



### **Ambit Biosciences and Astellas Enter Strategic Partnership to Research, Develop and Commercialize FLT3 Kinase Inhibitors in Multiple Indications**

#### **Ambit to Receive a \$40 Million Upfront Cash Payment; Up to \$350 Million in Pre-Commercialization Milestones, Double-Digit Royalties with Option to Co-promote and Share Profits in U.S.**

**SAN DIEGO AND TOKYO, DEC. 18 /PRNEWSWIRE/** -- Ambit Biosciences Corporation and Astellas Pharma Inc. today announced that they have entered into a worldwide agreement to jointly develop and commercialize FLT3 kinase inhibitors in oncology and non-oncology indications. This partnership includes AC220, Ambit's lead clinical-stage investigational drug that entered into a Phase 2 clinical trial earlier this month in relapsed/refractory acute myeloid leukemia (AML), and other undisclosed FLT3 kinase inhibitors. AC220 is a novel, orally available, potent and highly selective small molecule that was specifically designed as a second generation FMS-like tyrosine kinase-3 (FLT3) inhibitor using Ambit's proprietary drug discovery engine, KINOMEscan(TM).

The companies will collaborate to develop AC220 for AML and other indications. The parties will also collaborate on a research and development program for a series of novel FLT3 inhibitors for a variety of oncology and non-oncology indications. The companies will share equally in the responsibilities and expenses for the development of AC220 and any additional products in the U.S. and Europe, while Astellas will have sole responsibility to fund development in all other territories. Under the terms of the agreement, Ambit will receive an up-front cash payment of \$40 million and will be eligible to receive pre-commercialization payments of up to \$350 million.

Astellas will have sole responsibility for funding and implementing the commercialization of all products, and Ambit will be entitled to post-approval milestone payments upon the achievement of certain sales thresholds, as well as tiered double-

digit royalties on net sales. In the U.S., Ambit will also have the option to co-promote AC220 and other products under a profit sharing arrangement where Astellas and Ambit share equally in profits and losses generated from U.S. sales.

"We are pleased to have entered into a great partnership with Ambit," stated Masafumi Nogimori, president and chief executive officer of Astellas. "We believe that AC220, as the most selective and advanced FLT3 kinase inhibitor, has the potential to provide a new treatment option for AML where high unmet medical needs exist. Astellas is strongly committed to focus on oncology and this partnership is a significant milestone to establish our franchise in oncology."

"With their strategic commitment to the development and commercialization of innovative oncology products, Astellas is an ideal partner for Ambit," said Scott Salka, Chief Executive Officer of Ambit Biosciences. "This collaboration establishes a comprehensive and global leadership position in the discovery and development of FLT3 kinase inhibitors, and we look forward to working closely with Astellas to explore the clinical utility of AC220 in AML and other indications."

#### **About AC220**

AC220, Ambit's lead product candidate, is being developed in collaboration with Astellas Pharma Inc. and is a novel, potent, highly selective, orally bioavailable second-generation FLT3 inhibitor. AC220 is currently under evaluation in a Phase 2 clinical trial designed to support potential registration of AC220 as monotherapy treatment in adult and elderly patients with relapsed/refractory AML that have the internal tandem duplication (ITD) mutation in the FLT3 kinase. AML is one of the most common types of blood cancers in adults, and the FLT3 kinase is mutated and constitutively activated in 25-40 percent of such patients. FLT3 ITD mutations predict poor prognosis and decreased response to existing treatments, including chemotherapy and hematopoietic stem cell transplant. Ambit leveraged KINOMEscan(TM), the company's proprietary, high-throughput method for screening small molecule compounds against a large number of human kinases, to advance AC220 from initial chemistry to clinical candidate

selection for IND-enabling studies in only 18 months.

#### **About Acute Myeloid Leukemia (AML)**

Acute myeloid leukemia is a form of blood cancer. According to the American Cancer Society, approximately 13,000 new cases of AML will be diagnosed in the United States in 2008. The median age of a patient with AML is about 67 years. Standard treatment for patients 60 years or older with AML includes systemic combination chemotherapy. The median survival for patients receiving induction chemotherapy, which is associated with high mortality, is 6-11 months, with shorter survival for patients over the age of 60 years. The five-year survival rate for AML is less than 15 percent. According to a report from Decision Resources, the U.S. AML market is expected to more than double by 2015.

#### **About Ambit Biosciences**

Ambit Biosciences is a privately-held biopharmaceutical company engaged in the discovery and development of small molecule kinase inhibitors for the treatment of cancer, inflammatory disease, and other indications. Ambit employs a novel and proprietary kinase profiling technology, KINOMEScan(TM), to screen compounds against 442 human kinases.

Ambit's lead compound, AC220, is in clinical development for the treatment of AML and other indications. Ambit has initiated a Phase 2 pivotal trial in patients with relapsed or refractory AML and plans to commence several other clinical studies with AC220 in 2010. Ambit's clinical pipeline also includes AC480, an oral pan-HER inhibitor that was in-licensed from BMS. Ambit is conducting Phase 2 studies with AC480 in patients with solid tumor cancers. Additionally, Ambit has an advancing pool of preclinical candidates targeting BRAF (in collaboration with Cephalon), JAK2, Aurora, and CSF1R. Through its KINOMEScan Division, Ambit markets its technology as a profiling service. For more information, visit [www.ambitbio.com](http://www.ambitbio.com).

**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 pharmaceuticals. Astellas has approximately 15,000 employees worldwide. The organization is committed to becoming a global category leader in urology, immunology & infectious diseases, neuroscience, DM complications & metabolic diseases and oncology. For more information on Astellas Pharma Inc., please visit our website at <http://www.astellas.com/en>.

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