

# Achilles Therapeutics Announces Independent Data and Safety Monitoring Committee Review with a Positive Recommendation to Continue with Current Study Design of the Phase I/IIa CHIRON and THETIS Trials

February 5, 2021

London, UK 5 February 2021 – Achilles Therapeutics ("Achilles" or the "Company"), a clinical-stage biopharmaceutical company developing precision T cell therapies to treat solid tumors, today announced that an Independent Data and Safety Monitoring Committee (IDSMC) has completed its first review of the ongoing, first-in-human Phase I/IIa CHIRON and THETIS trials and has recommended that both clinical trials continue as planned. In this review of the first six patients dosed with the Company's Clonal Neoantigen Targeting T cell therapy (cNeTs), the overall tolerability profile was generally similar to that of standard tumor-infiltrating lymphocyte (TIL) products that have not been enriched for cNeT reactivities, with the lymphodepletion regimen accounting for most higher-grade adverse events. Additionally, initial data from the first six patients provide encouraging evidence of cNeT engraftment. Based on these observations, the Company plans to increase the administered cNeT doses in the next series of monotherapy patients.

"This independent safety review along with the initial data from our CHIRON and THETIS trials are promising and are based on patients that have been dosed with cNeTs at the lower end of our prospectively targeted therapeutic dose range," said **Dr Iraj Ali, Chief Executive Officer of Achilles.** "We now plan to move to higher cNeT doses and also open a combination cohort in the THETIS trial evaluating the addition of a PD-1 inhibitor, following cNeT infusion, subject to further safety review."

Following the first disease evaluation by scan six-weeks post cNeT infusion, stable disease was observed in four out of the six patients and progressive disease in two. One patient had a reduction in the size of two of their four tumor lesions by approximately 55% and 90%. Engraftment data for our cNeTs are currently available from four patients, with evidence of engraftment in two. This tumor lesion reduction and the highest engraftment was in the patient who received the highest cell dose.

"In the field of T-cell therapies, engraftment and expansion of tumor-reactive T cells post infusion have been correlated to clinical response, therefore seeing engraftment of cNeTs at these relatively low dose levels is encouraging," **commented Dr Karl Peggs, Chief Medical Officer of Achilles.** "Importantly, we have demonstrated our capability to track cell engraftment, expansion, and persistence as a result of our ability to characterize our product at the level of individual cNeT reactivities, in addition to quantifying polyclonality of the infused cNeTs and of the engrafted cells."

Enrollment of patients is expected to begin in the second half of 2021 with both the higher cNeT doses and in combination with a PD-1 inhibitor following cNeT infusion.

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### Notes for Editors:

#### **About CHIRON and THETIS**

The CHIRON study is an open-label, multi-center Phase I/IIa trial evaluating the safety, tolerability, and clinical activity of cNeT therapy as a single dose in adult patients with advanced metastatic NSCLC. The THETIS study is an open-label, multi-center Phase I/IIa trial evaluating the safety, tolerability, and clinical efficacy of cNeT therapy as a single dose in patients with recurrent or metastatic malignant melanoma as monotherapy and in combination with a PD-1 inhibitor.

#### **About Achilles Therapeutics**

Achilles is a clinical stage, biopharmaceutical company developing precision T cell therapies targeting clonal neoantigens: protein markers unique to the individual that are expressed on the surface of every cancer cell. The Company has two ongoing Phase I/Ila trials, the CHIRON trial in patients with advanced non-small cell lung cancer (NSCLC) and the THETIS trial in patients with recurrent or metastatic melanoma. Achilles uses DNA sequencing data from each patient, together with its proprietary PELEUS™ bioinformatics platform, to identify clonal neoantigens specific to that patient, and then develop precision T cell-based product candidates specifically targeting those clonal neoantigens.

For further information please visit the Company's website at: <a href="www.achillestx.com">www.achillestx.com</a>.

## Forward-Looking Statements

This press release contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. The forward-looking statements in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except

to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

#### Further information:

Lee M. Stern – VP, IR & External Communications +1 (332) 373-2634

I.stern@achillestx.com

Consilium Strategic Communications
Mary-Jane Elliott, Sukaina Virji, Melissa Gardiner
+44 (0) 203 709 5000
achillestx@consilium-comms.com