



## **Pipeline Therapeutics Initiates Phase 1 Clinical Trial of PIPE-307**

March 2, 2021

**SAN DIEGO, March 2, 2021** – Pipeline Therapeutics, a biopharmaceutical company focused on the development and commercialization of first-in-class small molecules for neuroregeneration, today announced the initiation of a Phase 1 study of PIPE-307, a selective antagonist of the muscarinic M1 receptor, in up to 72 healthy volunteers.

The randomized, double-blind, placebo-controlled, single- and multiple-ascending dose Phase 1 clinical trial of PIPE-307 will primarily assess the safety and tolerability profile of PIPE-307, as well as measure the effect of PIPE-307 on pharmacokinetics. The study will be conducted exclusively in Australia at a single center.

“Evaluating PIPE-307 in healthy volunteers is a critical step in our effort to identify the appropriate dose selection for the follow-on Phase 2 study, to be conducted in patients with multiple sclerosis,” said Stephen Huhn, MD, Chief Medical Officer and Senior Vice President of Clinical Development at Pipeline Therapeutics. “While immune-modulatory approaches reduce relapse rate, there is currently no effective restorative therapy on the market that targets remyelination in order to address the progressive disability associated with multiple sclerosis.”

“PIPE-307 is the second of Pipeline Therapeutics’ programs to enter the clinic in less than a year, making this an important milestone for the company,” said Carmine Stengone, President & CEO of Pipeline Therapeutics. “We will likely further broaden our development pipeline following the near-term readout from our PIPE-505 Phase 1/2a trial in sensorineural hearing loss, as we seek to maximize the potential of our neuroregenerative technology in areas of high unmet medical need.”

Pipeline expects to announce results from the PIPE-307 Phase 1 study in the second half of 2021.

### **About Pipeline Therapeutics**

Pipeline Therapeutics is a biopharmaceutical company focused on the development and commercialization of first-in-class small molecules for neuroregeneration, including synaptogenesis, remyelination and axonal repair. The company’s lead clinical program, PIPE-505, is currently enrolling patients in a phase 1/2a study to treat sensorineural hearing loss (SNHL) associated with speech-in-noise disability. The company has also initiated a Phase 1 healthy volunteer study for its second clinical program, PIPE-307, targeting multiple sclerosis. In addition, Pipeline has a portfolio of further programs addressing a range of neurological disorders and conditions.