Timber Pharmaceuticals Announces Fast Track Designation Granted by FDA for TMB-001 in Severe Subtypes of Congenital Ichthyosis

Company expects to launch pivotal Phase 3 ASCEND clinical trial to evaluate TMB-001 within the next 60 days

BASKING RIDGE, NJ, April 28, 2022 (GLOBE NEWSWIRE) -- via NewMediaWire – Timber Pharmaceuticals, Inc. ("Timber" or the “Company”) (NYSE American: TMBR), a clinical-stage 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 Fast Track designation to TMB-001, a topical isotretinoin formulated using the company’s patented IPEG™ delivery system, for the treatment of X-linked recessive ichthyosis (XRI) and autosomal recessive congenital ichthyosis lamellar ichthyosis (ARCI-LI).

“Based on the clinical success that TMB-001 has shown to date, we believe we have an important opportunity to dramatically improve the lives of people living with congenital ichthyosis (CI) who currently have no FDA-approved treatments and limited standard of care options,” said John Koconis, Chairman and Chief Executive Officer of Timber. “The designation of Fast Track status is a significant achievement that speaks to the unmet need in CI. Now we can communicate frequently with the FDA throughout our pivotal Phase 3 ASCEND clinical trial with the goal of earlier drug approval and access by patients.”

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. CI is a group of rare genetic keratinization disorders that lead to dry, thickened, and scaling skin. In patients with severe subtypes of CI, including XRI and ARCI-LI, cutaneous manifestations include large, dark scaling throughout the body.

Timber completed the Phase 2b CONTROL study evaluating TMB-001 in moderate to severe CI. Data demonstrated a clinically meaningful reduction in targeted and overall severity of CI along with a favorable safety profile. A sub-analysis of the study presented at the American Academy of Dermatology (AAD) 2022 Annual Meeting showed patients achieved treatment success with TMB-001 regardless of the subtype of CI. Based on FDA feedback at a completed End-of-Phase 2 meeting, Timber intends to initiate the pivotal Phase 3 ASCEND clinical trial within the next 60 days.

A Fast Track designation allows for more frequent meetings and written communication from the FDA to discuss a drug's development plan and the design of proposed clinical trials to ensure collection of appropriate data needed to support drug approval. Fast Track designation also allows FDA to conduct a rolling review of an NDA or BLA, which means that a drug company can submit completed sections of its application to FDA for review, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. A drug that receives Fast Track designation may also be eligible for Accelerated Approval and Priority Review.

About Timber Pharmaceuticals, Inc.

Timber Pharmaceuticals, Inc. is a clinical-stage 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, 2021 as well as other documents filed by the Company from time to time thereafter 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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