Timber Pharmaceuticals Reports Positive Top-line Results from Phase 2b CONTROL Study Evaluating TMB-001 in Moderate to Severe Congenital Ichthyosis

- *Data demonstrate reduction in targeted and overall severity of CI in patients treated with topical IPEG™ TMB-001 (topical isotretinoin)*
- *Company planning for end-of-Phase 2 meeting with FDA in the beginning of 2022*
- *Phase 3 study is expected to begin in Q2 2022*

Basking Ridge, NJ, Oct. 07, 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 positive top-line data from its Phase 2b CONTROL study evaluating TMB-001, an investigational topical isotretinoin formulated using Timber's patented IPEG™ delivery system, in patients with moderate to severe congenital ichthyosis (CI).

CI is a group of rare, genetic keratinization disorders that lead to dry, thickened, and scaling skin. People living with CI may have limited range of motion, chronic itching, an inability to sweat, high risk of secondary infections. There are no approved medications for CI and the current common management of this chronic disease is focused on reducing scaling or improving skin lubrication with both systemic and topical treatments.

The Phase 2b CONTROL study was a randomized, double-blind, vehicle-controlled study designed to assess the efficacy and safety of two concentrations of TMB-001 (0.05% and 0.1% isotretinoin) for the treatment of two distinct subtypes of moderate-to-severe CI (X-linked recessive and lamellar ichthyosis) in patients (n=33) nine years old or older. Subjects applied TMB-001 twice daily for 12 weeks. The primary endpoint was the reduction of targeted ichthyosis severity, determined by a 50 percent or greater reduction in the validated Visual Index for Ichthyosis Severity (VIIS) scaling score (or VIIS-50), a clinically meaningful change. Secondary endpoints included reduction in overall ichthyosis severity, as measured by a two-point improvement using the Investigator Global Assessment (IGA) scale, also considered to be a clinically relevant improvement. The study was not designed or powered for statistical analysis of the endpoints and was intended to provide information for future development.

Top-line results including descriptive statistics are described below:

- In the PP population, 100 percent (nominal $p= .04$) and 40 percent (nominal $p= ns$) of patients treated with TMB-001 0.05% and 0.1%, respectively, achieved VIIS-50 compared to 40 percent in the vehicle group.
- In the ITT population, 64 percent (nominal $p= 0.17$) and 40 percent (nominal $p= ns$) of patients treated with TMB-001 0.05% and 0.1%, respectively, achieved VIIS-50 compared to 33 percent in the vehicle group.
- In the PP population, 100 percent (nominal $p=.002$) and 60 percent (nominal $p=ns$) of patients treated with TMB-001 0.05% and 0.1%, respectively, achieved a ≥2 point improvement in the IGA at week 12 compared to 10 percent in the vehicle group.
- In the ITT population, 55 percent (nominal $p=.02$) and 40 percent (nominal $p=ns$) of patients treated with TMB-001 0.05% and 0.1%, respectively, achieved a ≥2 point improvement in the IGA at week 12 compared to 8 percent in the vehicle group.
- TMB-001 was generally well tolerated with a similar incidence of adverse events (AEs) across treatment groups. The most frequent AEs were local adverse effects common for such topical treatments. There were no treatment-related serious adverse events (SAE).

"We are extremely pleased with the encouraging data generated by the Phase 2b CONTROL study of TMB-001. The study was not powered or intended to show statistical significance, but we demonstrated clinically meaningful efficacy with a favorable safety profile that support the continued development of our lead product candidate," said John Koconis, Chairman and Chief Executive Officer of Timber. "We look forward

to additional study data and plan to present the full data set at scientific congresses or peer-reviewed journal publication in the near future."

"These topline results demonstrate the potential of TMB-001 to be an important option for the treatment of CI where no FDA-approved treatments are currently available and the standard of care is limited to the use of emollients or keratinolytics to reduce scaling and dryness," said Alan Mendelsohn, M.D., Chief Medical Officer of Timber. "We are committed to fulfilling the unmet need of CI patients and continuing to develop TMB-001 as quickly as possible. I would like to thank all of those who helped us to rapidly advance the CONTROL trial during the pandemic including the outstanding team of investigators and clinical sites and particularly the patients who participated in the study."

In 2018, the U.S. Food & Drug Administration (FDA) awarded TMB-001 a $1.5 million grant to support Phase 2a and Phase 2b clinical trials through its Orphan Products Clinical Trials Grant program. Timber is planning for an end-of-Phase 2 meeting with the FDA in the beginning of 2022 and expects to begin the Phase 3 study of TMB-001 in the second quarter of 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 other sclerotic skin diseases. 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 Annual Report on Form 10-K for the year ended December 31, 2020 as well as other documents that may be filed by the Company from time to time 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.

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