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MyMD Pharmaceuticals® Provides Dosing Update on Phase 2 Multi-Center Clinical Trial of MYMD-1® as a Therapy for Delaying Aging and Extending Healthy Lifespan

- Currently, there are no FDA-approved treatments for sarcopenia/frailty -

- MyMD is only 3 patients away from dosing its final patient in its first Phase 2 clinical trial of lead drug candidate MYMD-1® -

BALTIMORE, MD--(BUSINESS WIRE)-- MyMD Pharmaceuticals, Inc.® (Nasdaq: MYMD) ("MyMD" or "the Company"), a clinical stage biopharmaceutical company developing groundbreaking therapies for the treatment of serious and debilitating autoimmune and inflammatory diseases, today announced a dosing update on its fully-funded Phase 2 clinical trial of lead drug candidate MYMD-1®, an orally available next-generation TNF-alpha inhibitor, as a therapy for chronic inflammation associated with sarcopenia and frailty (NCT05283486).

The Safety Review Committee has confirmed no safety or toxicity issues with the first 30 patients enrolled in this study and has voted unanimously to escalate to the final dose level. Thirty patients enrolled in Cohorts 1, 2, and 3 have completed dosing and end of study visits. To date, three subjects from Cohort 4 have completed end of study visits. There are no outstanding study visits and all 30 patients have officially completed all study parameters and been discharged from the study.

"We are proud of the notable progress that we have made thus far on our first Phase 2 study of MYMD-1," said Chris Chapman MD, President, Director, and Chief Medical Officer at MyMD Pharmaceuticals. "As we move into the final cohort of this study, we remain hopeful in MYMD-1's potential to transform future treatment of sarcopenia/frailty in the aging population."

The Phase 2 multi-center double-blind, placebo controlled, randomized study (NCT05283486) is currently ongoing to investigate the efficacy, tolerability and pharmacokinetics of MYMD-1 in the treatment of chronic inflammation associated with sarcopenia/frailty inpatients aged 65 years or older. The study's primary objective is to demonstrate reduction of chronic inflammatory markers in patients treated with MYMD-1® versus placebo. To qualify for the clinical trial, patients' biomarkers during the screening period must be within the following criteria: IL-6 ≥ 2.5pg/mL; and/or sTNFR-1 ≥ 1500pg/mL. To date, MyMD has randomized and dosed 37 of 40 total patients across Cohorts 1 (n=10;

600mg), 2 (n=10; 750mg), 3 (n=10; 900mg) and 4 (n=7; 1050mg).

On average, it is estimated that 5 to 13% of elderly people between the ages of 60 and 70 are affected by sarcopenia. These numbers increase to 11 to 50% for those aged 80 or above.[1] Currently, there are no FDA approved treatments for chronic inflammation associated with sarcopenia/frailty for those aged 65 years or older.

"The aging disorders market is expected to be at least $600 billion by 2025[2]," continued Dr. Chapman. "TNF-α blockers are the most prescribed drugs by revenue, a global market of approximately $40 billion per year.[3] Studies have shown that a slowdown in aging that increases life expectancy by one year is worth $38 trillion and by 10 years is worth $367 trillion.[4]"

MYMD-1® is an oral next-generation TNF-α inhibitor with the potential to transform the way that TNF-α based diseases are treated due to its selectivity and ability to cross the blood brain barrier. MyMD is planning early-stage trials for rheumatoid arthritis and will provide guidance as the program develops.

About MyMD Pharmaceuticals
MyMD Pharmaceuticals, Inc. (Nasdaq: MYMD), is a clinical stage biopharma company developing groundbreaking therapies for the treatment of serious and debilitating autoimmune and inflammatory diseases. MyMD's lead clinical candidate, MYMD-1®, is an orally available next-generation TNF-α inhibitor with the potential to transform the way that TNF-α based diseases are treated. MYMD-1®, with its small molecule design, improved safety profile and ability to cross the blood brain barrier, has the promise to provide meaningful therapeutic solutions to patients not served by current TNF-α inhibitors and as a potential therapy for CNS-based inflammatory and autoimmune diseases. MYMD-1® has demonstrated the potential to slow the aging process and extend healthy lifespan. The company is evaluating MYMD-1® in Phase 2 studies for sarcopenia/frailty, a result of the aging process, as well as early-stage trials for rheumatoid arthritis (RA), with the potential to expand into other applications.

MyMD's second therapeutic candidate is Supera-CBD, a novel, synthetic, non-toxic cannabidiol (CBD) analog that is 8000 times more potent a CB2 agonist (activator) than plant-based CBD. The U.S. Drug Enforcement Administration (DEA)'s scientific review concluded Supera-CBD will not be considered a controlled substance or listed chemical under the Controlled Substances Act (CSA) and its governing regulations or require scheduling during development. In addition to its potential role in managing addiction, anxiety, chronic pain and seizures, Supera-CBD has also been shown to have anti-inflammatory effects. 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 Company’s Annual Report on Form 10-K for the year ended December 31, 2021, filed by MyMD on March 31, 2022, as may be supplemented or amended by the Company’s Quarterly Reports on Form 10-Q. 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.

References:

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