



## Clovis Oncology and Avila Therapeutics Sign \$209 Million Partnership for the Worldwide Development and Commercialization of EGFR Mutant-Selective Inhibitor

- Avila's oral, small molecule program targets cancer-causing mutant forms of the EGF receptor (EGFR)
- Innovative treatment approach for non-small cell lung cancer (NSCLC) patients with disease resistant to current therapy
- Potency against key disease mutation, T790M, while minimizing activity against the wild-type (normal) EGFR to increase therapeutic index and avoid side effects of current standard of care
- Clovis to lead accelerated clinical development plan including companion diagnostic to prospectively identify T790M-positive NSCLC patients

Boulder, CO, and Waltham, MA, USA. May 25, 2010.

Clovis Oncology, Inc., a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents, and Avila Therapeutics, Inc., a biotechnology company designing targeted covalent drugs, announced today an agreement for the development and commercialization of Avila's epidermal growth factor receptor (EGFR) mutant-selective inhibitor (EMSI) program, currently in pre-clinical development for the treatment of non-small cell lung cancer (NSCLC). The EMSI program targets the T790M mutant form of the EGFR associated with clinical resistance to Tarceva® (erlotinib) and Iressa® (gefitinib)<sup>i</sup>, as well as targeting the initial activating EGFR mutations, including L858R and exon 19 deletions. It does so while also sparing the wild-type (normal) EGFR and may thus treat refractory NSCLC while minimizing dose-limiting side effects. Because the program targets both the sensitive activating mutations as well as the primary resistance mechanism, T790M, it has the potential to treat both first- and second-line NSCLC patients with EGFR mutations, for whom there is great unmet medical need.

"The T790M mutation seems to be the predominant mechanism underlying the development of resistance of EGFR-mutant lung cancers to specific EGFR kinase inhibitors, and it may well explain why the dramatic responses seen in these cases are of relatively short duration. The development of a drug that is both mutant-specific and capable of irreversibly binding the enzyme is one of the most exciting new developments in this field," said Dr. Daniel Haber, director of the Massachusetts General Hospital Cancer Center, who led a team that initially discovered EGFR mutations in lung cancer. "Such an inhibitor could overcome this resistance mutation at dosage levels that would spare the wild type EGFR in normal tissues. This could prove to be of major clinical significance," he added.

Under the terms of the agreement, Avila and Clovis Oncology will collaborate on the pre-clinical development of the EMSI product candidate. Clovis Oncology will be fully responsible for all aspects of development and commercialization, including development of companion diagnostics to prospectively identify patients with clinically-arising resistance mutations of the EGFR. In addition to research support, Avila will receive an upfront fee and be eligible to receive development, regulatory and sales-based milestone payments, with a total potential value of \$209 million. Avila will also receive tiered royalties on product sales and will share in selected sublicense income.

“Avila’s EMSI program has demonstrated very encouraging data against both the T790M resistance mutation and the initiating activating mutations and we are very pleased to initiate this partnership with them,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “We plan to file an IND as rapidly as possible and initiate an accelerated clinical development program, including the use of a companion diagnostic to identify patients with NSCLC who possess the T790M mutation. We believe that this program has the potential to meaningfully improve outcomes in patients with EGFR-mediated non-small cell lung cancer.”

“Clovis Oncology is an ideal partner with whom to advance this exciting program given their deep experience developing oncology drugs and their commitment to develop a companion diagnostic to identify the right patients for the drug,” said Katrine Bosley, President and CEO of Avila Therapeutics. “Resistance mutations in cancer-causing proteins are uniquely amenable to the targeted covalent inhibition enabled by Avila’s platform and working together with Clovis will accelerate advancement of this program.”

### About Lung Cancer

Lung cancer is the most common cancer worldwide with 1.35 million new cases annually, and NSCLC accounting for almost 85 percent of all lung cancers. NSCLC progresses rapidly with a five year survival rate in advanced NSCLC patients of less than 5%. Activating EGFR mutations are key drivers of NSCLC malignancy in 10-15% of patients of European descent and approximately 30% of patients of East Asian descent.

Currently, agents for the treatment of NSCLC patients include Tarceva® and Iressa®, both non-selective EGFR inhibitors. Both agents have significant skin-rash and diarrhea as side effects related to inhibition of the wild-type (normal) EGFR in skin and intestine respectively. Acquired resistance to Tarceva and Iressa occurs after a median of 12 months, driven in approximately 50% of cases by a “gatekeeper mutation” called T790M. Patients with tumors containing this secondary resistance EGFR mutation are clinically resistant to both first generation EGFR inhibitors (Tarceva and Iressa) as well as second generation pan-ErbB inhibitors currently in clinical development. By inhibiting both T790M and the initial activating mutations, the EMSI program offers the prospect of effective drug treatment for first and second-line NSCLC patients with activating EGFR mutations. With sparing of the wild-type EGFR, the EMSI program could also offer a much improved therapeutic window compared to current therapies in a first-line setting.

### About Clovis Oncology, Inc.

Clovis Oncology, Inc. is a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the U.S., Europe and additional international markets. Clovis intends to target development programs at specific subsets of cancer populations, and will simultaneously develop diagnostic tools that direct a compound in development to the population that is most likely to benefit from its use. The Company is currently developing CO-101 which is in Phase 2 development for the treatment of pancreatic cancer. The Company is collaborating with Ventana Medical Systems to develop a companion diagnostic to identify patients with low tumor expression of hENT1 and therefore likely to benefit from CO-101. The Company is headquartered in Boulder, Colorado, and has additional offices in San Francisco and Cambridge, England. For more information about Clovis Oncology, please visit the Company's website at [www.clovisoncology.com](http://www.clovisoncology.com).

### About Avila Therapeutics

Avila focuses on design and development of targeted covalent drugs to achieve best-in-class outcomes that cannot be achieved through traditional chemistries. This approach is called "protein silencing". The company's product pipeline has been built using its proprietary Avilomics™ platform and is currently focused on viral infection, cancer, and autoimmune disease. 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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<sup>i</sup> Tarceva and Iressa are registered trademarks of OSI Pharmaceuticals, Inc. and AstraZeneca, respectively.