DRUG APPROVALS – 24th NOVEMBER 2021

FDA Approves KEYTRUDA® as Adjuvant Therapy for Patients With Renal Cell Carcinoma RCC at Intermediate-High or High Risk of Recurrence Following Nephrectomy, or Following Nephrectomy and Resection of Metastatic Lesions

"Despite decades of research, limited adjuvant treatment options have been available for earlier-stage renal cell carcinoma patients who are often at risk for recurrence. In KEYNOTE-564, pembrolizumab reduced the risk of disease recurrence or death by 32%, providing a promising new treatment option for certain patients at intermediate-high or high risk of recurrence," said Dr. Toni K. Choueiri, director, Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, and professor of medicine, Harvard Medical School. "With this FDA approval, pembrolizumab may address a critical unmet treatment need and has the potential to become a new standard of care in the adjuvant setting for appropriately selected patients."

European Commission approves Gavreto (pralsetinib) for the treatment of adults with RET fusion-positive advanced NSCLC

"Today's approval represents an important step forward in delivering precision medicine to people with RET fusion-positive advanced non-small cell lung cancer, for whom treatment options have historically been limited," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "By using cancer genomic profiling upfront, healthcare professionals may identify specific genetic alterations that predict clinical benefit of targeted treatment options like Gavreto in the first-line setting."

European Commission Approves QINLOCK® for the Treatment of 4L GIST

"With a complex disease like advanced GIST, the availability of new efficacious and tolerable treatment options is critical for patients," said Jean-Yves Blay, M.D., Ph.D., professor of Medicine at the Université Claude Bernard, Lyon, France. "The treatment of advanced GIST patients who initially respond to traditional tyrosine kinase inhibitors but eventually develop tumor progression due to secondary mutations has remained an area of high unmet medical need in Europe. In the INVICTUS study, QINLOCK demonstrated compelling clinical benefit in progression-free and overall survival and was well tolerated3. This product brings a new hope for those patients who failed currently approved kinase inhibitors."