TRIAL/PROGRAM STATUSES – 20th October 2021

First Patient Enrolled in International Ph 3 ARTEST Clinical Trial of Enobosarm in Metastatic Breast Cancer

“While endocrine therapies have been the mainstay of breast cancer treatment for decades, these therapies have all focused on the estrogen receptor. Targeting the AR, a demonstrated tumor suppressor, provides us with an opportunity to bring a truly novel hormone treatment approach to patients who have AR+ER+HER2- metastatic breast cancer,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru Inc. “We already have substantial safety information about enobosarm therapy as it has been evaluated in 25 clinical trials comprising over 2,000 patients with approximately 350 patients dosed at 9mg or higher doses. Enobosarm is well tolerated and has also resulted in improvements in quality of life including reported better physical function, mobility, and pain in metastatic breast cancer patients. Furthermore, a recent Phase 2 study in heavily pretreated patients with metastatic breast cancer confirmed that enobosarm’s efficacy was best in women that had 40% or greater expression of the androgen receptor in their breast cancer.”

First Patient Dosed in Chinese Bridging Trial Evaluating Pelareorep-Paclitaxel Combination Treatment in Breast Cancer

"Adlai's bridging trial is an important step forward for pelareorep's clinical development path in China, which has a rapidly growing pharmaceutical market that is currently the second-largest in the world," said Andrew de Guttadauro, President of Oncolytics Biotech U.S. and Global Head of Business Development. "We are very pleased that dosing in the trial has commenced and congratulate our partner on this notable achievement. Looking ahead, we are eager to continue our partnership with Adlai as we work to advance pelareorep towards registration in major global markets."

Ph 1b Expansion Study of TTX-080 in Advanced Refractory or Resistant Malignancies Initiated

“The initiation of the Phase 1 dose expansion study is an important milestone for the TTX-080 clinical development program,” said Christine O’Brien, Chief Executive Officer, Tizona. “As a novel checkpoint inhibitor, the TTX-080 program offers an opportunity to apply new understandings of immune regulation within the tumor microenvironment in solid tumor indications where patient outcomes remain a major unmet medical need.”

First Patient Dosed in Ph 1b Study of NT-I7 (efineptakin alfa) and Kymriah® (tisagenlecleucel) in R/R Large B-Cell Lymphoma

“We have shown in multiple animal models that the addition of NT-I7 to CAR T-cells substantially increased CAR T-cell proliferation, persistence, and target-specific tumor killing, resulting in significantly prolonged survival of the treated animals,” said NgocDiep Le, M.D., Ph.D., Executive VP and Chief Medical Officer of NeoImmuneTech (NIT). “Now that we have begun dosing in this study, we look forward to evaluating the potential of NT-I7 therapy to prolong clinical response and survival for patients with r/r LBCL.”

Enrollment Completed in Ph 2 Study of Nant Cancer Vaccine for 3L+ Metastatic Pancreatic Cancer Patients—90% Patients Exceeded Historical Survival Rates to Date

"Patients with advanced metastatic pancreatic cancer who have failed all standards of care have very grave prognoses with few treatment options. This study was to explore if the Nant Cancer Vaccine could address this unmet need," said Patrick Soon-Shiong, M.D., Founder and Global Chief Scientific and Medical Officer of ImmunityBio, Inc. "It is gratifying to note that patients in this study, who had progressed after up to six lines of prior therapy, have exceeded historical survival rates despite having very advanced pancreatic cancer upon enrollment."

Enrollment Completed in EV-103 Trial Cohort K Combining PADCEV® (enfortumab vedotin-ejfv) With Pembrolizumab as 1L Treatment for Advanced Urothelial Cancer

"Completing enrollment in this study is an important step in investigating the potential for the combination of PADCEV and KEYTRUDA to treat metastatic urothelial cancer," said Roger Dansey, M.D., Chief Medical Officer, Seagen. "If results of this study are compelling, we may have the opportunity to submit them to the FDA as part of an application for accelerated approval."

First Patient Dosed With PVSRIPO in Ph 1/2 LUMINOS-103 Bladder Cancer Sub-Study

"PVSRIPO has shown impressive responses with monotherapy in patients participating in two phase 1 clinical trials focused on glioblastoma and melanoma," said Matt Stober, president and CEO at Istari Oncology. "We look forward to further evaluating its therapeutic value as we aim to expand the potential treatment options for patients living with bladder cancer."

First Patient Dosed in Ph 1 Clinical Study of RPTR-168 (PRIME IL-12) for R/R HPV-16-Positive Tumors

"We have developed RPTR-168 to target five distinct antigens known to play a role in HPV-16-positive tumor development and armed it with the potent immunomodulatory agent IL-12 using Repertoire's proprietary tethering technology," said John Cox, chief executive officer, Repertoire Immune Medicines. "RPTR-168 is Repertoire's second investigational candidate to advance to Phase 1 clinical study. This milestone reflects our team's commitment to advancing our programs from early research and discovery to the clinical study stage."