REGULATORY NEWS – 9th MARCH 2022

Current Topline Data from the SIENDO Study Unlikely to Support sNDA Approval; New Study of Selinexor in the Advanced or Recurrent p53 WT Endometrial Cancer to be initiated to Support a Future sNDA Submission

"We strongly believe in selinexor's potential in patients with p53 wild-type and are excited to further evaluate it in this patient population to better understand its potential to address the unmet need in women with endometrial cancer," said Sharon Shacham, Chief Scientific Officer of Karyopharm. "Given the significant need for new therapeutic options, we have a tremendous sense of urgency to design and enroll a new trial as quickly as possible and believe we are well-positioned to do so working with our existing SIENDO clinical trial sites."

U.S. FDA BLA/sNDA PDUFA Date for Ublituximab Plus UKONIQ® (U2) to Treat Patients with CLL and SLL extended

Michael S. Weiss, Chairman and Chief Executive Officer of TG Therapeutics stated, “As mentioned on our earnings call earlier this week, we believed an extension of the PDUFA date was a likely scenario especially given the proposed timing of the upcoming ODAC meeting. We hope this extension provides the time needed to give proper attention and review to the U2 BLA/sNDA.” Mr. Weiss continued, “We continue to believe in the potential of U2 to provide a meaningful treatment option to patients with CLL and SLL.”

U.S. FDA Accepts for Priority Review sBLA for Opdivo (nivolumab) Plus Chemotherapy as Neoadjuvant Treatment for Resectable Non-Small Cell Lung Cancer

“While significant progress has been made in how we treat non-small cell lung cancer, there remains a strong need for new options that can prevent recurrence and improve clinical outcomes, especially when a patient’s cancer is caught in earlier stages,” said Abderrahim Oukessou, M.D., vice president, thoracic cancers development lead, Bristol Myers Squibb. “The FDA’s acceptance of our application marks an important step in our effort to offer patients and physicians the first immunotherapy-based option that can be given before surgery to extend the time patients can continue living without disease progression or recurrence. We look forward to working with the FDA to potentially bring this regimen to patients in the U.S., where lung cancer is the leading cause of cancer deaths.”