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MyMD Pharmaceuticals Enrolls First Patient in Phase 2 Clinical Trial of MYMD-1 as a Therapy for Delaying Aging and Extending Healthy Lifespan

Efficacy data from fully funded Phase 2 trial is expected in first half of 2022

BALTIMORE--(BUSINESS WIRE)-- [MyMD Pharmaceuticals, Inc.](#) (Nasdaq: MYMD) ("MyMD" or "the Company"), a clinical stage pharmaceutical company committed to extending healthy lifespan, today announced that the first patient has been enrolled in the Company's Phase 2 clinical trial of lead candidate MYMD-1, an oral immune regulator drug, as a therapy for delaying aging and expanding healthy lifespan.

The primary endpoint for the Phase 2 double-blind, placebo-controlled clinical trial is to achieve a reduction in the circulating levels of (TNF- α), tumor necrosis factor receptor I (TNFRI) and IL-6. TNF- α and IL-6 are the proteins in the body that cause inflammation and help activate the process of aging. The secondary measures of the trial will be the safety, tolerability, and pharmacokinetics in this population of patients.

"In a Phase 1 clinical trial of MYMD-1, we demonstrated the drug's statistically significant efficacy in reducing levels of TNF- α , a key player in causing pathological aging, in the blood. The FDA has approved TNF- α reduction as the primary endpoint for our Phase 2 study, which we believe positions us well for a successful Phase 2 outcome," said Chris Chapman, M.D., President, Director and Chief Medical Officer of MyMD. "The initiation of patient enrollment in this study advances our mission to slow the aging process, prevent loss of muscle tissue in aging, limit frailty, and extend healthy lifespan."

MyMD has stated that there are no FDA-approved drugs for treating aging disorders and extending healthy lifespan humans, a market expected to be at least \$600 billion by 2025¹ according to a major investment bank. TNF- α blockers are the most prescribed drugs by revenue, a global market of approximately \$40 billion per year,² and, according to [Nature Aging](#) journal,³ a slowdown in aging that would increase life expectancy by one year is worth \$38 trillion and by 10 years is worth \$367 trillion.

In addition to aging, MYMD-1's distinct action in regulating the immune system and treating chronic inflammation is being developed for the treatment of autoimmune disease, including rheumatoid arthritis (RA), multiple sclerosis (MS), diabetes, and inflammatory bowel disease.

"We intend to begin writing protocols for a Phase 2 pilot study of MYMD-1 for rheumatoid arthritis early this year," Dr. Chapman noted. "The rising prevalence of rheumatoid arthritis and other autoimmune and inflammatory diseases are driving demand for TNF inhibitors like MYMD-1, and we believe our orally administered drug with very low toxicity would be disruptive to the \$60 billion market for RA if approved by the FDA for this indication."

Rheumatoid arthritis affects approximately 40 million people worldwide.⁴

About MYMD-1

Originally developed for autoimmune diseases, MYMD-1's primary purpose is to slow the aging process, prevent sarcopenia and frailty, and extend healthy lifespan. Because it can cross the blood-brain barrier and gain access to the central nervous system (CNS), MYMD-1 is also positioned to be a possible treatment for brain-related disorders. Its mechanism of action and efficacy in diseases including multiple sclerosis (MS) and thyroiditis have been studied through collaborations with several academic institutions. MYMD-1 is also showing promise in pre-clinical studies as a potential treatment for post- COVID-19 complications and as an anti-fibrotic and anti-proliferation therapeutic.

MYMD-1 has shown effectiveness in pre-clinical studies in regulating the immune system by performing as a selective inhibitor of tumor necrosis factor-alpha (TNF- α), a driver of chronic inflammation. Unlike other therapies, MYMD-1 has been shown in these pre-clinical studies to selectively block TNF- α when it becomes overactivated in autoimmune diseases and cytokine storms, but not block it from doing its normal job of being a first responder to any routine type of moderate infection. MYMD-1's ease of oral dosing is another differentiator compared to currently available TNF- α blockers, all of which require delivery by injection or infusion. No approved TNF inhibitor has ever been dosed orally. In addition, the drug is not immunosuppressive and has not been shown to cause the serious side effects common with traditional therapies that treat inflammation.

About MyMD Pharmaceuticals, Inc.

MyMD Pharmaceuticals, Inc. (Nasdaq: MYMD), a clinical stage pharmaceutical company committed to extending healthy lifespan, is focused on developing two novel therapeutic platforms that treat the causes of disease rather than only addressing the symptoms. [MYMD-1](#) is a drug platform based on a clinical stage small molecule that regulates the immune system to control TNF- α , which drives chronic inflammation, and other pro-inflammatory cell signaling cytokines. MYMD-1 is being developed to delay aging, increase longevity, and treat autoimmune diseases and COVID-19- associated depression. The Company's second drug platform, [Supera-CBD](#), is being developed to treat chronic pain, addiction and epilepsy. Supera-CBD is a novel synthetic derivative of cannabidiol (CBD) and is being developed to address and improve upon the rapidly growing CBD market, which includes both FDA approved drugs and CBD products not currently regulated as drugs. For more information, visit www.mymd.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release may contain forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to be materially different from any expected future results, performance, or achievements. Forward-looking statements speak only as of the date they are made and none of MyMD nor its affiliates assume any duty to update forward-looking statements. Words such as "anticipate," "believe," "could," "estimate," "expect," "may," "plan," "will," "would" and other similar expressions are intended to identify these forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include,

without limitation: the timing of, and MyMD's ability to, obtain and maintain regulatory approvals for clinical trials of MyMD's pharmaceutical candidates; the timing and results of MyMD's planned clinical trials for its pharmaceutical candidates; the amount of funds MyMD requires for its pharmaceutical candidates; increased levels of competition; changes in political, economic or regulatory conditions generally and in the markets in which MyMD operates; MyMD's ability to retain and attract senior management and other key employees; MyMD's ability to quickly and effectively respond to new technological developments; MyMD's ability to protect its trade secrets or other proprietary rights, operate without infringing upon the proprietary rights of others and prevent others from infringing on MyMD's proprietary rights; and the impact of the ongoing COVID-19 pandemic on MyMD's results of operations, business plan and the global economy. A discussion of these and other factors with respect to MyMD is set forth in the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021, filed by MyMD on November 12, 2021 (as amended on November 15, 2021). Forward-looking statements speak only as of the date they are made and MyMD disclaims any intention or obligation to revise any forward-looking statements, whether as a result of new information, future events or otherwise.

¹ <https://www.cnbc.com/2019/05/08/techs-next-big-disruption-could-be-delaying-death.html>

² October 9, 2019, Tumor Necrosis Factor (TNF) Inhibitor Drugs Market, Acumen Research and Consulting

³ *Nature Aging* | VOL 1 | July 2021 | p. 616–623

⁴ https://academic.oup.com/ije/article/50/Supplement_1/dyab168.034/6361231

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