Repare Therapeutics Presents RP-3500 Dose Selection Phase 1 Monotherapy Safety Data from the Phase 1/2 TRESR Clinical Trial at the 2022 ESMO Targeted Anticancer Therapies Congress

March 7, 2022

Dose optimization provides robust evidence to advance RP-3500 into Phase 2 studies with a recommended dose and schedule

CAMBRIDGE, Mass. & MONTREAL--(BUSINESS WIRE)--Mar. 7, 2022-- Repare Therapeutics Inc. (“Repare” or the “Company”) (Nasdaq: RPTX), a leading clinical-stage precision oncology company enabled by its proprietary synthetic lethality approach to the discovery and development of novel therapeutics, today announced the presentation of monotherapy dose selection and safety data from its Phase 1/2 TRESR (Treatment Enabled by SNIPRx) clinical trial of RP-3500 at the 2022 ESMO Targeted Anticancer Therapies (TAT) Congress. RP-3500 is a potent and selective oral small molecule inhibitor of ATR (Ataxia-Telangiectasia and Rad3-related protein kinase) in development for the treatment of solid tumors with specific synthetic-lethal genomic alterations, including those in the ATM gene (Ataxia-Telangiectasia mutated kinase).

“The data featured today at ESMO TAT continues to show that RP-3500 is well tolerated. The dose optimization approach used in the trial provides robust evidence to support the recommended phase two dose and schedule in our ongoing trials. We believe these data confirm a well differentiated and likely best in class profile of RP-3500,” said Maria Koehler, MD, PhD, Chief Medical Officer of Repare. “We look forward to presenting updated clinical data from 120 patients enrolled in the Phase 1/2 TRESR trial in the first half of this year.”

Key Findings from the TRESR Phase 1 Safety Data:

TRESR is a first-in-human, multi-center, open-label Phase 1/2 dose-escalation and expansion clinical trial, designed to establish the recommended Phase 2 dose (RP2D) and schedule, evaluate safety and pharmacokinetics and identify preliminary anti-tumor activity associated with RP-3500, given alone and in combination with talazoparib. The study also examined biomarker responses and their relationship with RP-3500 antitumor activity.

Safety data presented in the oral presentation include a comprehensive safety analysis from three monotherapy dosing schedules of RP-3500 at therapeutic doses:

- 120mg once daily, 3 days on/4 days off
- 160mg once daily, 3 days on/4 days off
- 160mg once daily, 3 days on/4 days off, 2 weeks on/1 week off

Highlights from the data presented at ESMO TAT congress include:

- This comprehensive safety analysis confirmed the acceptable tolerability of the recommended phase 2 dose (160mg 3 days/4 days off)
- Anemia was the most common reported toxicity with less than 25% of patients experiencing grade 3 toxicities
- A dose modification plan that includes 2 alternative dosing schedules was established to mitigate the on-target toxicity of anemia and maintain patients on an RP-3500 dosing schedule that targets antitumor activity
- A nomogram, based on cycle 1 assessment of toxicities, is being prospectively evaluated to identify patients at increased risk of anemia and inform early intervention

Oral Presentation Details:

Title: Comprehensive Dose-Finding Strategy for Single-Agent RP-3500, a Highly Selective Inhibitor of Ataxia-Telangiectasia and Rad3-Related (ATR) Kinase
Presenter: Dr. Elisa Fontana, Sarah Cannon Research Institute UK
Abstract Number: 202
Session Title: DNA Damage Repair

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 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 its lead product candidate RP-3500, a potential leading ATR inhibitor currently in Phase 1/2 clinical development, as well as RP-6306, a CCNE1-SL inhibitor, and a Polθ inhibitor program. For more information, please visit reparerx.com.

Forward-Looking Statement

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. 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 clinical development of the Company’s pipeline and its research and development programs, including the anticipated timing, anticipated patient enrollment, trial outcomes or associated costs of its Phase 1/2 TRESR clinical trial of RP-3500. 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 impacts of the COVID-19 pandemic 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, 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 Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission (“SEC”) and the Québec *Autorité des Marchés Financiers* ("AMF") on March 1, 2022, and its other documents subsequently filed with or furnished to the SEC and AMF. 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.

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