# Elios Therapeutics Announces Interim Phase IIb Results of TLPLDC, a Personalized Therapeutic Cancer Vaccine for the Treatment of Melanoma, at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting

*Interim Phase IIb Data Show Promising Reduction In Risk of Recurrence and a Well-Tolerated Safety Profile in Patients with Resected, High-Risk Melanoma*

AUSTIN, Texas, June 1, 2018 /PRNewswire/ -- Elios Therapeutics, a biopharmaceutical company developing innovative autologous, particle-delivered, dendritic cell cancer vaccines, today announced interim data from the ongoing prospective, randomized, double-blind, placebo-controlled Phase IIb clinical trial of the TLPLDC (tumor lysate, particle-loaded, dendritic cell) vaccine in patients with Stage III and IV, resected melanoma will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting on June 4, 2018 in Chicago, Illinois (Abstract # 9525).

The planned interim analysis was conducted after the first 120 patients enrolled in the trial had been randomized and treated for at least 6 months. In the per treatment population, TLPLDC showed a meaningful 32 percent reduction in the relative risk of recurrence (TLPLDC 29.4 percent vs. placebo 43.3 percent, p = 0.07) with a median follow-up of 12.6 months. There was no difference in recurrence in the intent-to-treat population (TLPLDC 56.6 percent, placebo 54.1 percent, p=0.65) with 11.9 months median follow-up. Overall, TLPLDC was safe and well-tolerated. In the study, only 33 percent of participants experienced any adverse event, and 98.6 percent of those were grade 1 and 2 events that included injection site reactions and flu-like symptoms. No serious adverse events were reported.

"The interim data evaluating the TLPLDC vaccine as an adjuvant treatment to prevent melanoma recurrences are very encouraging, suggesting clinical activity and demonstrating an attractive safety profile," said George E. Peoples, M.D., chief medical officer at Elios Therapeutics. "These data, combined with the recently reported results of our open label Phase II study demonstrating the synergistic effects of the TLPLDC vaccine in combination with checkpoint inhibitors, suggest a strong rationale for further clinical development in a Phase III program."

Detailed results from the ongoing Phase IIb study evaluating TLPLDC will be presented on Monday, June 4, 2018:

- **Abstract 9525 (Poster #352)**: Interim analysis of a prospective, randomized, double-blind, placebo-controlled, Phase IIb trial of the TLPLDC vaccine to prevent recurrence in resected Stage III or IV melanoma patients
- **Presenter**: John W. Myers, M.D., San Antonio Military Medical Center, Houston, TX
- **Data/Time**: Monday, June 4, 2018 from 1:15 PM - 4:45 PM CDT
- **Session**: Melanoma/Skin Cancers Poster Session – Hall A

**About the Study Design**
Elios Therapeutics is conducting a prospective, randomized, double-blind, placebo-controlled Phase IIb trial to evaluate the safety and efficacy of TLPLDC in patients with resected Stage III and IV melanoma. The primary endpoint is 2 year disease-free survival (DFS).

In the study, 120 participants were randomized (2:1) to receive either TLPLDC vaccine or placebo to prevent recurrence. TLPLDC or placebo vaccines were initiated within 3 months of completion of standard of care (SoC) therapies and were given at 0, 1, 2, 6, 12, and 18 months. Study participants were followed for recurrence per SoC. The interim analysis was

pre-specified at 6 months from randomization of the 120th study participant. Survival analysis was performed on the intent-to-treat and per treatment populations. The latter excludes early recurrences during the primary vaccine series (up to 6 months).

**About TLPLDC**

The TLPLDC (tumor lysate, particle-loaded, dendritic cell) vaccine is an autologous, personalized, therapeutic cancer vaccine designed to stimulate the immune system to recognize tumor cells and fight a patient's specific cancer. TLPLDC is made from a patient's own tumor and dendritic cells – the most potent antigen-presenting cells in the body. Once TLPLDC is injected, the tumor lysate-loaded dendritic cells present the tumor antigens to the immune system, stimulating the induction of tumor-specific, activated T cells that are able to find and destroy tumor cells that may remain in the body. TLPLDC is currently being studied as a monotherapy and in combination with SoC checkpoint inhibitor therapy in a Phase IIb clinical trial for the treatment of late-stage melanoma at leading academic cancer centers in the United States.

**About Elios Therapeutics, LLC**

Elios Therapeutics, LLC, is a biopharmaceutical company developing a portfolio of innovative therapeutic cancer vaccines targeting unmet medical needs across a broad range of tumor types. Elios' lead product, TLPLDC, is a personalized therapeutic cancer vaccine designed to attack cancer cells by igniting innate and adaptive immune responses which increase a patient's own production of T cells to fight their specific cancer. For more information, please visit www.eliostherapeutics.com.

**Forward-Looking Statements**

*This document contains forward-looking statements relating to the Company's strategy, objectives, business development plans and financial position. All statements other than statements of historical facts included in this document, including, without limitation, statements regarding the Company's future financial position, strategy, anticipated investments, costs and results, status and results of clinical trials, size of patient population, plans, outcomes of product development efforts, and objectives of management for future operations, may be deemed to be forward-looking statements. You can identify forward-looking statements by words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty or future events or outcomes.*

*These forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause the Company's actual results, performance, or achievements or industry results to be materially different from those contemplated, projected, forecasted, estimated or budgeted, whether expressed or implied, by these forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results. None of these forward-looking statements constitutes a guarantee of the future occurrence of such events or of actual results. These statements are based on data, assumptions, and estimates that the Company believes are reasonable.*

*The forward-looking statements contained in this document are made only as of the date hereof. Except as otherwise required by law, the Company expressly disclaims any obligation or undertaking to release publicly any updates of any forward-looking statements contained in this document to reflect any change in its actual results, assumptions, expectations or any change in events, factors, conditions, or circumstances on which any forward-looking statement contained in this document is based.*

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