

#### 1. About APS001

A novel anticancer agent currently being developed by Shinshu University venture Anaeropharma Science, APS001 is a recombinant *Bifidobacterium* modified to express the cytosine deaminase (CD) gene. It is currently being investigated in preclinical studies as a novel anticancer agent with the potential to express anti-tumor effects when administered in combination with the antifungal agent 5-fluorocytosine (5-FC).

APS001 is administered by intravenous infusion, and selectively localizes to and proliferates in hypoxic solid tumors, resulting in the expression of the CD enzyme. When APS001 is administered in the presence of 5-FC, the CD enzyme expressed in solid tumors inherently facilitates the local conversion of 5-FC to 5-Fluorouracil (5-FU), an established anticancer agent, which results in the expression of anti-tumor effects. With preclinical studies having demonstrated that APS001 leads intratumoral 5-FU concentration to extraordinarily high levels not seen with other 5-FU-based drugs, the new drug is expected to offer increased anti-tumor effects.

#### 2. About the Bifidobacterium Drug Delivery System

The search for novel anticancer drug candidates that utilize *Bifidobacterium* as a Drug Delivery System (DDS) is aimed at establishing a protein delivery *Bifidobacterium* strain (novel anticancer drug candidate) capable of tumor selective delivery of candidate proteins using *Bifidobacterium* that selectively localizes to and proliferates in the hypoxic solid tumors environment. This kind of *Bifidobacterium* is expected to produce and secrete a high concentration of candidate proteins in targeted solid tumors.

Furthermore, Anaeropharma Science is now receiving funding from the Japan Science and Technology Agency and the New Energy and Industrial Technology Development Organization regarding a portion of the research described in 1 and 2 above.

#### 3. About Anaeropharma Science, Inc.

Corporate Name:	Anaeropharma Science, Inc.
Date of Establishment:	August 9, 2004
Capital:	100 million yen
Scope of Business:	Development of novel anticancer drugs and drug delivery systems that utilize <i>Bifidobacterium</i>
Representative:	Tetsuya Mishima, President & CEO
Number of Employees:	16
Headquarters:	2F, Yaesu Fuji Building,
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	Tokyo, JAPAN 103-0028
Laboratory:	7F, Shinshu University Asahi Life Science Building,
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	Nagano 390-8621 JAPAN

#### 4. About Eisai Co., Ltd.

Eisai Co., Ltd. is a research-based *human health care (hhc)* company that discovers, develops, and markets products throughout the world. Eisai focuses its efforts in three therapeutic areas: integrative neuroscience, including neurology and psychiatric medicines; integrative oncology, which encompasses oncotherapy and supportive-care treatments; and vascular and immunological reactions. Eisai contributes to the well-being of people around the world through a global network of research facilities, manufacturing sites and marketing subsidiaries. For more information about Eisai Co., Ltd., please visit www.eisai.co.jp/index-e.html.