March 20, 2023

MyMD Pharmaceuticals® and Charles River Present Positive Data for Next Generation, Oral TNF-α Inhibitor MYMD-1® in Rheumatoid Arthritis

Preclinical results showed MYMD-1® significantly reduced histopathological changes and the severity of standard arthritis clinical trial measures compared to placebo; demonstrate future potential to disrupt the TNF-α inhibitor market

BALTIMORE--(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, is presenting data from a preclinical study of investigational, oral TNF-α inhibitor MYMD-1® at the 2023 Society of Toxicology Annual Meeting (SOT) in Nashville, TN. Study results comparing MYMD-1 to placebo were very highly significant and showed MYMD-1 reduced histopathological changes and the severity of standard arthritis clinical trial measures.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20230320005115/en/

The study was designed to investigate the anti-inflammatory effects of MYMD-1® in a rheumatoid arthritis (RA) model that mimics features of arthritis in humans and included commonly used clinical arthritis endpoints. Histopathology parameters were very highly significant vs placebo for composite score ($p<0.0001$), bone resorption ($p<0.0001$), periosteal/exostatic change ($p<0.001$), inflammation ($p<0.001$), pannus/synovial hyperplasia ($p<0.001$), and in life pawn volume ($p<0.001$). Disease severity (total composite score) was reduced by 47% with MYMD-1® at 450 mg/kg/day orally versus a 37% reduction for etanercept 10 mg/kg by subcutaneous injection (see attached graphs).

"These results demonstrate the potential of MYMD-1® to inhibit arthritis development as shown in this research model," said Sonia Edaye, Lead Investigator and Pharmacology/Discovery Scientist at Charles River Laboratories. "Unlike current TNF-α inhibitors, MYMD-1® can be given orally and is a promising investigational new drug for rheumatoid arthritis."

"These very highly significant results are exciting and pave the way for our plans to develop MYMD-1 as a potential treatment for rheumatoid arthritis," said Chris Chapman MD, President, Director, and Chief Medical Officer at MyMD Pharmaceuticals. "With its

differentiated oral administration and selectivity, MYMD-1® has strong potential as a next-generation TNF-α inhibitor that may one day offer a new and meaningful therapeutic solution for the more than 1 million people affected by RA in the US[1], many of whom are not served by current options."

Poster #3046/P148 entitled "A Naturally Occurring Novel Therapeutic and Oral Selective Inhibitor of TNF-α, MYMD-1® *(Isomyosamine)* Significantly Reduced the Inflammation and Disease Severity in Murine Model of Collagen Antibody-Induced Arthritis," is scheduled for poster presentation today March 20, 2023, at 9:00 AM CT.

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.

Study Design

The research model was induced by an intravenous injection of a monoclonal antibodies cocktail that directed to collagen type II on Day 1 (sensitization), followed by an intraperitoneal injection of the endotoxin LPS on Day 6 (boost immunization). Three doses of MYMD-1® (50, 250 and 450 mg/kg/day) were tested, and the dose formulations were administered by oral gavage, twice daily, starting at the onset of the disease (Day 8 in this study). Etanercept (a biologic TNF-α inhibitor) and Dexamethasone (a glucocorticoid) were also administered respectively twice weekly by subcutaneous injection (10 mg/kg) and daily by oral gavage (3 mg/kg) as positive controls.

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) has determined that Supera-CBD will not be classified as a regulated chemical 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

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7085464/

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