January 15, 2025

TNF Pharmaceuticals Announces Positive Clinical Data Supporting Clinical Trial Expansion

Set to begin larger Phase 2b study in sarcopenia and new trial in GLP-1-induced sarcopenia and frailty

Transformative potential for novel TNF-alpha inhibitor drug:
Estimated $40 billion TNF inhibitor market and $50 billion GLP-1 agonist 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 it has achieved a key safety data milestone supporting expanded and longer-term clinical studies of its novel TNF-alpha (TNF-α) inhibitor drug, isomyosamine, in multiple indications.

The Company successfully completed an FDA-recommended study of isomyosamine that demonstrated clinical safety throughout 13 weeks of treatment at all dose levels evaluated.

"Positive data from this milestone study confirms isomyosamine's historically strong safety profile and enables us to extend the duration of future clinical trials," said Mitchell Glass, M.D., President and Chief Medical Officer of TNFA. "We believe we are fully equipped to advance our comprehensive isomyosamine platform in a longer-term clinical trial in sarcopenia and future studies in multiple conditions associated with immunometabolic dysregulation."

Trials, Indications, and Markets

Sarcopenia/frailty: TNFA plans to launch a Phase 2b clinical trial of isomyosamine's efficacy in sarcopenia early in the first quarter of 2025. The study will further explore the drug's efficacy in sarcopenia/frailty following statistically significant positive results from an earlier Phase 2 clinical study. The sarcopenia treatment market is estimated to be $3.07 billion in 2024 and is expected to grow at a compound annual growth rate (CAGR) of 4.48% and is estimated to reach $4.02 billion by 2029.[1]

GLP-1 muscle loss: the Company recently announced a planned trial of isomyosamine as a treatment for GLP-1-induced sarcopenia and frailty. The fully funded study is expected to evaluate TNF-α levels in patients receiving GLP-1 agonist Wegovy or Ozempic who show signals for increased inflammation associated with sarcopenia. Currently valued at $49.3 billion, the GLP-1 agonist market is projected to reach $105 billion by 2029, growing at an expected CAGR of 19.2% from 2023 to 2029.[2] According to the Centers for Disease Control

and Prevention, obesity costs the U.S. healthcare system nearly $173 billion annually.[3]

TNF inhibitor drug category: the global market value for TNF inhibitors was estimated to be $39.7 billion in 2024. Growing at an expected CAGR of 3.6% for the next five years, the TNF inhibitor market is expected to reach $47.3 billion by 2029.[4]

About Isomyosamine

Isomyosamine (MYMD-1®) 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 TNF-α plays a causative role in the pathogenesis of various age-related diseases.

About TNF Pharmaceuticals, Inc.

TNF Pharmaceuticals, Inc. (Nasdaq: TNFA), 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. Isomyosamine 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. Isomyosamine 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. Examples of such statements include, but are not limited to, statements regarding the Company's ability to launch and the timing of the Company's planned trial of MYMD-1 as a treatment for GLP-1-induced sarcopenia and frailty. 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.

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

[2] Global Data, March 2024

[3] Centers for Disease Control and Prevention (CDC), About Obesity, January 2024

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

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