

MyMD Pharmaceuticals Receives FDA IND Clearance to Begin Phase 2 Trial of MYMD-1 for Extending Healthy Lifespan

Believed to be the only IND application ever cleared by the FDA for a Phase 2 trial of a patented drug for delaying aging

Phase 2 trial recruiting begins immediately; efficacy data expected by the end of the first quarter of 2022

[MyMD Pharmaceuticals, Inc.](#) (Nasdaq: MYMD) (“MyMD” or “the Company”), a clinical stage pharmaceutical company committed to extending healthy lifespan by delaying aging, announced today that it has received U.S. Food and Drug Administration clearance of its Investigational New Drug (IND) application for the Phase 2 trial of MYMD-1 as a therapy for delaying aging and prolonging healthy lifespan. Recruitment for the Phase 2 trial will begin immediately, and efficacy data is expected by the end of first quarter of 2022.

“To our knowledge, ours is the only IND application ever accepted by the FDA for a Phase 2 trial of a patented drug that seeks to delay aging. While there are other TNF-alpha, IL-6 and IL-17 blockers on the market, they are used for other indications; those drugs are not approved by the FDA for treating aging, frailty, and sarcopenia (loss of muscle tissue),” explained Chris Chapman, M.D., President, Director and Chief Medical Officer of MyMD. “Our treatment designed for delaying aging has a distinctive drug profile of oral delivery, selectivity, and very low toxicity as compared with TNF blockers, all of which are delivered by injection only.

“MYMD-1 is designed to become the first and only FDA-approved therapeutic solution for delaying aging and prolonging healthspan—i.e. years of life with minimized chronic disease and maximized good health,” Dr. Chapman continued. “For multiple health and safety reasons, we believe orally dosed MYMD-1 is vastly superior to any of the available TNF inhibitors on the market today, one of which is the best-selling drug in the world.”

As cleared by the FDA, the primary endpoint of the Phase 2 double-blind, placebo-controlled clinical trial is to achieve a reduction in the circulating levels of tumor necrosis factor-alpha (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. Chronic inflammation is the common factor in aging and all aging-related diseases including frailty, sarcopenia, and autoimmunity. Since TNF- α is the master regulator of inflammation, MYMD-1’s function as a TNF- α inhibitor targets one of the root causes of aging, not just the symptoms. The secondary measures will be the safety, tolerability, and pharmacokinetics in this population of patients.

The market for treating aging disorders and extending healthy lifespan is 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.

About MYMD-1

Originally developed for autoimmune diseases, MYMD-1’s primary purpose is to slow the aging process, prevent sarcopenia (loss of muscle tissue in aging) 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 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 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.

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

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.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20211116005385/en/>

MyMD Contact:

Robert Schatz

(646) 421-9523

rschatz@mymd.com

www.mymd.com

News Provided by Business Wire via QuoteMedia