

## News Release

### **Anaeropharma Science Initiates First-in-Human Trial of Novel Recombinant Bifidobacterial Anti-cancer Agent APS001F for Advanced Solid Tumors**

Tokyo, Japan -- March 28, 2013 -- Anaeropharma Science Inc. announced today that it has initiated a Phase I clinical trial of APS001F in patients with advanced solid tumors in the United States. The first-in-human dose-escalation trial enrolls patients with advanced and/or metastatic solid tumors whose disease is no longer considered responsive to available treatments. The trial is designed to evaluate safety, tolerability and efficacy of the study agent.

#### ***About APS001F***

APS001F is a living recombinant bifidobacterium to express the cytosine deaminase (CD) gene. Bifidobacterium is a non-pathogenic obligate anaerobe and a major component of normal human intestinal flora. It is well-known that the majority of human solid tumors contain hypoxic regions, mainly due to insufficient vascular formation. When APS001F is administered intravenously, APS001F localizes and grows in the hypoxic regions of tumors, which results in expression of the CD enzyme in tumors. 5-FC, a commercially available anti-fungal agent, which is administered orally, is converted to 5-FU, an active anti-tumor agent, by the CD enzyme expressed by APS001F in tumors. The novel therapy is expected to have the advantage of limiting the systemic toxicity of 5-FU due to the local formation of 5-FU in tumors. It also allows 5-FU to achieve high concentration in tumors, which results in clear anti-tumor efficacy.

#### ***About Tumor Hypoxia***

The majority of human solid tumors contain regions of acute or chronic hypoxia, mainly due to insufficient and unusual angiogenesis. Tumor hypoxia is a prognostic factor, commonly associated with aggressive tumor growth and poor survival rate. These microenvironments cause decreased uptake of chemotherapeutic drugs. Though many drugs and technologies exploiting tumor hypoxia have been explored in clinical trials, no effective anti-cancer drugs or methods based on tumor hypoxia have been developed to date. A critical factor in the success of this strategy is the need to develop adequate delivery of anti-cancer drugs targeting regions of tumor hypoxia. APS001F has great potential to achieve adequate delivery of the objective anti-cancer drug.

#### ***About Anaeropharma Science, Inc.***

Anaeropharma is a biopharmaceutical company engaged in research and development of drug candidates that target hypoxic microenvironments of tumors by using recombinant bifidobacterium. This approach offers broad potential to be more effective to solid tumors and less toxic to healthy tissues than conventional anti-cancer drugs. The fundamental technology to create such drug candidates was invented by researchers at Shinshu University, Nagano, Japan.

# Anaeropharma Science

*Source: Anaeropharma Science, Inc.*

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