September 13, 2021

MyMD Pharmaceuticals Announces Fourth Quarter 2021 Initiation of Phase 2 Clinical Trial of MYMD-1 for Extending Healthy Lifespan

Key objective of the trial is to reduce levels of the protein that causes inflammation and activates aging, TNF-α, in the blood

MYMD-1 is designed to become the first and only FDA-approved therapeutic solution for delaying aging and prolonging lifespan

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 it intends to initiate dosing for a Phase 2 trial of MYMD-1's function in delaying aging early in the fourth quarter of 2021. Interim efficacy analysis from this study is expected in the first quarter of 2022.

The primary goal of this Phase 2 double-blind, placebo-controlled clinical trial is to achieve a reduction in the levels of tumor necrosis factor-alpha (TNF-α) in the blood. TNF-α is the protein in the body that causes inflammation and helps activate the process of aging.

"If MYMD-1 can demonstrate TNF-α reduction in the blood, our immunometabolic regulator could eventually become the first and only FDA-approved therapeutic solution for delaying aging and prolonging lifespan," stated Chris Chapman, M.D., President, Director and Chief Medical Officer of MyMD. "MYMD-1 is designed to address massive markets, giving it the opportunity to transform major health sectors across the medical landscape."

"Chronic inflammation is the common factor in aging and all aging-related diseases including frailty, sarcopenia (loss of muscle tissue), and autoimmunity. Since TNF-α is the master regulator of inflammation, MYMD-1's function as a TNF-α inhibitor targets the root cause of aging, not just the symptoms," said Adam Kaplin, M.D., Ph.D., Chief Scientific Officer. "Positive data from this important study would significantly advance MYMD-1's potential to become a blockbuster drug for inflammation and aging."

MYMD-1's ease of oral dosing is a groundbreaking 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. The second and third key differentiators are selectivity and low toxicity. Unlike other therapies, MYMD-1 is designed to selectively block TNF-α when it becomes overactivated in autoimmune diseases and cytokine storms, but not to block it from doing its normal job of being a first responder to any routine type of moderate infection. In addition, the drug is not immunosuppressive and has not been shown to cause serious side effects common with traditional therapies that treat inflammation.

Commenting on the size and scope of the market for delaying aging, Dr. Chapman added, “There are no FDA-approved drugs for treating aging disorders and extending healthy lifespan in humans, a market expected to be at least $600 billion by 2025[1] according to a major investment bank. TNF-α blockers are the most prescribed drugs by revenue, a global market of about $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.”

MYMD-1’s primary purpose is to slow the aging process and extend human lifespan, but it is also showing promise as a potential treatment for COVID-19-related complications, and as an anti-fibrotic and anti-prolific therapeutic. Because it can cross the blood-brain barrier, MYMD-1 is also positioned to be a possible treatment for multiple sclerosis and other brain-related disorders.

In addition to the upcoming Phase 2 aging trial, MyMD previously announced that it intends to initiate a Phase 2 trial of MYMD-1 as a therapy for COVID-19-associated depression and cytokine elevation in the fourth quarter of 2021, with initial trial data expected in the first quarter of 2022.

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 and decline rather than only addressing the symptoms. MYMD-1 is a drug platform based on a clinical stage small molecule that regulates the immunometabolic system to control TNF-α, a driver of chronic inflammation, and other pro-inflammatory cell signaling cytokines. MYMD-1 is being developed to treat aging and longevity, autoimmune diseases, and COVID-19- associated depression and cytokine elevation. The Company’s second drug platform, Supera-CBD, is being developed to treat chronic pain, addiction and epilepsy. Based on a novel synthetic derivative of cannabidiol (CBD), Supera-CBD is being developed to address 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 June 30, 2021, filed by MyMD on August 16, 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

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Source: MyMD Pharmaceuticals, Inc.