American Gene Technologies Granted FDA Orphan Drug Designation For Phenylketonuria

ROCKVILLE, MD, UNITED STATES, October 18, 2018 /EINPresswire.com/ -- American Gene Technologies (AGT), a leading gene and cell therapy company in the discovery and development of lentiviral vector based therapeutics, announces that the U.S. Food and Drug Administration (FDA) received orphan-drug designation #DRU-2018-6572 for the treatment of phenylketonuria (PKU) using its proprietary, lentiviral vector based technology. PKU is a debilitating inherited disease affecting 1 in 13,500 children born in the U.S. Mandatory screening identifies affected children who can be supported with a strict synthetic diet that does not cure disease. If successful, AGT's lentiviral vector approach will provide a permanent cure, improving quality of life for more than 16,000 people living with PKU in the U.S. alone.

"We are pleased to receive this orphan drug designation from the FDA for AGT's vector technology to treat PKU. Our technology demonstrates promising potential to address an unmet medical need in treating this rare disease," said Jeff Galvin, CEO and Founder of AGT. "We believe this orphan designation will enable AGT to formally shape and advance its PKU program."

About American Gene Technologies (AGT):

AGT is an emerging gene and cell therapeutics company with a proprietary lentiviral platform capable of broad applications including: large and orphan indications, infectious disease, immune-oncology, and monogenic disorders. AGT expects to take its patented, lead candidate for an HIV Cure into the clinic in 2019. It has pioneered a novel immuno-oncology approach of stimulating gamma-delta (γδ) T cells to attack a variety of cancers. Four key patents in AGT's novel immuno-oncology approach have been granted. AGT has a diverse portfolio of patent filings surrounding key tools and components in viral vectors, gene therapy, and regenerative medicine.

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