

# Press Release

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## Aeglea BioTherapeutics Submits CTA Application for its Novel Engineered Human Enzyme Designed to Treat Homocystinuria (ACN00177)

### **Company Expects to Initiate a Phase 1/2 Trial in the Second Quarter of 2020**

AUSTIN, Texas, Jan. 13, 2020 (GLOBE NEWSWIRE) -- Aeglea BioTherapeutics, Inc. (NASDAQ:AGLE), a clinical-stage biotechnology company developing next-generation human enzyme therapeutics as solutions for diseases with high unmet medical need, today announced it has filed a Clinical Trial Application (CTA) with the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) for ACN00177, a novel engineered human enzyme therapy designed to treat homocystinuria, a serious metabolic disorder that results in elevated levels of plasma homocysteine. The Company expects to initiate a Phase 1/2 trial in the second quarter of 2020.

"Currently, people diagnosed with homocystinuria face a debilitating chronic disease, poor quality of life and inadequate treatments, including severe lifelong dietary restrictions," said Anthony G. Quinn, M.B. Ch.B., Ph.D., Aeglea's president and chief executive officer. "Aeglea's innovative platform has engineered a novel enzyme which, by reducing plasma homocysteine levels, has the potential to transform the patient experience with this challenging disease."

### **About ACN00177 in Homocystinuria**

Aeglea is developing ACN00177 for the treatment of patients with cystathionine beta synthase (CBS) deficiency, also known as Classical Homocystinuria. Homocysteine accumulation plays a key role in multiple progressive and serious disease-related complications, including thromboembolic vascular events, skeletal abnormalities including severe osteoporosis, developmental delay, intellectual disability, lens dislocation and severe myopia. ACN00177 has been designed as a novel recombinant human enzyme, which degrades the amino acid homocysteine and its related homocystine dimer. With this mechanism, ACN00177 is intended to lower the abnormally high blood levels of homocysteine to the normal range in patients with homocystinuria. Preclinical data demonstrated that the ACN00177 improved important disease-related abnormalities and survival in a mouse model of homocystinuria. The Company has submitted a Clinical Trial Application (CTA) with the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) and expects to initiate a Phase 1/2 trial in the second quarter of 2020.

## About Aeglea BioTherapeutics

Aeglea BioTherapeutics is a clinical-stage biotechnology company redefining the potential of human enzyme therapeutics to address rare and other high burden diseases with unmet medical need. Aeglea's lead product candidate, pegzilarginase, is in a Phase 3 pivotal trial for the treatment of Arginase 1 Deficiency and has received both Rare Pediatric Disease and Breakthrough Therapy Designation. Aeglea has an active discovery platform with programs for homocystinuria and cystinuria. The Company has submitted a Clinical Trial Application (CTA) for ACN00177 for homocystinuria with the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) and expects to initiate a Phase 1/2 trial in the second quarter of 2020. For more information, please visit <http://aegleabio.com>.

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