TRIAL/PROGRAM STATUSES -17th November 2021

Ph 2 Clinical Trial of Aspacytarabine for R/R MDS and AML to be initiated

"This new trial is an important step forward in expanding the reach of aspacytarabine to a broader patient population, addressing the unmet needs in the treatment of relapsed/refractory AML and MDS," said Dr. Ruth Ben Yakar, Chief Executive Officer of Biosight. "Initiating an additional trial furthers our clinical momentum, building on updated, encouraging data from our ongoing first-line Phase 2b study presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting and the receipt of Orphan Medicinal Product Designation for the European Medicines Agency. GFM is an ideal partner to expand the clinical evaluation into MDS with their extensive network of hematology centers, including registered centers of excellence, and we look forward to applying their expertise in clinical trials, treatments and diagnostics as we advance this Phase 2 trial."

New, single-arm Ph 3 pivotal study of UGN-102 for the treatment of low-grade, intermediate-risk NMIBC planned

"We have worked diligently with the FDA over the past several years to define the unmet need in low-grade NMIBC, with a particular focus on the intermediate risk population that typically experiences multiple recurrences," said Liz Barrett, President and Chief Executive Officer of UroGen. "We are preparing to initiate a single-arm pivotal study of UGN-102 to form the basis for a New Drug Application for UGN-102 in the treatment of low-grade, intermediate-risk NMIBC. We believe this new study increases the probability of regulatory success for UGN-102 given its streamlined design in addition to the encouraging results observed from our Phase 2 OPTIMA II study."

First Patient Enrolled in APOLLO 613 Ph 1/2 Clinical Trial of CPI-613® (Devimistat) in Patients with Relapsed Clear Cell Sarcoma

"With the aggressive nature of clear cell sarcoma, finding a treatment for this rare cancer is a priority of ours," said Sanjeev Luther, President and CEO of Rafael Pharmaceuticals. "Enrolling a patient so soon after we opened the trial demonstrates the dire need for a treatment and the hope that devimistat brings to the rare cancer community. We opened two additional sites in order to increase access to the trial for patients in need."

Ph 2 Merkel Cell Carcinoma Clinical Trial (MANTRA-3) of Milademetan Planned

"We are very excited about the recent preclinical data generated for milademetan in Merkel cell carcinoma, and believe the data warrant moving the program into a clinical study," said Avanish Vellanki, co-founder and chief executive officer of Rain. "We hope to address the immense unmet medical need for patients after relapsing on first-line checkpoint inhibitors."

Global Ph 3 Zanidatamab Trial in First-Line HER2-Positive Gastroesophageal Adenocarcinoma (GEA) Launched

"We are incredibly excited to launch our second pivotal, and first Phase 3 clinical trial for zanidatamab, HERIZON-GEA-01," said Ali Tehrani, Ph.D., Zymeworks' President & CEO.

“Gastrointestinal cancers have significant unmet patient need and we have the opportunity to help a large and growing patient population. With two potential Biologics License Applications over the next 3 years, we believe zanidatamab has the potential to achieve blockbuster status and position Zymeworks as the leader in the treatment of HER2-positive GI cancers.”

Enrollment Completed in Ph 3 CONTACT-01 Pivotal Trial of Cabozantinib + atezolizumab in Previously Treated mNSCLC

“Patients with advanced non-small cell lung cancer urgently need new treatment options after disease progression following immunotherapy and chemotherapy,” said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. “Following promising early results in the previously treated advanced non-small cell lung cancer cohort of the phase 1b COSMIC-021 trial, we are eager to learn more about how cabozantinib in combination with atezolizumab may benefit this patient population. Completing enrollment of CONTACT-01 is an important step forward, and we look forward to sharing top-line results when the data mature.”

First Patient Dosed in Ph 2 Study of NT-I7 (efineptakin alfa) + atezolizumab in 1L Locally Advanced or Metastatic NSCLC

“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.”

First Patient Dosed in Ph 1/2 Study of CA-4948 Combination Therapy in Patients with R/R AML or High-Risk MDS

"As we look ahead, we plan to provide a clinical data update in January from our ongoing clinical studies, including safety data from our Phase 1 study of CI-8993 and the latest safety and efficacy data from our CA-4948 study in AML/MDS patients with spliceosome or FLT3 mutations."