Merlin Biotech, a Pennsylvania startup focused on hard-to-treat cancers, announces major milestones

- The FDA has designated MER-101 as a drug for a rare pediatric disease and conditionally designates Merlin's marketing application as a "rare pediatric disease product application" carrying eligibility for a Priority Review Voucher that have recently sold between $108M to $158M.
- Japanese Patent Office has granted a broad patent on Merlin's target with an expiration date of 2039.
- Merlin has raised over $1M in non-dilutive and dilutive funds.

Doylestown, PA / September 2, 2024 / The US Food and Drug Administration (FDA) has conditionally designated Merlin Biotech, Inc.'s, marketing application for MER-101 as a "rare pediatric disease product application" *pending the final determination whether the application meets all of the eligibility criteria set forth in section529(a)(4) of the FD&C Act at the time of approval or licensure.* With this designation and upon approval of MER-101, Merlin would receive a Priority Review Voucher (PRV). A PRV is transferable and salable, have recently sold between $108M to $158M.

From the FDA, "the rare pediatric disease PRV program aims to incentivize drug development for rare pediatric diseases. Under this voucher program, a sponsor who receives an approval for a drug or biological product for a rare pediatric disease may qualify for a voucher that can be redeemed to receive priority review for a different product. The sponsor may also transfer or sell the voucher to another sponsor. FDA awards rare pediatric disease PRVs to sponsors of rare pediatric disease products that are approved and meet certain criteria. Prior to submitting a marketing application for its drug, a sponsor that plans to request a rare pediatric disease PRV may request rare pediatric disease designation."

The Japanese Patent Office has granted a broad patent (No. 7531490) on the MER-101 target, with an expiration date of November 27, 2039. The same patent application is under review in other major markets including the United States.

Merlin has raised over $1M raised in non-dilutive and dilutive funds.

With sufficient seed funding, Merlin will complete the FDA directed pre-clinical studies and MER-101 will begin clinical trials for adult indications in Australia in 2026. Shortly thereafter pivotal clinical studies for the pediatric indication will begin in the United States. Given the high unmet medical need, Merlin anticipates an accelerated review and approval process.

"FDA's condition designation and Japan's granting of the patent are key milestones in accelerating this remarkable immune-therapy for hard-to-treat cancers," said Randall N. Hyer, MD, PhD, MPH, the CEO of Merlin Biotech. "I look forward to getting MER-101 into the clinic as soon as possible."

3805 Old Easton Road | Doylestown, PA 18902 | 215-589-6300 | info@merlinbiotech.com

ABOUT MERLIN BIOTECH INC.

Merlin Biotech, Inc., is a pre-clinical biotechnology company founded in 2022 based at the Pennsylvania Biotechnology Center in Philadelphia and Doylestown, PA. Merlin is developing MER-101, a novel cancer immune therapy with broad pediatric and adult solid cancer indications. Merlin is led by Dr. Randall N. Hyer, a former Moderna SVP and industry veteran with multiple drug approvals. Merlin's scientific advisory board comprises numerous prominent researchers and clinicians including Stanley A. Plotkin, MD, and Nobel Laureate Harvey J. Alter, MD.

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For inquiries, contact Lily Paulovic at info@merlinbiotech.com or tel 215 589 6111.

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