TRIAL/PROGRAM STATUS – 6th October 2021

First Patient Dosed in Ph 2 Trial of mRNA-based Individualized Immunotherapy BNT122 in Colorectal Cancer Patients

“This trial is an important milestone in our efforts to bringing individualized immunotherapies to patients.” said Özlem Türeci, M.D., Co-founder and Chief Medical Officer of BioNTech. “Many cancers progress in such a way that the patient initially appears tumor-free after surgery, but after some time tumor foci that were initially invisible grow and form metastases. In this clinical trial in patients with colorectal cancer, we aim to identify high-risk patients with a blood test and investigate whether an individualized mRNA vaccine can prevent such relapses.”

First Patient Dosed in Ph 1 Expansion Trial of SIRPα Antagonist mAB BI 765063 + Ezabenlimab, in Patients with Advanced Endometrium or Colorectal Tumors

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, said: “In Step 2 of the Phase 1 trial, we look forward to hopefully confirming the safety and expanding on the early signals of clinical efficacy of BI 765063 in two debilitating tumor types, advanced colorectal and advanced endometrium. This also marks the next planned milestone in our collaboration agreement with Boehringer Ingelheim which provides OSE with a continued stable financial base to steadily grow our first-in-class immuno-oncology pipeline.”

First Group of Patients Dosed with Berubicin in the Potentially Pivotal Study for the Treatment of Glioblastoma Multiforme (GBM)

"I am extremely pleased with the progress made to-date in this potentially pivotal trial. Our team has been working intensely to open sites in the U.S. and in Europe, understanding where we can best advance this important study. With hundreds of potentially competing GBM trials currently enrolling patients, the fact that we've been able to bring these initial sites on-line and get patients enrolled and dosed not only supports our strategic evaluation and selection, but also allows our data demonstrating Berubicin's potential effectiveness to continue to convince the medical community that we have a new drug with impressive potential. With the de-risked profile of Berubicin, its mechanism of action, history of development, encouraging Phase 1 data, and safety in study design, I am personally more optimistic about our work than at any time since joining the Company," commented John Climaco, CEO of CNS Pharmaceuticals.

First Patient dosed in Dose Confirmation Study of SY-2101, a Novel Oral Form of Arsenic Trioxide, in Acute Promyelocytic Leukemia

“The current standard of care cures most patients but is tremendously burdensome, requiring regular and lengthy infusions of an IV formulation of ATO over nearly a yearlong course of treatment,” said Farhad Ravandi, M.D., Professor of Medicine, Chief of Section of Acute Myeloid Leukemia, Department of Leukemia at The University of Texas – MD Anderson Cancer Center. “An oral form of ATO that offers similar efficacy while dramatically reducing the treatment burden would represent a major advance for APL patients. The preliminary Phase 1 data for SY-2101

are very promising, and I look forward to its continued advancement in the current and future studies."

APOLLO613 Ph 1/2 Trial of CPI-613® (devimistat) + Hydroxychloroquine in Patients with Relapsed Clear Cell Sarcoma Begins Enrollment

"Clear cell sarcoma is truly one of the most challenging sarcomas to treat, as it often spreads quickly to other parts of the body and prognosis is generally poor," said Sanjeev Luther, President and CEO of Rafael Pharmaceuticals. "The opening of this trial at City of Hope and several other sites across the country has the potential to grant a population with significant unmet medical needs a promising new treatment option."

First Patient Dosed in Ph 2 OASIS Trial of Oral SM-88 for Patients with Metastatic HR+/HER2- Breast Cancer After Treatment with a CDK4/6 Inhibitor

"Metastatic breast cancer is still an incurable disease and represents the second-leading cause of cancer death in women.2 The sobering statistics speak to the urgent need to find novel effective therapies that address this difficult-to-treat cancer. As this important trial begins, we are encouraged by the results in breast cancer patients from our prior first-in-human study and compassionate use program, which showed broad anti-tumor activity, including complete responses. We believe the compelling data support our strategic decision to further evaluate oral SM-88 in this setting, and we are hopeful that we will repeat the promising early activity. If so, we believe an effective drug with SM-88's demonstrated tolerability profile would offer patients an attractive treatment option, while maintaining quality of life," said Richie Cunningham, Chief Executive Officer of TYME.

Last Patient Enrolled in Ph 2 MOUNTAINEER Trial Evaluating TUKYSA® (Tucatinib) Regimen in HER2-Positive Metastatic Colorectal Cancer

"Completing enrollment in the MOUNTAINEER trial is an important step toward potentially bringing this therapy to patients with HER2-positive metastatic colorectal cancer," said Roger D. Dansey, M.D., Chief Medical Officer, Seagen. "We previously expanded the size of this trial, with the intention of supporting registration under accelerated approval regulations in the United States. We look forward to receiving the trial results to potentially address a significant unmet medical need for patients."