Contineum Therapeutics Expands Clinical Development of PIPE-791 With FDA Authorization of Its Investigational New Drug (IND) Application for Chronic Pain

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- Phase 1b study for the potential treatment of osteoarthritis and low back pain expected to commence in the first quarter of 2025
- Initial data readout planned for early 2026
- Neuropathic component of chronic pain linked to LPA1 activation

SAN DIEGO--(BUSINESS WIRE)--Nov. 18, 2024-- Contineum Therapeutics, Inc. (NASDAQ: CTNM) (Contineum or the Company), a clinical stage biopharmaceutical company focused on discovering and developing novel, oral small molecule therapies that target biological pathways associated with specific clinical impairments in the treatment of neuroscience, inflammation and immunology (NI&I) indications, today announced authorization of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) for PIPE-791 for the treatment of chronic pain associated with two separate indications, osteoarthritis (OA) and low back pain (LBP). PIPE-791 is a novel, brain penetrant, small molecule antagonist of the lysophosphatidic acid 1 receptor (LPA1R).

The exploratory Phase 1b, randomized, double-blind, placebo-controlled, crossover, multi-center study is expected to begin in the first quarter of 2025. The Company expects to enroll approximately 40 patients at up to five sites, and a treatment duration of 28 days. Contineum anticipates topline data from the PIPE-791 Phase 1b chronic pain study in early 2026.

“We’re pleased to expand PIPE-791 clinical development to include the potential treatment of chronic pain in a limited, exploratory, signal-seeking study,” said Carmine Stengone, CEO, Contineum Therapeutics. “Researchers have shown that LPA pathways have been specifically implicated in the neuropathic components of preclinical pain models and clinical biomarker studies. This is a first step to evaluate how PIPE-791 may provide a potentially differentiated, non-opioid treatment option for patients with OA and LBP.”

Chronic pain is often associated with neuropathic symptoms caused by aberrant signaling in the central nervous system (CNS) leading to heightened sensitivity to painful stimuli. LPA1 activation has been shown to contribute to persistent hypersensitivity, characteristic of neuropathic pain, by promoting the demyelination of nerve fibers, increasing neuronal excitability and enhancing neuroinflammatory responses in the CNS (Company research, Ueda 2020). By selectively blocking LPA1 receptor activity, an LPA1 antagonist may prevent or reverse the maladaptive changes in the nervous system that initiate and maintain the chronic pain state.

OA is the most common joint disease characterized by chronic pain and decreased mobility. OA affects approximately 33 million people in the United States. Current pharmacological treatments for pain associated with OA consist of non-steroidal anti-inflammatory drugs (NSAIDs), topical agents, antidepressants and steroid injections.

LBP is a common musculoskeletal condition that can be associated with spinal degeneration, nerve compression and inflammation. Low back pain affects approximately 45 million people in the United States. Over-the-counter or prescription NSAIDs, antidepressants, steroid injections, muscle relaxants and opioids are commonly used for pain and inflammation reduction.

With the addition of the PIPE-791 Phase 1b chronic pain study, the Company continues to expect its cash, cash equivalents and marketable securities of $213.9 million as of September 30, 2024, are sufficient to fund its planned operations through 2027.

About Contineum Therapeutics

Contineum Therapeutics (Nasdaq: CTNM) is a clinical stage biopharmaceutical company focused on discovering and developing novel, oral small molecule therapies for NI&I indications with high unmet need. Contineum is focused on targeting biological pathways associated with specific clinical impairments, that Contineum believes, once modulated, may demonstrably impact the course of disease. Contineum has a pipeline of internally-developed programs to address multiple NI&I disorders. Contineum has two drug candidates in clinical trials, PIPE-791, an LPA1 receptor antagonist in clinical development for idiopathic pulmonary fibrosis and progressive multiple sclerosis, and PIPE-307, a selective inhibitor of the M1 receptor in clinical development for relapsing-remitting multiple sclerosis (RRMS). PIPE-307 is being developed pursuant to a global license and development agreement between Contineum and Janssen Pharmaceutica NV, a Johnson & Johnson company, who has also announced plans to initiate a Phase 2 trial of PIPE-307 in depression in 2024. For more information, please visit www.contineum-tx.com.

Forward-Looking Statements

Certain statements contained in this press release, other than historical information, constitute forward-looking statements within the meaning of the federal securities laws. Forward-looking statements include, but are not limited to, statements regarding the Company’s clinical trial and product development plans and timelines, including, but not limited to, the expected initiation of the PIPE-791 chronic pain study and the timing thereof; the design and goals of the PIPE-791 chronic pain study; the expected timing of the topline data from the PIPE-791 chronic pain study; the indications, anticipated benefits of, and market opportunities for its drug candidates; its cash runway; its business strategies and plans; and the quotations of the Company’s management. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond the Company’s control and may cause its actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties, include, but are not limited to, the following: the Company is heavily dependent on the success of PIPE-791 and PIPE-307, both of which are in the early stages of clinical development, and neither of these drug candidates may progress through clinical development or receive regulatory approval; the results of earlier preclinical studies and clinical trials, including those conducted by third parties, may not be predictive of future results and unexpected adverse side effects or inadequate efficacy of the Company’s drug candidates may limit their development, regulatory approval and/or commercialization; the timing and outcome of research, development and regulatory review is uncertain; clinical studies and preclinical studies may not proceed at the time or in the manner expected, or at all; the potential for our programs and prospects to be negatively impacted by developments relating to our competitors, including the results of studies or regulatory determinations relating to our competitors; risks associated with reliance on third parties to successfully conduct clinical trials and, in the case of PIPE-307, the Company’s reliance upon Johnson & Johnson to develop PIPE-307 for depression or any other

indication other than RRMS and, after completion of the VISTA trial, Johnson and Johnson's decision, in its sole discretion, whether or not further develop PIPE-307 for RRMS; the Company has incurred significant operating expenses since inception and it expects that its operating expenses will continue to significantly increase for the foreseeable future; the Company's license agreement with Johnson & Johnson may not result in the successful development of PIPE-307; the Company may be unable to obtain, maintain and enforce intellectual property protection for its technology and drug candidates; and unstable market and economic conditions and military conflict may adversely affect our business and financial condition and the broader economy and biotechnology industry. Additional risks and uncertainties that could affect the Company's business, operations and results are included under the captions, "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in its most recent filing on Form 10-Q and in other filings that it makes with the SEC from time to time. These documents are available on the Company's website at www.contineum-tx.com under the Investor section and on the SEC's website at www.sec.gov. Accordingly, readers should not rely upon forward-looking statements as predictions of future events. Except as required by applicable law, the Company undertakes no obligation to update publicly or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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Steve Kunszabo
Contineum Therapeutics
Senior Director, Investor Relations & Corporate Communications
858-649-1158
skunszabo@contineum-tx.com

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