



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

November 21, 2023

Peter Maag, Ph.D.
Chief Executive Officer
Kyverna Therapeutics, Inc.
5980 Horton St., STE 550
Emeryville, CA 94608

Re: Kyverna Therapeutics, Inc.
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted November 9, 2023
CIK No. 0001994702

Dear Peter Maag:

We have reviewed your amended draft registration statement and have the following comments.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Amendment No. 1 to Draft Registration Statement submitted November 9, 2023

Prospectus Summary

Overview, page 1

1. We note your response to comment 1 and reissue. Your disclosure on page 1 stating KYV-101 is "based on a [CAR] that has completed a 20-patient Phase 1 trial in oncology conducted by the National Institutes of Health" makes it appear that KYV-101 may not be the same product candidate used by the NIH in its Phase 1 trial. Please revise to disclose what technology you have developed versus what technology you have in-licensed. To the extent KYV-101 and the NIH product candidate differ, revise to disclose why it is appropriate to discuss the results from the NIH Phase 1 trial to support your proof of concept.

2. We note your disclosure that the differentiated properties of KYV-101, which was designed with a fully human single-chain fragment variable, are critical for the potential success of CAR T cells as autoimmune disease therapies, and we note your disclosure that you believe that the favorable profile of KYV-101 has the potential to be critical for the application of CAR T-cell therapies in indications such as autoimmune diseases. In this regard, we note your inclusion of data from the Schett Group case series and the disclosure on page 134 that patients with autoimmune diseases have been observed to tolerate treatment with CAR T-cell therapies without experiencing the Grade 3 and above CRS and ICANS adverse events seen in oncology trials. If known, explain the understanding of the tolerability of CAR T-cell therapy in patients with autoimmune diseases. For example, if in patients with B cell malignancies, where patients presumably have higher B cell counts, the higher proportion of CRS and ICANS can be explained by a higher number of B cells being depleted by the treatment than would be the case in autoimmune patients, please clarify the competitive advantage of your fully human single-chain fragment variable, or explain what other differentiated properties, or other aspects of the favorable profile, of KYV-101 provide you with a competitive advantage. We note, in this regard, the design goals described in the second paragraph on page 123 which do not appear to be mentioned in your summary. Also, please indicate in your disclosure on page 134 whether the Schett Group case series involved more fully humanized CAR T therapies than the therapies used in the DLBCL indications.

Translating transformational oncology experience with cell therapies to autoimmune diseases, page 2

3. As requested by comment 2, please indicate whether statistically meaningful conclusions can be drawn at this time from the clinical data referenced in the third paragraph of this section.

Our pipeline and programs, page 3

4. We note your response to comment 11 and reissue in part. Please revise your pipeline tables on pages 3 and 115 to disclose the undisclosed indication for your CAR T & Other Approaches program and expand the discussion on page 116 to discuss your research supporting your statement that "the use of antigen-specific T-regs, possibly through use of a CAR, holds promise by enhancing homing to antigen-specific effector T cells or sites of inflammation." We also note you now depict the clinical progress of two different studies for KYV-101's lupus nephritis indication in your pipeline table, including a progress bar for approval in Europe. Please revise to remove the individual study progress rows and revert to a single row depicting the overall current phase of development for the program as it appears from your disclosure that you are not currently pursuing regulatory approval in Europe but only conducting clinical trials in Europe. Revise to include a footnote disclosing that KYV-101's Fast Track designation in lupus nephritis does not assure that you will experience a faster development process, regulatory review or regulatory approval process compared to conventional FDA procedures as you disclose on page 58.

Peter Maag, Ph.D.
Kyverna Therapeutics, Inc.
November 21, 2023
Page 3

5. We note your revised disclosure in response to comment 13. For the study you reference, please clarify what models were used for the *in vivo* comparisons, for example, mice or humans.

Systemic Sclerosis (SSc) Disease Overview, page 129

6. We note your revisions in response to comment 15. Please continue to revise to discuss the clinical development of KYV-101 for systemic sclerosis. Disclose the trial design, number of patients, and primary and secondary endpoints.

Notes to Financial Statements

6. Significant Agreements, page F-16

7. We note your response to prior comment 25 and the revised disclosure. Please revise to clarify whether the entire amount is now due upon the consummation of a qualified financing. Also, clarify the disclosure on page 100 for when the \$6.3 million is due.

Please contact Jenn Do at 202-551-3743 or Vanessa Robertson at 202-551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Daniel Crawford at 202-551-7767 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Jeffrey T. Hartlin, Esq.