UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LIQUIDIA TECHNOLOGIES, INC., *Plaintiff*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, *Defendants*.	Case No. 1:24-cv-02428-JDB

PLAINTIFF LIQUIDIA TECHNOLOGIES, INC.'S
MOTION FOR PRELIMINARY INJUNCTION

Pursuant to Federal Rule of Civil Procedure 65 and Local Civil Rule 65.1, Plaintiff Liquidia Technologies, Inc. ("Liquidia"), by undersigned counsel, respectfully moves this Court for a preliminary injunction enjoining an August 16, 2024 decision (the "Exclusivity Decision") by Defendants U.S. Food and Drug Administration ("FDA"), Robert M. Califf, M.D. (in his official capacity as Commissioner of Food and Drugs), U.S. Department of Health and Human Services ("HHS"), and Xavier Becerra (in his official capacity as Secretary of HHS) (collectively, "FDA" or "Defendants"), in which the FDA has refused (for a second time in the past three years) to grant full approval of Liquidia's first drug product, Yutrepia, despite findings by the agency on two occasions that Yutrepia is a safe and effective drug that warrants approval.

Liquidia makes this motion for preliminary injunction on the ground that Defendants' Exclusivity Decision to grant three-year new clinical investigation exclusivity ("NCI exclusivity") to Tyvaso DPI exceeded FDA's statutory authority, was arbitrary and capricious, and was contrary

to law. The Exclusivity Decision unlawfully penalizes the sponsor (Liquidia) who actually developed the innovation at issue (dry powder inhalation) long before United Therapeutics Corporation ("UTC") filed the Tyvaso DPI NDA, while prolonging UTC's decades-long monopoly on treprostinil for another nine months—far beyond the statutory limits prescribed by Congress—to the detriment of patients, competition, and the public health.

All factors strongly favor this Court's issuance of a preliminary injunction. Liquidia is likely to prevail on the merits because FDA's Exclusivity Decision violates the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act. Preliminary injunctive relief would serve the public interest by ensuring that FDA adheres to the framework Congress created for awarding NCI exclusivity only for significant innovations, and that NCI exclusivity applies only to innovations supported by those new clinical investigations. Such relief would also serve the public interest by ensuring that patients suffering from pulmonary arterial hypertension ("PAH") and pulmonary hypertension associated with interstitial lung disease ("PH-ILD") have prompt access to Yutrepia's potentially life-saving treatment. The Exclusivity Decision is causing immediate and irreparable harm to both Liquidia, by preventing Liquidia from distributing its first drug candidate, and to patients nationwide, who would greatly benefit from access to Yutrepia.

The grounds for this motion are set forth more fully in the accompanying Memorandum of Law, as well as the declarations of Mike Kaseta and Sonia W. Nath submitted herewith.

Liquidia requests, pursuant to Local Civil Rule 65.1(d) and for the reasons more fully set forth in its supporting memorandum, that the Court schedule a hearing on this motion as soon as possible after the filing of this application to avoid severe irreparable harm. Liquidia respectfully requests that the Court schedule oral argument **no later than** September 17, 2024.

As required by Local Civil Rule 7(m), counsel for Liquidia conferred with counsel for Defendants on August 26 and 27, 2024. Defendants' counsel informed undersigned counsel that Defendants oppose the relief requested in this motion. Because the requested relief would be entered against FDA and the other federal defendants, it presents no risk of monetary damage to those parties, such that no bond is necessary pursuant to Rule 65(c) of the Federal Rules of Civil Procedure.

Accordingly, Liquidia respectfully requests that this Court issue a preliminary injunction setting aside the Exclusivity Decision and requiring FDA to grant full approval to Yutrepia for both the PAH and PH-ILD indications, or at minimum PH-ILD.

Dated: August 27, 2024

Respectfully submitted,

By: */s/ Sonia W. Nath*

Sonia W. Nath (DC Bar No. 977095)
David E. Mills (DC Bar No. 401979)
Robby Saldaña (DC Bar No. 1034981)
Matt K. Nguyen (DC Bar No. 1736777)
COOLEY LLP
1299 Pennsylvania Ave., NW, Suite 700
Washington, DC 20004-2400
Telephone: (202) 842-7800
Facsimile: (202) 842-7899
snath@cooley.com
dmills@cooley.com
rsaldana@cooley.com
mnguyen@cooley.com

Kathleen R. Hartnett (DC Bar No. 483250)
COOLEY LLP
3 Embarcadero Center, 20th Floor
San Francisco, CA 94111-4004
Telephone: (415) 693-2000
Facsimile: (415) 693-2222
khartnett@cooley.com

Counsel for Plaintiff Liquidia Technologies, Inc.