December 9, 2024

TNF Pharmaceuticals Presents Statistically Significant Phase 2a Trial Results for Novel Sarcopenia/Frailty Treatment at Prestigious International Conference

Based on successful Phase 2a data, Company set to initiate Phase 2b sarcopenia study in early 2025; currently securing centers of excellence to begin enrollment

First oral TNF-α inhibitor, if approved, would offer potential patient benefit in an approximate $40 billion TNF inhibitor market

BALTIMORE--(BUSINESS WIRE)-- TNF Pharmaceuticals, Inc. (Nasdaq: TNFA) ("TNFA" or the "Company"), a clinical stage biopharmaceutical company committed to developing novel oral therapies for autoimmune and inflammatory conditions, today announced that significant positive topline results from a Phase 2a study of its lead drug candidate MYMD-1® (isomyosamine) was presented at a prestigious international congress of global experts in sarcopenia and related disorders held December 6–8, 2024 in Washington, D.C.

"In our view, MYMD-1 could become a consequential therapeutic solution for patients not served by current TNF-alpha inhibitors," said Mitchell Glass, M.D., President and Chief Medical Officer of TNFA. "With no FDA-approved treatments available to sarcopenia/frailty patients that target this disease itself, there is a large unmet medical need for effective therapies. Plus, the estimated $3 billion sarcopenia treatment market is just a subset of the broader TNF inhibitor market which was estimated to be $40 billion in 2024.

"Based on the positive results from our MYMD-1 Phase 2a study, we are set to launch a Phase 2b study in sarcopenia/frailty early in the first quarter of 2025," Dr. Glass added.

The presentation, 'Isomyosamine for the Treatment of Sarcopenia in Elderly Population,' describes the results of a double-blind, placebo-controlled study in patients aged 65 years or older with chronic inflammation associated with sarcopenia/frailty. Subjects in the trial who were given once daily oral doses of MYMD-1 showed significant decreases in several biomarkers attributed to chronic inflammation, including tumor necrosis factor-alpha (TNF-α) (P=0.008), Interleukin-6 (IL-6) (P=0.03) and soluble TNF-α receptor 1 (sTNFR1) (P=0.02) at several timepoints throughout the 28 days of treatment. No serious adverse events were reported.

The global market value for TNF inhibitors was estimated to be $39.7 billion for 2024. Growing at an expected 3.6% CAGR for the next five years, the TNF inhibitor market is expected to reach $47.3 billion by 2029.[1]

Sarcopenia is the progressive loss of muscle mass and strength primarily due to aging. Based on conservative calculations, at least 50 million people were affected by sarcopenia in 2018, and the disease is projected to affect over 200 million over the next four decades due

to the growing elderly population.[2] The sarcopenia treatment market is estimated to be $3.07 billion in 2024 and is expected to grow at a CAGR of 4.48% to $4.02 billion by 2029.[3]

Approximately 10% to 16% of the elderly worldwide suffer from sarcopenia.[4] In addition to the elderly, sarcopenia is estimated to affect more than 1 in every 10 young adults of most ethnicities.[5] With no FDA-approved treatments for sarcopenia itself, as opposed to its symptoms, the estimated $40+ billion in related hospitalization costs is a considerable economic burden on the U.S. healthcare system.[6]

The 17th International Conference of the Society on Sarcopenia, Cachexia, & Wasting Disorders joins researchers, clinicians, academic experts, investigators and industry leaders from around the world. SCWD is a non-profit scientific organization comprised of an international and multidisciplinary group of healthcare professionals primarily active in these fields.

About MYMD-1®

MYMD-1® (isomyosamine) is a novel plant alkaloid small molecule shown to regulate the immuno-metabolic system through the modulation of numerous pro-inflammatory cytokines including TNF-alpha (TNF-α), an immune cell signaling protein and inflammatory cytokine responsible for inducing and maintaining the inflammatory process. TNF-α is located upstream of a cascade of molecular signals that induces inflammation and helps activate the process of aging. Many in vivo and in vitro studies have shown that TNFα plays a causative role in the pathogenesis of various age-related diseases.

About TNF Pharmaceuticals, Inc.

TNF Pharmaceuticals, Inc. (Nasdaq: TNFA) (formerly known as MyMD Pharmaceuticals, Inc.), 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 treat diseases and disorders marked by acute or chronic inflammation. 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.tnfpharma.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 neither the Company 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 Company's ability to maintain compliance with the Nasdaq Stock Market's listing standards; the timing of, and the Company's ability to, obtain and maintain regulatory approvals for clinical trials of the Company's pharmaceutical candidates; the timing and results of the Company's planned clinical trials for its pharmaceutical candidates; the amount of funds the Company requires for its pharmaceutical candidates; increased levels of competition; changes in political, economic or regulatory conditions generally and in the markets in which the Company operates; the Company's ability to retain and attract senior management and other key employees; the Company's ability to quickly and effectively respond to new technological developments; and the Company'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 the Company's proprietary rights. A discussion of these and other factors with respect to the Company is set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed by the Company on April 1, 2024, and subsequent reports that the Company files with the Securities and Exchange Commission. Forward-looking statements speak only as of the date they are made, and the Company disclaims any intention or obligation to revise any forward-looking statements, whether as a result of new information, future events or otherwise.

[1] Mordor Intelligence, TNF Inhibitors Market Size (2024 - 2029)

[2] *Biology*, Sarcopenia Is Associated with an Increased Risk of Postoperative Complications… (2023)

[3] Mordor Intelligence, Sarcopenia Treatment Market Size & Share Analysis - Growth Trends & Forecasts (2024 - 2029)

[4] Metabolism journal, Epidemiology of sarcopenia: Prevalence, risk factors, and consequences (2023)

[5] Metabolism journal, Sarcopenia in youth (2023)

[6] *Journal of Frailty & Aging,* Economic Impact of Hospitalizations in US Adults with Sarcopenia (2019)

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Source: TNF Pharmaceuticals, Inc.