

**FOR IMMEDIATE RELEASE:**

## **Agensys, an Affiliate of Astellas, Announces Initiation of Phase I Clinical Trial of AGS-16M8F for Renal Cancer**

Santa Monica, CA – September 1, 2010 – Agensys, Inc., an affiliate of Tokyo-based Astellas Pharma Inc., today announced that they have initiated a Phase I clinical trial of AGS-16M8F an antibody-drug conjugate (ADC) that is being developed for the treatment of metastatic renal cancer. An ADC uses the specific binding properties of an antibody to target a toxin in tumor cells, resulting in selective tumor cell killing.

“Despite the availability of several therapies for the treatment of metastatic renal cancer, there is a significant need for new renal cancer therapies,” said Leonard Reyno, M.D., Senior Vice President and Chief Medical Officer at Agensys. “We believe AGS-16M8F, which is an ADC designed to deliver the potent cytotoxic agent MMAF directly to tumor cells, has the potential to provide a new therapeutic option for this disease.”

The single-agent, Phase I, open-label, dose-escalation study will evaluate the safety and tolerability of AGS-16M8F in patients with renal cancer and identify the maximum tolerated dose. Secondary objectives include assessing the pharmacokinetics and antitumor activity of AGS-16M8F and identifying a recommended dose and regimen for future clinical trials. The study is designed to enroll approximately 50 patients at multiple centers in the United States.

Dr. David Stover, Vice President and Head of Research at Agensys, noted that AGS-16M8F is an ADC composed of a fully human monoclonal antibody directed to ectonucleotide pyrophosphatase/phosphodiesterase 3 (ENPP3), a novel cancer target identified by Agensys to be upregulated in the majority of renal cancers.

The antibody is attached to a highly potent, synthetic agent, monomethyl auristatin F (MMAF), via a non-cleavable linker using Seattle Genetics’ proprietary technology. The novel linker system is designed to be stable in the bloodstream and release the potent cell-killing agent once inside antigen-expressing cancer cells. This approach is intended to spare non-targeted cells and thus reduce many of the toxic effects of traditional chemotherapy while enhancing the antitumor activity.

### **About Renal Cancer**

The American Cancer Society estimates there to be more than 58,000 new cases of renal cancer and more than 13,000 are expected to die from the disease in the United States in 2010. Overall, the lifetime risk of getting renal cancer is about 1 in 70. This risk is higher in men than in women. Renal cancer is the 9<sup>th</sup> leading cause of cancer-related death for both men and women. The 5-year survival rates for people diagnosed with any stage of renal cancer is 68 percent.

### **About Agensys**

Agensys, Inc., an affiliate of Astellas Pharma Inc., is developing a pipeline of therapeutic fully human monoclonal antibodies (MAbs) to treat cancers. The MAb product pipeline is based on Agensys’ diverse portfolio of proprietary, clinically relevant cancer targets. Agensys’ target

portfolio and related products are protected by a large patent estate. The Company has full capabilities to generate, develop and manufacture antibody products. Agensys is progressing a pipeline of both naked and antibody-drug conjugated (ADC) therapeutic antibodies, directed at a variety of cancer indications, including those of the prostate, kidney, pancreas, ovary, bladder, lung, colon, breast and skin. ADC products are based on drug platform technologies developed by Seattle Genetics. Agensys is developing a growing pipeline of clinical stage functional MAbs and ADC products.

### **About Astellas**

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 15,000 employees worldwide. The organization is committed to becoming a global category leader by rapidly establishing a business model in urology, immunology & infectious diseases, neuroscience, DM complications & metabolic diseases and oncology. Astellas has discovered a treatment for over-active bladder (OAB), Vesicare<sup>®</sup> (solifenacin succinate) and an immunosuppressant, Prograf<sup>®</sup> (tacrolimus), which have enabled Astellas to become an established leader in both Urology and Transplant. For more information on Astellas Pharma Inc., please visit Astellas' website at <http://www.astellas.com/en>.

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