Compound	Area of Interest and Areas of Non-Interest
enzalutamide	❑ New approaches for treatment of prostate cancer, including drug and non-drug (modality) combinations ❑ Research in early stages of prostate cancer ❑ Adverse event management under standard enzalutamide dosing ❑ Biomarkers to inform response, resistance and treatment decisions ❑ Patient reported outcomes and quality of life in prostate cancer ❑ New screening, artificial intelligence, & diagnosis technology in conjunction with prostate cancer treatment ❑ Understanding mechanisms of androgen receptor inhibitor action and resistance ❑ Treatment of oligometastatic disease **The following proposal types will not be considered at this time:** All tumor types other than prostate cancer
gilteritinib	❑ FLT3 mutation positive (FLT3 m+) malignancies, acute myeloid leukemia (AML) and other ❑ Targeted drug combinations with gilteritinib in FLT3 mutation positive (FLT3 m+) acute myeloid leukemia (AML) ❑ Maintenance therapy in FLT3 mutation positive (FLT3 m+) acute myeloid leukemia (AML) ❑ Minimal residual disease and impact on treatment outcomes in gilteritinib treated acute myeloid leukemia (AML) patients **The following proposal types will not be considered at this time:** Wild type FLT3 acute myeloid leukemia (AML) or any other malignancy

enfortumab vedotin	**Practice Informing – EV monotherapy** ❑ Special populations o UTUC (upper tract urothelial carcinoma) o Rare histology o Platinum ineligible ❑ Earlier use in mUC (metastatic urothelial cancer) o Platinum ineligible ❑ Patient management and disease burden evaluation (inclusive of HEOR concepts) **Proof of Concept** ❑ mUC (metastatic urothelial cancer) o Combinations/ sequences with approved therapies and sound rationale ▪ Targeted therapies ❑ Muscle invasive o UTUC (upper tract urothelial carcinoma) o Bladder sparing o LN+ (lymph node positive) disease ❑ Nectin-4 expressing tumors not in basket (multi-cohort) trial **Biomarkers Pre-clinical** ❑ Nectin-4 expression adenocarcinoma, squamous cell carcinoma ❑ Nectin-4 expression in other tumors ❑ Resistance pathway/ overcoming resistance ❑ Predictors of efficacy / toxicity **The following proposal types will not be considered at this time:** Dosing, route of administration or scheduling changes, NMIBC (non-muscle invasive bladder cancer) or MIBC (muscle invasive bladder cancer) that conflicts with development program, combinations with unapproved drugs.

isavuconazonium sulfate	❑ Real world experience, including pharmacokinetic data, regarding the use of isavuconazonium sulfate with new molecules used in oncology and immunology ❑ Real-world evidence/experience, including incidence and outcome, of invasive pulmonary aspergillosis and other invasive fungal infections in non-traditional hosts, such as post-severe influenza/ARDS, COVID-associated secondary infections, etc. ❑ Real-world evidence/experience regarding management of complicated/serious invasive fungal infections with combination antifungal therapy ❑ Use of isavuconazonium sulfate for prophylaxis ❑ Use of isavuconazonium sulfate in the treatment of endemic fungi
mirabegron	Real World Evidence research to confirm clinical trial results (Databases, registries, networks of care analysis for treatment patterns, clinical outcomes, non-interventional and retrospective data analysis) ❑ Studies to support personalized medicine in overactive bladder (OAB), including clinical phenotyping, biomarkers, prediction tool, etc. ❑ Mirabegron in patients with comorbidities (e.g. subgroups of patients in regular practice, overweight overactive bladder patients (OAB), male patients with benign prostatic hyperplasia (BPH), male or female overactive bladder OAB patients with impaired sexual function) ❑ Patient's self-administered overactive bladder (OAB) management tool ❑ New Patient Reported Outcomes ❑ Impact of the timing of mirabegron dose on nocturia (e.g. morning vs. evening dosing) ❑ Epidemiological studies in the evolution of overactive bladder (OAB) prior to diagnosis and treatment **The following proposal types are not being considered at this time:** Clinical trials in the current indication including pediatric overactive bladder and neurogenic detrusor over-activity.

ipragliflozin	❑ Clinical and mechanistic studies regarding effects of sodium-glucose co-transporter 2 inhibition with ipragliflozin focusing on micro- and macro-vascular function, heart failure, cardiovascular risks in type 2 diabetes mellitus and type 1 diabetes mellitus. ❑ Clinical and mechanistic studies regarding the effects of sodium-glucose co-transporter 2 inhibition with ipragliflozin on renal function in patients with type 2 diabetes mellitus and type 1 diabetes mellitus. ❑ Clinical and mechanistic studies regarding the effects of sodium-glucose co-transporter 2 inhibition with ipragliflozin on other comorbidities frequently associated with type 2 diabetes mellitus and type 1 diabetes mellitus. ❑ Clinical and mechanistic studies regarding the effects of sodium-glucose co-transporter 2 inhibition with ipragliflozin on metabolic control and the cardio-renal axis in type 2 diabetes mellitus and type 1 diabetes mellitus. ❑ Observational research regarding the effects of sodium-glucose co-transporter 2 inhibition on micro / macro vascular complications in patients with type 2 diabetes mellitus and type 1 diabetes mellitus. **The following proposal types are not being considered at this time:** Safety studies of ipragliflozin, comparator studies with other sodium-glucose co-transporter 2 inhibitors
tacrolimus	**ADVAGRAF: Real World Evidence research including:** ❑ Database, registries, networks of treatment pattern of long-term clinical outcomes in liver/kidney transplantation (non-interventional and retrospective data) ❑ Conversion from Prograf to Advagraf, de novo use of Advagraf (e.g. dose, trough level, renal function) ❑ Risk factors evaluation related to treatment outcomes, (e.g. intrapatient variability, adherence) ❑ COVID-19 related **PROGRAF:** ❑ Epidemiological studies in those countries who have launched/pre-launch autoimmune disease indication ❑ Efficacy and safety outcome of Prograf treatment on auto-immune patients. **The following proposal types are not being considered at this time:** Very low dose tacrolimus regimens (e.g. <3ng/ml), comparison study between generics with Prograf or Advagraf in terms of purity, pharmcokinetic or bioequivelance analysis, comparison studies between Prograf & Advagraf.

	Please note: Studies proposing very low dose tacrolimus regimens (e.g. targeting levels <3ng/ml) or studies with switch to Advagraf when tacrolimus levels are already low (e.g. <5ng/ml), would not be supported due to the potential risk of immunological injury.
roxadustat	❑ Clinical outcomes ❑ Special populations (e.g. inflamed patients, diabetes, chronic kidney disease stage 3a/b, HIV nephropathy, African descent, renal transplant, etc) ❑ Iron metabolism ❑ Treatment patterns ❑ Patient reported outcomes ❑ Mechanistic and biomarker studies ❑ Renal anaemia epidemiology ❑ Real world use of roxadustat in dialysis dependent and not-dialysis dependent chronic kidney disease anaemia (efficacy and safety) ❑ Long term renal effects of roxadustat (estimated glomerular filtration rate (eGFR) preservation) **The following proposal types are not being considered at this time:** Off-label use studies, and safety-related studies with roxadustat (primary endpoint: safety)