# Timber Pharmaceuticals Receives Orphan Drug Designation from U.S. FDA for TMB-003 for the Treatment of Systemic Sclerosis

*Timber Expects to Submit Investigational New Drug (IND) Application to the FDA in 2022*

WOODCLIFF LAKE, N.J., Jan. 12, 2021 (GLOBE NEWSWIRE) -- via NewMediaWire -- Timber Pharmaceuticals, Inc. ("Timber" or the “Company”) (NYSE American: TMBR), a biopharmaceutical company focused on the development and commercialization of treatments for rare and orphan dermatologic diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to TMB-003, the company’s locally delivered formulation of sitaxsentan, for the treatment of systemic sclerosis.

“People who are living with systemic sclerosis or scleroderma often struggle with their quality of life because the condition can be disfiguring and may cover joints and cause pain that affects movement and mobility,” said John Koconis, Chief Executive Officer of Timber. “Currently there is no FDA approved treatment for any cutaneous symptoms in scleroderma. We are pleased to receive orphan drug designation for our investigational treatment and look forward to advancing into clinical stage research.”

The Orphan Drug Designation program provides orphan status to drugs and biologics that are intended for the treatment, prevention or diagnosis of a rare disease or condition that affects less than 200,000 people in the U.S. Systemic sclerosis is a group of rare autoimmune connective tissue disorders (CTD) characterized by inflammation and thickening of the skin and other connective tissues from excessive collagen deposition. Systemic sclerosis leads to abnormalities in the skin, joints, and internal organs.

Sitaxsentan is a highly selective endothelin (ET-A) receptor antagonist, which is a class of drugs previously developed in oral form for the treatment of pulmonary arterial hypertension (PAH). TMB-003 is a locally delivered formulation of sitaxsentan that has the potential to reduce collagen while addressing systemic safety concerns associated with oral administration. Timber is in the preclinical stages of evaluating TMB-003 for the treatment of scleroderma and expects to submit an Investigational New Drug (IND) application to the FDA in 2022.

**About Timber Pharmaceuticals, Inc.**

Timber Pharmaceuticals, Inc. is a biopharmaceutical company focused on the development and commercialization of treatments for rare and orphan dermatologic diseases. The Company's investigational therapies have proven mechanisms-of-action backed by decades of clinical experience and well-established CMC (chemistry, manufacturing and control) and safety profiles. The Company is initially focused on developing non-systemic treatments for rare dermatologic diseases including congenital ichthyosis (CI), facial angiofibromas (FAs) in tuberous sclerosis complex (TSC), and scleroderma. For more information, visit www.timberpharma.com .

**Forward-Looking Statements**

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, competitive position, intellectual property rights, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential, "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be

materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's Form 10-Q filed on August 18, 2020 and its other filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

**For more information, contact:**

Timber Pharmaceuticals, Inc.
John Koconis
Chief Executive Officer
jkoconis@timberpharma.com

Investor Relations:
Stephanie Prince
PCG Advisory
(646) 762-4518
sprince@pcgadvisory.com

Media Relations:
Adam Daley
Berry & Company Public Relations
(212) 253-8881
adaley@berrypr.com