Repare Therapeutics Announces Fast Track Designation Granted by the FDA for Lunresertib in Combination with Camonsertib for the Treatment of Platinum-Resistant Ovarian Cancer

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CAMBRIDGE, Mass. & MONTREAL--(BUSINESS WIRE)--Jun. 4, 2024-- Repare Therapeutics Inc. (“Repare” or the “Company”) (Nasdaq: RPTX), a leading clinical-stage precision oncology company, today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to lunresertib in combination with camonsertib for the treatment of adult patients with CCNE1 amplified, or FBXW7 or PPP2R1A-mutated platinum-resistant ovarian cancer.

Lunresertib in combination with camonsertib is currently being evaluated in Repare’s MYTHIC Module 2 Phase 1 dose expansion clinical trial at the recommended Phase 2 dose in patients with ovarian and endometrial cancers harboring CCNE1 amplification or FBXW7 or PPP2R1A mutations. In addition to the Fast Track designation announced today, the FDA previously granted Fast Track designation to lunresertib in combination with camonsertib for the treatment of adult patients with CCNE1 amplified, or FBXW7 or PPP2R1A mutated endometrial cancer in the third quarter of 2023. Repare expects to present data from the MYTHIC Module 2 dose expansion cohorts in approximately 20-30 patients each with ovarian and endometrial cancer in the fourth quarter of 2024.

“The FDA’s decision to grant Fast Track designation supports our goal of quickly and efficiently developing the lunresertib-camonsertib combination for patients with genomically-defined platinum-resistant ovarian cancer,” said Maria Koehler, MD, PhD, Executive Vice President and Chief Medical Officer of Repare. “Ovarian cancer patients need therapies that provide long-term benefit beyond that observed with standard of care. Our precision medicine approach targets treatment to patients who could most benefit from a well-tolerated alternative to chemotherapy.”

The FDA’s Fast Track process is designed to facilitate the development and expedite the review of therapies intended to treat serious conditions and address unmet medical needs to potentially bring important new medicines to patients earlier. Companies whose programs are granted FTD are eligible for more frequent interactions with the FDA during clinical development and potentially accelerated approval and/or priority review, if relevant criteria are met. For more information on Fast Track Designation, please visit the FDA’s website at https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.

About Repare Therapeutics’ SNIPRx® Platform

Repare’s SNIPRx® platform is a genome-wide CRISPR-based screening approach that utilizes proprietary isogenic cell lines to identify novel and known synthetic lethal gene pairs and the corresponding patients who are most likely to benefit from the Company’s therapies based on the genetic profile of their tumors. Repare’s platform enables the development of precision therapeutics in patients whose tumors contain one or more genomic alterations identified by SNIPRx® screening, in order to selectively target those tumors in patients most likely to achieve clinical benefit from resulting product candidates.

About Repare Therapeutics Inc.

Repare Therapeutics is a leading clinical-stage precision oncology company enabled by its proprietary synthetic lethality approach to the discovery and development of novel therapeutics. The Company utilizes its genome-wide, CRISPR-enabled SNIPRx® platform to systematically discover and develop highly targeted cancer therapies focused on genomic instability, including DNA damage repair. The Company’s pipeline includes lunresertib (also known as RP-6306), a PKMYT1 inhibitor currently in Phase 1/2 clinical development; camonsertib (also known as RP-3500), a potential leading ATR inhibitor currently in Phase 1/2 clinical development; RP-1664, a Phase 1 PLK4 inhibitor; RP-3467, a preclinical Polθ ATPase inhibitor program; as well as additional, undisclosed preclinical programs. For more information, please visit www.reparerx.com and follow @Reparerx on X (formerly Twitter) and LinkedIn.

SNIPRx® is a registered trademark of Repare Therapeutics Inc.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 and securities laws in Canada. All statements in this press release other than statements of historical facts are “forward-looking statements. These statements may be identified by words such as “aims,” “anticipates,” “believes,” “could,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “seeks,” “will” and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding: the design, objectives, initiation, timing, progress and results of current and future preclinical studies and clinical trials of the Company’s product candidates, including the expansion of its Phase 1 MYTHIC trial evaluating lunresertib alone and in combination with camonsertib and expected data from the dose expansion cohorts; the potential benefits of Fast Track designation, including frequency of interactions with the FDA during clinical development and potentially accelerated approval and/or priority review; the Company’s planned expansion of development of lunresertib plus camonsertib combination; the tolerability, efficacy and clinical progress of camonsertib, lunresertib, RP-1664 and RP-3467; the potential of RP-3467 as a best-in-class Polθ ATPase inhibitor; the potential synergies of lunresertib in combination with camonsertib; and the benefits and ability to discover further targets and clinical candidates from the Company’s discovery platform. These forward-looking statements are based on the Company’s expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties that could cause the Company’s clinical development programs, future results or performance to differ materially from those expressed or implied by the forward-looking statements. Many factors may cause differences between current expectations and actual results, including: the potential that success in preclinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate; the impacts of macroeconomic conditions, including the conflict in Ukraine and the conflict in the Middle East, heightened inflation and uncertain credit and financial markets, on the Company’s business, clinical trials and financial position; unexpected safety or efficacy data observed during preclinical studies or clinical trials; clinical trial site activation or enrollment

rates that are lower than expected; the Company's ability to realize the benefits of its collaboration and license agreements; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process; and unexpected litigation or other disputes. Other factors that may cause the Company's actual results to differ from those expressed or implied in the forward-looking statements in this press release are identified in the section titled "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 filed with the Securities and Exchange Commission ("SEC") and the Québec Autorité des Marchés Financiers ("AMF") on May 7, 2024. The Company expressly disclaims any obligation to update any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law. For more information, please visit www.reparerx.com and follow Repare on Twitter at @RepareRx and on LinkedIn.

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