

TRIAL/PROGRAM STATUSES – 3rd NOVEMBER 2021

[ARTISTRY-7 Ph 3 Trial of Nemvaleukin Alfa Initiated in Patients With Platinum-Resistant Ovarian Cancer](#)

"The initiation of our phase 3 study of nemvaleukin in platinum-resistant ovarian cancer is an important milestone for the nemvaleukin clinical development program and reflects our commitment to focusing on the high unmet need of patients living with difficult-to-treat cancers such as platinum-resistant ovarian cancer," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President of Research & Development at Alkermes. "ARTISTRY-7 is designed to build upon the durable and deepening responses observed in heavily pre-treated patients with platinum-resistant ovarian cancer in the ongoing ARTISTRY-1 study. We look forward to sharing updates from ARTISTRY-7 as the study progresses and as we advance toward potential registration."

[First Patient Dosed in Global Ph 2 TRUST-II Study for Taletrectinib in ROS1 Fusion-Positive Lung Cancer](#)

"Taletrectinib dosing of the first patient in our global Phase 2 ROS1 fusion-positive TRUST-II lung cancer trial represents a key milestone for our lead ROS1-directed clinical program," said Bing Yan, MD, Co-Founder and Chief Medical Officer of AnHeart Therapeutics. "Based on the broad expression of ROS1 fusions across different cancer types, and our recent clinical data presented at ASCO and CSCO showing taletrectinib antitumor activity with a promising safety and efficacy profile, we are proud of advancing this investigational candidate as a potential new therapy for ROS1 fusion-positive lung cancer."

[First Patient Dosed in the Pivotal Clinical Study of KN046 for the Treatment of PD-\(L\)1 Refractory Advanced NSCLC](#)

The principal investigator Professor Caicun Zhou, Director of the Department of Oncology from Shanghai Pulmonary Hospital Affiliated to Tongji University, commented, "In recent years, major progress has been made in lung cancer treatment, especially immunotherapies *have brought significant clinical benefits to patients. However, there is still no effective option for PD-(L)1 refractory NSCLC patients. Through ENREACH-LUNG-02 study, we look forward to bringing new treatment options to these patients with huge unmet needs."

[Last Patient Enrolled in Ph 3 Pivotal INNOVATE-3 Trial of Tumor Treating Fields in Ovarian Cancer](#)

"This is a major step forward for our clinical trial program and an important achievement for patients, trial investigators and our company," said William Doyle, Novocure's Executive Chairman. "Ovarian cancer is the fifth leading cause of cancer death in women, impacting

nearly 100,000 patients annually in the U.S., Europe and Japan, alone. INNOVATE-3 is the largest abdominal trial to complete enrollment in Novocure history, and we are excited to be enhancing the clinical field in support of people with this deadly disease.”

[Ph 2 Cohort expanded and New Sub-Studies added to Existing Clinical Collaboration of Nirogacestat + BLENREP in Patients with Relapsed or Refractory Multiple Myeloma](#)

“We continue to remain intensely focused on advancing nirogacestat as a potential best-in-class cornerstone of BCMA combination therapy for patients with multiple myeloma and are pleased with the progress that has been made with our collaborator GSK,” said Saqib Islam, Chief Executive Officer of SpringWorks. “We believe in the emerging role of nirogacestat as a BCMA potentiator and we look forward to working with GSK to advance the expanded program.”

[First Patient Dosed in Ph 2 Trial of ONA-XR in Metastatic Breast Cancer](#)

“Context is honored to have WON Co-Principal Investigators Sailaja Kamaraju, MD, MS, Associate Professor at the Medical College of Wisconsin, Milwaukee and Kari Wisinski, MD, Professor, Interim Chief of the Division of Hematology, Medical Oncology and Palliative Care for the Department of Medicine at UW-Madison to spearhead this important research collaboration and explore this combination as a potential additional treatment option for patients living with this devastating disease,” said Martin Lehr, CEO of Context Therapeutics. “We hope this study will provide a robust picture of how ONA-XR works in advanced ER+, PR+, HER2- breast cancer and inform the design of a future Phase 3 trial.”

[Ph 3 Clinical Trial ECLIPSE for Lu 177 PSMA I&T Initiated](#)

“We are committed to working closely with the FDA to potentially bring this new therapeutic radiopharmaceutical agent to patients and their healthcare professionals,” said Curium Vice President of Medical and Compliance, Ed Porter. “We look forward to engaging additional clinical trial sites as we finalize our clinical development program.”

[UV1 to be investigated in a new Ph 2 clinical trial in combination with pembrolizumab in NSCLC](#)

“We see this new trial as a significant opportunity for Ultimovacs to make a difference to the lives of thousands of patients with advanced lung cancer.” said Carlos de Sousa, CEO of Ultimovacs. “Our extensive Phase II program is aimed at building a substantial evidence base that UV1 in combination with checkpoint inhibitors can stimulate the immune response resulting in enhanced treatment outcomes.”