January 29, 2025

TNF Pharmaceuticals Launches Study Series Aimed at Preserving Lean Muscle Mass During GLP-1 Weight Loss Treatment

Series of studies to observe signals of inflammation and TNF-alpha levels in patients taking GLP-1s including Wegovy® or Ozempic®

Lean body mass accounts for up to 40% of weight loss from GLP-1 treatments

Potential entry into high growth GLP-1 market of nearly $50 billion in 2024, projected value of $100 billion by 2029

BALTIMORE--(BUSINESS WIRE)-- TNF Pharmaceuticals, Inc. (Nasdaq: TNFA) ("TNF" or the "Company"), a clinical stage biopharmaceutical company committed to developing novel therapies for autoimmune and inflammatory conditions, today announced that it has initiated the first in a series of studies to evaluate the impact of its novel oral TNF-alpha (TNF-α) inhibitor drug, isomyosamine, in preserving lean muscle mass during and after GLP-1 treatment for weight loss and chronic weight management.

"The body of evidence for the GLP-1 drug class shows that up to 40% of total weight loss in GLP-1 patients is lean body mass including skeletal muscle mass,[1]" said Mitchell Glass, M.D., President and Chief Medical Officer of TNF. "The purpose of our clinical study series is to assess isomyosamine's potential to preserve lean muscle mass during and following GLP-1 weight loss in chronic overweight and obese patients of all age groups."

The first study examines TNF-α levels in patients receiving the GLP-1 agonist Wegovy® or Ozempic® who show signs of increased inflammation associated with sarcopenia, which is the progressive loss of muscle mass. Isomyosamine targets excess pro-inflammatory TNF-alpha, a primary cause of sarcopenia.

"Findings from the initial observational study will inform our forward move into multiple planned clinical studies designed to evaluate isomyosamine's effects in our target population of GLP-1 patients," Dr. Glass continued. "Our collaboration partner, Renova Health, is using its proprietary AI and machine learning technology to analyze and identify optimal patient pools and study sites, enabling an efficient progression of our study series over the coming months."

"We are proud to partner with TNF to tackle the critical challenges faced by patients using GLP-1 medications," said David Jacobs, Chief Executive Officer of Renova Health. "This

collaboration is expected to allow us to leverage our advanced AI and machine learning capabilities for precise cohort selection and patient engagement, enabling us to uncover deeper, more meaningful patient insights that will enhance the study's impact."

Valued at $49.3 billion in 2024,[2] the GLP-1 receptor agonist market is projected to reach $105 billion in 2029, growing at a projected compound annual growth rate (CAGR) of 19.2% from 2023 to 2029.[3] According to the Centers for Disease Control and Prevention, obesity costs the U.S. healthcare system nearly $173 billion annually.[4]

About Isomyosamine

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 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, the success and timing of, the Company's planned trial of isomyosamine (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.

_____

[1] Drug Discovery and Development, March 2024

[2] Research and Markets, GLP-1 Market: Industry Trends and Global Forecasts to 2035…., August 2024

[3] Global Data, March 2024

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

View source version on businesswire.com:
https://www.businesswire.com/news/home/20250129231553/en/

Investor Contact:
Robert Schatz
(646) 421-9523
rschatz@tnfpharma.com
www.tnfpharma.com

Source: TNF Pharmaceuticals, Inc.