



Filana Therapeutics Presents TSC-Related Epilepsy Program at Eilat XVIII

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Presentation described the biological rationale for the evaluation of simufilam in TSC-related epilepsy

AUSTIN, Texas, May 05, 2026 (GLOBE NEWSWIRE) -- Filana Therapeutics, Inc. (NASDAQ: FLNA, "Filana Therapeutics", the "Company"), a biotechnology company currently focused on developing therapies for Tuberous Sclerosis Complex (TSC)-related epilepsy, today announced that it delivered a scientific presentation at Eilat XVIII (the Eighteenth Eilat Conference on New Antiepileptic Drugs and Devices) in Madrid, Spain. The presentation outlined the biological rationale underlying the Company's clinical development program evaluating simufilam in TSC-related epilepsy.

"We are pleased to engage with the epilepsy community at this important international meeting. This gathering has provided the opportunity to discuss the scientific and clinical rationale for our simufilam program in TSC-related epilepsy," said **Rick Barry, President and Chief Executive Officer** of Filana Therapeutics, Inc. "In the meantime, we are focused on the work necessary to address the clinical hold, and we will provide updates as they become available."

About TSC and TSC-related Epilepsy

TSC is a rare genetic disorder resulting from a mutation in the *TSC1* or *TSC2* gene. These mutations affect the mechanistic target of rapamycin (mTOR) pathway and can cause tumors to grow in multiple organs¹. Epilepsy is the most common health issue affecting the TSC community, with 80% to 90% of TSC patients experiencing seizures². TSC-related epilepsy affects approximately 45,000 people in the U.S.^{3,4} Most patients start having seizures within their first year of life³. Even with multiple approved treatments, more than 60% of TSC patients remain refractory to antiepileptic therapy⁵.

TSC Program Status

Filana Therapeutics is working to address the previously disclosed request for information from FDA that was contained in a December 2025 Clinical Hold Letter, including the submission of additional preclinical data and protocol design modifications. The Company intends to submit a response to FDA following completion of these activities and expects to provide a program update in the coming months.

About Filana Therapeutics, Inc.

Filana Therapeutics, Inc. (NASDAQ: FLNA), is a biotechnology company focused on developing novel, investigational therapies to modulate the filamin A protein for the treatment of central nervous system disorders, such as tuberous sclerosis complex (TSC)-related epilepsy, and other diseases associated with dysregulation or overexpression of filamin A.

For more information, please visit: <https://www.FilanaTx.com>

References:

1. <https://www.tscalliance.org/researchers/preclinical-research/>
2. Crino P, Nathanson K, Petri Henske, E. *The Tuberous Sclerosis Complex*. *N Engl J Med*. (2006) 355 (13):1345-56. [DOI: 10.1056/NEJMra055323](https://doi.org/10.1056/NEJMra055323)
3. Zhang L, Huang T, Teaw S, Nguyen LH, Hsieh LS, Wong X, Burns LH, Bordey A. [Filamin A inhibition reduces seizure activity in a mouse model of focal cortical malformations](https://doi.org/10.1126/scitranslmed.aay0289). *Science Translational Medicine*. (2020) 12(531):eaay0289. [DOI: 10.1126/scitranslmed.aay0289](https://doi.org/10.1126/scitranslmed.aay0289)
4. <https://www.tscalliance.org/understanding-tsc/what-is-tsc/>
5. Chu-Shore, C. J., Major, P., Camposano, S., Muzykewicz, D., & Thiele, E. A. (2010). *The natural history of epilepsy in tuberous sclerosis complex*. *Epilepsia*, 51(7), 1236–1241. <https://doi.org/10.1111/j.1528-1167.2009.02474.x>

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Cautionary Note Regarding Forward-Looking Statements:

This news release contains forward-looking statements that may include but are not limited to statements regarding: our ability to successfully engage with, and satisfactorily respond to, requests for additional information from the U.S. Food and Drug Administration (FDA) concerning the full clinical hold on our investigational new drug application (IND) for simufilam in TSC-related epilepsy and the timing and outcomes of such interactions, the timing and plans to conduct clinical studies with simufilam following approval of our IND, the potential for simufilam as a treatment for TSC-related epilepsy and other potential indications, and the timing of anticipated milestones. These statements may be identified by words such as “anticipate”, “before”, “believe”, “could”, “expect”, “forecast”, “intend”, “may”, “pending”, “plan”, “possible”, “potential”, “prepares for”, “will”, and other words and terms of similar meaning.

Such statements are based on our current expectations and projections about future events. Such statements speak only as of the date of this news release and are subject to a number of risks, uncertainties and assumptions, including, but not limited to, those risks relating to our ability to provide FDA with additional information, including additional pre-clinical data, and modifying the proposed clinical trial protocol design, to satisfy completion of FDA’s review and release of full clinical hold, the ability to advance preclinical studies related to TSC-related epilepsy, and other potential indications, the ability to initiate an initial proof-of-concept study of simufilam in TSC-related epilepsy, and other risks inherent in drug discovery and development or specific to Filana Therapeutics, Inc., as described in the section entitled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2025 and subsequent reports to be filed with the SEC. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from expectations in any forward-looking statement. In light of these risks, uncertainties and assumptions, the forward-looking statements and events discussed in this news release are inherently uncertain and may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Except as required by law, we disclaim any intention or responsibility for updating or revising any forward-looking statements. For further information regarding these and other risks related to our business, investors should consult our filings with the SEC, which are available on the SEC’s website at www.sec.gov.

All of our pharmaceutical assets under development are investigational product candidates. These have not been approved for use in any medical indication by any regulatory authority in any jurisdiction and their safety, efficacy or other desirable attributes, if any, have not been established in any patient population. Consequently, none of our product candidates is approved or available for sale anywhere in the world.

Our clinical results from earlier-stage clinical trials or preclinical studies may not be indicative of future results from later-stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or any scientific data we present or publish.

We are in the business of new drug discovery and development. Our research and development activities are long, complex, costly and involve a high degree of risk. Holders of our common stock should carefully read our Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q in their entirety, including the risk factors therein. Because risk is fundamental to the process of drug discovery and development, you are cautioned to not invest in our publicly traded securities unless you are prepared to sustain a total loss of the money you have invested.



Source: Filana Therapeutics, Inc.