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# MyMD Pharmaceuticals® Advances Phase 2 Multi-Center Clinical Trial of MYMD-1® as a Therapy for Delaying Aging and Extending Healthy Lifespan

*Sarcopenia trial shows no evidence of toxicity or safety issues and patients were enrolled in the next higher dose of MYMD-1*

BALTIMORE--(BUSINESS WIRE)-- [MyMD Pharmaceuticals, Inc.](#)® (Nasdaq: MYMD) ("MyMD" or "the Company"), a clinical stage pharmaceutical company committed to developing novel therapies for age-related diseases, autoimmune and inflammatory conditions, announced further advancement of its fully funded Phase 2 clinical trial of lead drug candidate MYMD-1® as a therapy for delaying aging and expanding healthy lifespan. To date, the trial has completed dosing for the first patient cohort and dosing has been initiated in the next higher dose cohort. The trial's Safety Review Committee has confirmed no safety issues and no toxicity in the prior cohort and has voted unanimously to escalate to the next higher dose and begin enrolling the next cohort.

The Phase 2 multi-center double-blind, placebo controlled, randomized study ([NCT05283486](#)) investigates the efficacy, tolerability and pharmacokinetics of MYMD-1 in the treatment of chronic inflammation associated with sarcopenia/frailty in participants aged 65 years or older.

"As agreed upon with the FDA, the primary endpoint of our Phase 2 multi-center study is to demonstrate reduced levels of TNF-alpha (TNF- $\alpha$ ), a key player in associated pathological aging, in the blood of patients," said Chris Chapman, MD, President, Director and Chief Medical Officer of MyMD. "Having already demonstrated the drug's mechanism of action and efficacy in Phase 1, achieving the same primary endpoint as our current trial, we are pleased with the progress in Phase 2 to date. We continue to advance the trial and expect efficacy data in the second half of 2022."

In the Phase 1 dose-ranging study of MYMD-1 for delaying aging, subjects were treated with MYMD-1 or placebo and TNF- $\alpha$  levels were measured pre- and post-treatment. The data demonstrated a statistically significant decrease in TNF-alpha levels (p-value <0.05) found in MYMD-1 treated subjects, but no change in the participants given placebo. This data was consistent with outcomes from pre-clinical models pointing to the drug's potential role in reducing both frailty and inflammatory cytokines.

## Market Opportunity

MyMD has not identified any other FDA-approved drugs for treating aging disorders and

extending healthy lifespan humans, a market expected to be at least \$600 billion by 2025<sup>1</sup> according to a major investment bank. TNF- $\alpha$  blockers are the most prescribed drugs by revenue, a global market of approximately \$40 billion per year.<sup>2</sup> Aging is closely linked to multi-morbidities, frailty, and death due to conditions such as neoplastic, cardiovascular, neurodegenerative, metabolic, or autoimmune diseases.<sup>3</sup> Similarly, frailty, or a decline in physical function leading to greater risk of hospitalization, disability, and death, increases with age independent of underlying conditions or demographical characteristics.<sup>4</sup>

## **About MYMD-1**

MYMD-1, an oral selective inhibitor of tumor necrosis factor-alpha (TNF- $\alpha$ ), a driver of chronic inflammation, is being studied to slow the aging process, prevent sarcopenia and frailty, and extend healthy lifespan. MYMD-1 has shown effectiveness in pre-clinical and clinical studies in regulating the immune system. Unlike other therapies, MYMD-1 has been shown in these studies to selectively block TNF- $\alpha$  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- $\alpha$  blockers, all of which require delivery by injection or infusion. No FDA-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. 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.

## **About MyMD Pharmaceuticals, Inc.**

MyMD Pharmaceuticals, Inc. (Nasdaq: MYMD), a clinical stage pharmaceutical company committed to developing novel therapies for autoimmune and inflammatory conditions, 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- $\alpha$ , 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. 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](http://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 Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed by MyMD on March 31, 2022. 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.

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

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

<sup>3</sup> St Sauver JL, Boyd CM, Grossardt BR, Bobo WV, Finney Rutten LJ, Roger VL *et al*. Risk of developing multimorbidity across all ages in an historical cohort study: differences by sex and ethnicity. *BMJ Open*. 2015;**5**:e006413.

<sup>4</sup> Kochanek KD, Murphy SL, Xu J, Arias E. Deaths: Final Data for 2017. *Natl Vital Stat Rep*. 2019;**68**:1-77.

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