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## UNITED THERAPEUTICS CORPORATION FILES LAWSUIT AGAINST LIQUIDIA FOR INFRINGEMENT OF TYVASO PATENTS

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., June 5, 2020: United Therapeutics Corporation (Nasdaq: UTHR) announced today that it has filed a lawsuit in the U.S. District Court for the District of Delaware against Liquidia Technologies, Inc. (Liquidia) for infringement of the following patents relating to United Therapeutics' product Tyvaso® (treprostinil) Inhalation Solution: U.S. Patent Nos. 9,604,901 (the '901 patent) and 9,593,066 (the '066 patent), both of which expire in December 2028.

The lawsuit is based on a New Drug Application (NDA) filed by Liquidia with the U.S. Food and Drug Administration (FDA) requesting approval to market LIQ861, a dry powder inhalation formulation of treprostinil. The NDA was filed under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. In April 2020, United Therapeutics received a Paragraph IV notification letter from Liquidia indicating that Liquidia's NDA contains a certification alleging that LIQ861 will not infringe any of the patents then listed in the Orange Book for Tyvaso because those patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use, or sale of LIQ861. In March 2020, Liquidia filed petitions for *inter partes* review seeking to invalidate the '901 and '066 patents.

United Therapeutics filed its lawsuit within 45 days of receipt of notice from Liquidia of its NDA filing. As a result, under the Hatch-Waxman Act, the FDA is automatically precluded from approving Liquidia's NDA for up to 30 months or until the resolution of the litigation, whichever occurs first.

United Therapeutics intends to vigorously enforce its intellectual property rights relating to Tyvaso. However, given the unpredictability inherent in litigation, United Therapeutics cannot predict the outcome of this matter or guarantee the outcome of this litigation.

## **About United Therapeutics**

United Therapeutics Corporation focuses on the strength of a balanced, value-creating biotechnology model. We are confident in our future thanks to our fundamental attributes, namely our obsession with quality and innovation, the power of our brands, our entrepreneurial culture, and our bioinformatics leadership. We also believe that our determination to be responsible citizens – having a positive impact on patients, the environment, and society – will sustain our success in the long term.

Through our wholly owned subsidiary, Lung Biotechnology PBC, we are focused on addressing the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply. Lung Biotechnology is the first public benefit corporation subsidiary of a public biotechnology or pharmaceutical company.

## **Forward-looking Statements**

Statements included in this press release that are not historical in nature are "forwardlooking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, statements relating to our ability to successfully enforce our intellectual property rights, our ability to create value and sustain our success in the long-term, and our efforts to develop technologies that either delay the need for transplantable organs or expand the supply of transplantable organs. These forward-looking statements are subject to certain risks and uncertainties, such as those described in our periodic reports filed with the Securities and Exchange Commission, that could cause actual results to differ materially from anticipated results. Consequently, such forward-looking statements are qualified by the cautionary statements, cautionary language, and risk factors set forth in our periodic reports and documents filed with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We are providing this information as of June 5, 2020 and assume no obligation to update or revise the information contained in this press release whether as a result of new information, future events, or any other reason.

TYVASO is a registered trademark of United Therapeutics Corporation.

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