



**Avila Announces FDA Allowance of Partner Clovis Oncology's IND Application for CO-1686, an Oral EGFR Mutant-Selective Inhibitor**

***Triggers \$4 Million Milestone Payment to Avila***

Bedford, MA - January 19, 2012 – Avila Therapeutics™, Inc. a biotechnology company developing targeted covalent drugs that treat diseases through protein silencing, announced that it has achieved the first milestone in its Epidermal Growth Factor Receptor (EGFR) Mutant-Selective Inhibitor (EMSI) alliance with Clovis Oncology triggering a \$4 million milestone payment to Avila.

The U.S. Food and Drug Administration (FDA) has allowed an investigational new drug (IND) application to begin clinical investigation of CO-1686, a novel, oral, targeted covalent inhibitor of epidermal growth factor receptor (EGFR) mutations in non-small cell lung cancer (NSCLC). Initial Phase I/II studies with CO-1686 are expected to commence in the U.S. and Europe during the second quarter of 2012 and in Asia during the third quarter of 2012. CO-1686 is the second covalent drug to advance to clinical development from Avila's proprietary Avilomics™ platform, along with Avila's proprietary drug candidate AVL-292, a Bruton's Tyrosine Kinase (Btk) inhibitor in Phase Ib clinical development for the treatment of B-cell cancers.

"We are pleased with the tremendous progress that our partners at Clovis have made in advancing CO-1686 into development, particularly in NSCLC, a disease for which novel treatments are so sorely needed," said Katrine S. Bosley, CEO of Avila Therapeutics. "With this achievement we have now successfully created two clinical development candidates using our targeted covalent drug platform. This further demonstrates our ability to design and develop innovative medicines using Avilomics."

EGFR activating mutations occur in approximately 10 to 15 percent of NSCLC cases in Caucasian patients and approximately 30 to 35 percent in East Asian patients. These patients experience significant tumor response to erlotinib (Tarceva®) and gefitinib (Iressa®), which are first-generation EGFR inhibitors. However, most patients ultimately progress on erlotinib and gefitinib therapy, with approximately 50 percent of patients developing acquired resistance from a second, or "gatekeeper" mutation, T790M. CO-1686 was designed and developed to selectively target both the initial activating EGFR mutations as well as the T790M mutation, while sparing wild-type, or "normal" EGFR. Because CO-1686 spares wild-type EGFR, it has the potential to cause a lower incidence of skin rash and diarrhea, the primary toxicities associated with other EGFR inhibitors.

Because CO-1686 inhibits the initial activating mutations of EGFR as well as T790M mutations, it also has the potential to effectively treat first-line NSCLC patients. CO-1686 may prevent the T790M resistance from occurring, which could result in responses of greater duration and, because it does not inhibit wild-type EGFR, it may possess a more tolerable side-effect profile. CO-1686 is a targeted covalent, or permanent, inhibitor of EGFR mutations. As a covalent drug, CO-1686 forms a durable bond with its target mutations in a highly directed and controlled manner. Preclinical data presented in late 2011

demonstrated that CO-1686 causes tumor shrinkage in T790M-driven NSCLC xenograft models, and resulted in significant tumor growth inhibition at a variety of doses.

**About the Avila Alliance with Clovis Oncology**

Avila and Clovis Oncology entered into a partnership for the worldwide development and commercialization of an EGFR Mutant-Selective Inhibitor (EMSI) in May 2010. Under the terms of the agreement, the two companies collaborated on the preclinical development of the EMSI program and Clovis Oncology is fully responsible for worldwide development and commercialization, including development of companion diagnostics to prospectively identify patients with clinically-arising resistance mutations of the EGFR. Avila is eligible to receive development, regulatory and sales-based milestone payments, with a total potential value of \$209 million, as well as tiered royalties on potential future product sales.

**About Avila Therapeutics™, Inc.**

Avila Therapeutics is a clinical-stage biotechnology company focused on the design and development of targeted covalent drugs to achieve best-in class outcomes. This approach, called “protein silencing”, cannot be achieved through traditional chemistry techniques. The company’s product pipeline has been built using its proprietary Avilomics™ platform and is currently focused on cancer, viral infection and autoimmune disease. Avila’s most advanced product candidate, AVL-292, a potential treatment for cancer and autoimmune diseases, is currently in Phase 1 clinical testing. Avila is funded by leading venture capital firms: Abingworth, Advent Venture Partners, Atlas Venture, Novartis Option Fund, and Polaris Venture Partners. For additional information, please visit <http://www.avilatx.com>.

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