



Pipeline Therapeutics Announces Global License and Development Agreement for Investigational Neuroscience Therapy, PIPE-307

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– License and development agreement with Janssen leverages Pipeline's expertise in precision neuroregeneration and Janssen's development experience across nervous system disorders

SAN DIEGO, April 17, 2023 – Pipeline Therapeutics, ("Pipeline"), a clinical-stage biopharmaceutical company pioneering precision neuroregeneration, announced today that it has entered into a global license and development agreement with Janssen Pharmaceutica NV (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, for the investigational compound, PIPE-307 to treat nervous system disorders. PIPE-307 is an oral, highly selective antagonist of the muscarinic M1 receptor, which has completed two Phase 1 clinical trials in healthy patients and has received Investigational New Drug clearance from the Food and Drug Administration (FDA) to initiate clinical development in relapsing-remitting multiple sclerosis (RRMS) patients.

"We are excited to announce this agreement, which is aligned with our vision to maximize the reach of PIPE-307 through clinical evaluation in RRMS and other neurological disorders," said Carmine Stengone, President and CEO of Pipeline. "In addition, we are pleased that we will strengthen our financial position with the upfront payment from this agreement and equity investments from existing and new investors, enabling us to extend our runway and to continue advancing our portfolio in small molecule neuroregeneration."

Under the terms of the agreement, Pipeline will grant Janssen a worldwide, exclusive license to research, develop and commercialize PIPE-307 in all indications. Pipeline will have the right to continue to advance PIPE-307 for the treatment of RRMS through conduct of a Phase 2 clinical trial.

Upon closing of the transaction, Pipeline will receive \$50M in an upfront payment from Janssen and separately up to \$25M in an equity investment from Johnson & Johnson Innovation – JJDC, Inc. and up to \$25M in equity investments from Pipeline's existing investors. Pipeline is also eligible to receive approximately \$1 billion in success-based payments including clinical, regulatory and commercial milestones, as well as tiered double-digit royalty payments, which increase if the co-development option for PIPE-307 is exercised by Pipeline.

About PIPE-307 for Multiple Sclerosis

PIPE-307 is an oral, highly selective antagonist of the M1 muscarinic receptor commencing clinical studies in RRMS patients. The Company completed multiple Phase 1 studies of PIPE-307 in healthy patients, including a single- and multiple-ascending dose [study](#) to evaluate safety and pharmacokinetics, and a PET study to determine the occupancy of brain M1 after a single dose of PIPE-307 in healthy volunteers. In these studies, PIPE-307 demonstrated linear pharmacokinetic (PK) data consistent with preclinical modeling and was generally well tolerated across all dose cohorts. Importantly, analysis of a battery of neuropsychological measures, including tests involving psychomotor, attention, learning, and executive function, were administered in the Phase 1 study and showed no significant PK or dose related effects on cognitive function.

About Pipeline Therapeutics

Pipeline Therapeutics is a clinical-stage biopharmaceutical company pioneering the development and commercialization of first-in-class therapies for precision neuroregeneration including myelin restoration, synaptogenesis and axonal repair. The Company has a broad pipeline of programs to address multiple CNS disorders. Its flagship program, PIPE-307, has completed two Phase 1 clinical trials – a SAD/MAD study and a PET study – in healthy volunteers, and has received Investigational New Drug clearance from the Food and Drug Administration to initiate clinical development in relapsing-remitting MS patients.

For more information, please visit www.pipelinetherapeutics.com and engage with us on LinkedIn.

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