

Press Release

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Aeglea BioTherapeutics Doses First Uveal and Cutaneous Melanoma Patients in Phase 1 Cohort Expansions with Pegzilarginase

Topline Safety and Clinical Activity Data Expected in 4Q 2018

AUSTIN, Texas, March 08, 2018 (GLOBE NEWSWIRE) -- Aeglea BioTherapeutics, Inc. (NASDAQ:AGLE), a clinical-stage biotechnology company that designs and develops innovative human enzyme therapeutics for patients with rare genetic diseases and cancer, today announced the dosing of the first uveal and cutaneous melanoma patients with pegzilarginase (AEB1102) in its open-label Phase 1 cohort expansions. The Company expects to report topline data, including safety and clinical activity, in the fourth quarter of 2018.

“Given our encouraging dose escalation data with pegzilarginase, the start of these Phase 1 cohort expansions is an important next step in targeting the advanced solid tumors that we believe are vulnerable to arginine depletion,” said Anthony Quinn, MB ChB, Ph.D., interim chief executive officer of Aeglea. “This is an exciting time at Aeglea as we assess the clinical activity of sustained arginine depletion in melanoma. We expect to report topline data in the fourth quarter of this year.”

Aeglea also initiated studies with pegzilarginase in small cell lung cancer as monotherapy and in combination with pembrolizumab. Additionally, the Company is conducting an open-label Phase 1/2 trial and a long term extension study in patients with Arginase 1 Deficiency, a rare genetic disease. Regarding Arginase 1 Deficiency, Aeglea plans to report adult repeat dose data this month and adult and pediatric repeat dose data, along with pivotal trial design, in the second half of this year.

About Pegzilarginase (AEB1102) in Cancer

Pegzilarginase is an enhanced human arginase that enzymatically degrades the amino acid arginine. In some cancers, tumor cells stop producing specific amino acids and must acquire them from the blood, making the tumor cells susceptible to starvation through depletion of those amino acids. Aeglea is developing pegzilarginase to exploit vulnerabilities in some cancers that lead to an increased dependency on extracellular arginine. Pegzilarginase targets

these arginine dependent cancers by depleting blood arginine levels to below the normal range. Preclinical data demonstrated that the resulting arginine starvation inhibits proliferation, induces cell death, increases turnover of cell components and promotes anti-tumor immune responses. The Company's Phase 1 data in advanced solid tumors demonstrated that pegzilarginase was well tolerated at doses that produced marked and sustained reductions in blood arginine levels below the normal range.

About Aeglea BioTherapeutics

Aeglea is a clinical-stage biotechnology company that designs and develops innovative human enzyme therapeutics for patients with rare genetic diseases and cancer. The Company is developing pegzilarginase, its lead investigational therapy, for the treatment of Arginase 1 Deficiency, as monotherapy in arginine-dependent cancers and in combination with an immune checkpoint inhibitor for small cell lung cancer. In addition, Aeglea has an active research pipeline of other human enzyme-based approaches in both therapeutic areas. For more information, please visit <http://aegleabio.com>.

Safe Harbor / Forward Looking Statements

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, statements we make regarding the timing and success of our current and future preclinical and clinical trials, and the potential therapeutic benefits and economic value of our lead product candidate or other product candidates. Further information on potential risk factors that could affect our business and its financial results are detailed in our most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 filed with the Securities and Exchange Commission (SEC), and other reports as filed with the SEC. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise. For more information, please visit: <http://aegleabio.com>.

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