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TNF Pharmaceuticals Announces Trial to Explore Effects of Lead Candidate in Sarcopenia/Frailty Induced by GLP-1 Weight Loss Drugs

Fully funded study to evaluate Wegovy and Ozempic patients at risk for increased inflammation associated with sarcopenic muscle deterioration

Collaboration partner to use AI and machine learning to identify targeted patient pool

Potential entry into high growth GLP-1 market valued at nearly $50 billion in 2024 and projected to surpass $100 billion by 2029

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 entered into a collaborative agreement with Renova Health for a planned trial of its TNF-alpha (TNF-α) inhibitor drug isomyosamine (MYMD-1) 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.

"The GLP-1 drug class has transformed the pharmaceutical landscape in recent years as the prevalence of obesity surges to record numbers. While GLP-1 receptor agonists are highly effective in treating overweight and obesity, rapid and extensive weight loss can bring a range of dangerous complications including sarcopenic loss of muscle mass and bone density," said Mitchell Glass, M.D., President and Chief Medical Officer of TNFA. "Since our lead drug targets excess pro-inflammatory TNF-alpha, a primary cause of sarcopenia, we believe it could provide a much-needed solution for preserving muscle mass in GLP-1-induced weight loss.

"We look forward to collaborating with Renova Health, a leading innovator supporting superior healthcare outcomes. Together we will work to identify the optimal patient pool, sample size, dosing regimen, and other key objectives for a successful open label trial," Dr. Glass added.

Studies have shown that up to 40% of the total weight lost by GLP-1 patients is lean body mass, which includes skeletal muscle mass.[1] If proven effective in preserving lean muscle mass during GLP-1 weight loss, isomyosamine could become a first-in-class therapy for a massive population of younger and middle-aged overweight and obese patients globally.

"Renova Health is excited to partner with TNF Pharmaceuticals," said David Jacobs, CEO of Renova Health. "Together, we share a commitment to putting patients first and exploring innovative ways to achieve better outcomes at lower costs. This collaboration reflects our

dedication to treating patients as real people, not just data points."

Dr. Juliet Daniel, Medical Director of Renova Health, added, "This partnership combines Renova's 'Hyper-Personalized' patient engagement expertise with TNFA's promising research. Together, we aim to address key challenges in GLP-1 therapies and advance care for patients affected by inflammation and muscle loss."

Currently valued at $49.3 billion, GLP-1 agonists are expected to be the top selling drug class in 2024.[2] The GLP-1 agonist market is projected to reach $105 billion in 2029, growing at an expected 19.2% CAGR from 2023 to 2029.[3]

According to the CDC, obesity costs the U.S. healthcare system nearly $173 billion annually.[4]

TNFA is currently conducting a Phase 2 clinical trial of isomyosamine as a treatment for aging-related sarcopenia. Based on statistically significant positive results from the smaller Phase 2a study, the Company plans to launch a Phase 2b study early in the first quarter of 2025.

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 TNFα plays a causative role in the pathogenesis of various age-related diseases.

About Renova Health

Renova Health partners with large clinic practices, hospital systems, and accountable care organizations to help deliver better patient outcomes at a lower cost. The key to Renova Health's success is its highly skilled, caring, and passionate Personal Health Advocates that create and nurture a personal, trusting relationship with patients that helps to uncover deeper insights and ultimately leads to superior healthcare outcomes. For more information, visit www.renovahealth.care

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.

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[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

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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