Compound	Areas of Interest and Areas of Non-Interest
avacincaptad pegol intravitreal solution (ACP)	❑ Natural history of geographic atrophy (GA) in patients. ❑ Functional and patient-centric outcomes, especially those correlated with structure changes and/or biomarkers. ❑ Patient reported outcomes and QoL in response to ACP treatment. ❑ Use of artificial intelligence (AI) and other technologies in prediction, diagnosis, and management of GA. ❑ Biomarkers for the identification of high-risk patients, disease progression, or treatment outcome. ❑ Genetic and epidemiological data of GA patients. ❑ Treatment of GA in patients with other ocular and relevant comorbidities. ❑ Real world data studies on treatment patterns and outcomes. ❑ Behavioral science and attitudinal research on clinical decision making, patient choice, and adherence. ❑ Role of complement system in GA pathogenesis. **The following proposal types will not be considered at this time:** ❑ Head-to-head studies vs other complement-inhibitors or GA treatments. ❑ Switching patients between complement-inhibitors therapies. ❑ Use of ACP for conditions/diseases other than GA. ❑ Same eye injections of ACP and anti-VEGF therapy.
enfortumab vedotin (EV)	**Practice Informing:** ❑ Adverse Event prevention, treatment and mitigation. ❑ Retreatment • In patients previously exposed to enfortumab vedotin in muscle invasive bladder cancer (MIBC), locally advanced/metastatic urothelial cancer (la/mUC). ❑ Clinical resistance • In patients previously exposed to enfortumab vedotin. **Proof of Concept:** ❑ Combinations/sequences with targeted therapies • Evidence of monotherapy activity and safety in the relevant tumor type for one or both agents is required. ❑ Nectin-4* expressing tumors with scientific rationale/ unmet need. **HEOR:**

	❑ Patterns and outcomes of retreatment in urothelial cancer (UC). **The following proposal types will not be considered at this time:** ❑ Research for EV duplicative with: clinical development program (CDP) including EV-202**, ongoing ISR program, or ongoing/planned HEOR studies. ❑ Evaluation of altered route, dose or schedule of EV that are inconsistent approved local label. ❑ Combinations of EV with investigational/unapproved agents. ❑ Economic models and outputs with EV. ❑ Preclinical models of resistance with EV. ❑ Nectin-4 as a predictive biomarker that is duplicative with the development program. ** Nectin-4 expression testing is not required for UC [if Nectin-4 testing desired by investigator for UC, then testing is required via separate agreement with Q2 Solutions]. For non-UC tumors, Nectin-4 expression testing required unless there is sufficient evidence to support Nectin-4 expression in the tumor being studied.* *** Tumors included in EV-202 Trial are: HR+/HER2- Breast Cancer, Triple Negative Breast Cancer (TNBC), Squamous Non-Small Cell Lung Cancer (SNSCLC), Non-Squamous Non-Small Cell Lung Cancer (NSNSCLC), Head and Neck Cancer and Gastric, Gastroesophageal Junction or Esophageal Cancer. This includes any stage, all tumor associated subtypes and combinations until tumor development plan is implemented.*
enzalutamide	❑ Novel Hormonal Therapy (NHT) Rechallenge post NHT use in earlier stage of prostate cancer. ❑ Treatment approaches utilizing enzalutamide as backbone therapy, including treatment with new combinations. ❑ AE management under standard enzalutamide dosing. ❑ Biomarkers to inform response, resistance and treatment decisions. ❑ Patient reported outcomes and QoL in Prostate Cancer. ❑ New screening, artificial intelligence (AI), and diagnosis technology in conjunction with Prostate Cancer treatment. ❑ Understanding mechanisms of AR 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. ❑ Country-specific studies where there is no rationale for data generation in sub-populations. ❑ Healthcare Resource Utilization (Cost Analysis). ❑ Unapproved enzalutamide dosing.

fezolinetant	❑ Combination treatment (drug-drug or drug-device combinations, Traditional Chinese Medicine (TCM). ❑ Antidepressants, combination with vaginal oestrogen, Selective Estrogen Receptor Modulator (SERM), osteoporosis medication). ❑ Vasomotor symptoms (VMS) in the perimenopause population. ❑ Night sweats. ❑ VMS associated sleep disturbance. ❑ Breast cancer treatment induced VMS in women. ❑ Prostate cancer treatment induced VMS in men. ❑ Quality of Life and other patient reported outcomes (e.g. mood, sexual wellbeing, cognition, work productivity). ❑ Sub-populations (e.g. >60 years old, women with comorbidities). ❑ Special populations and other conditions (e.g. VMS associated with Systemic Lupus Erythematosus (SLE) and Parkinson's disease, hyper-androgenism Polycystic Ovary Syndrome (PCOS), endometriosis, uterine fibroids). ❑ Weight regulation e.g. weight change and redistribution of body fat associated with menopause. ❑ Previous or current hormone therapy users dissatisfied with their treatment outcome. ❑ Appropriate and relevant basic science and pre-clinical studies. ❑ Digital therapeutics in VMS in association with fezolinetant. **The following proposal types will not be considered at this time:** ❑ High dose fezolinetant. ❑ Drug-drug interactions. ❑ Head-to-head studies vs. hormonal treatment and Neurokinin 3 (NK3) antagonists. ❑ Special populations (precocious puberty and studies in children). ❑ Toxicity studies in male animals. ❑ Toxicity studies in juvenile animals.
gilteritinib	❑ FLT3 mutation positive (FLT3 m+) malignancies, acute myeloid leukemia (AML) and other (high risk myelodysplastic syndromes (HR-MDS)). ❑ Targeted drug combinations with gilteritinib in FLT3 m+ AML, sequencing with FLT3 inhibitors. ❑ Maintenance therapy in FLT3 m+ AML.

	❑ Minimal residual disease (MRD) and impact on treatment outcomes in gilteritinib treated AML patients, mechanisms of resistance and allelic ratio. ❑ Wild type FLT3 AML. **The following proposal types will not be considered at this time:** ❑ Pediatric studies. ❑ Bridge to transplant. ❑ Combination with other FLT3 inhibitors and head-to-head studies with other FLT3 inhibitors.
ipragliflozin	❑ Clinical and mechanistic studies regarding the effects of sodium-glucose co-transporter 2 (SGLT-2) inhibition with ipragliflozin associated type 1 diabetes mellitus (T1DM). ❑ Real World Evidence research Observational research regarding the effects of SGLT-2 inhibition on micro / macro vascular complications in patients with T2DM and T1DM. (databases, registries, clinical outcomes, non-interventional and retrospective data analysis). **The following proposal types are not being considered at this time:** ❑ Safety studies of Ipragliflozin, comparator studies with other SGLT- 2 inhibitors.
mirabegron	❑ Real world outcomes-based research (data availability within 2 to 3 years) assessing efficacy and safety in specific sub-groups of OAB patients which can help better characterize the place of mirabegron in OAB treatment. ❑ Patient centric outcomes, novel associated PROs, caregivers' QoL etc. with mirabegron use. ❑ Combination treatment with mirabegron e.g., botulinum toxin A (Botox), percutaneous tibial nerve stimulation (PTNS) or sacral nerve stimulation (SNS). ❑ Differentiation with antimuscarinics in relation to anti-cholinergic burden in vulnerable patients e.g., elderly with comorbidities and polypharmacy. ❑ Mirabegron efficacy and safety post-urological surgical procedures. **The following proposal types are not being considered at this time:** ❑ Paediatric OAB and NDO. ❑ General OAB disease research e.g., epidemiology, diagnosis and treatment, biomarkers etc. ❑ Alternate mirabegron dosing, head-head comparisons to Vibegron and small safety-only studies, CV outcomes.
peficitinib	❑ Efficacy of peficitinib in patients with rheumatoid arthritis.

	❑ Evaluation of peficitinib using biomarkers for rheumatoid arthritis. ❑ Evaluation of arthritis, synovitis or joint destruction in rheumatoid arthritis patients treated with peficitinib. ❑ Elucidation of pathophysiology of synovitis or joint destruction in rheumatoid arthritis patients treated with peficitinib.
roxadustat	❑ Clinical efficacy outcomes. ❑ Special populations: • Patients with CKD anaemia with a functioning renal transplant • HIV+ patients with anaemia of CKD (South Africa) ❑ Iron metabolism. ❑ Patient Reported Outcomes (PROs) adherence and persistence. ❑ Mechanistic and biomarker studies. ❑ Renal anaemia / anaemia of CKD epidemiology. **The following proposal types are not being considered at this time:** ❑ Off-label use studies. ❑ Studies with Roxadustat with safety as the primary endpoint (due to required size and length of such study). ❑ CKD progression. ❑ Single-arm interventional studies.
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 (AI) patients. **The following proposal types are not being considered at this time:**

	❑ Caution with very low dose tacrolimus regimens (e.g. <3ng/ml) due to concerns with immunological injury or in studies with switch to Advagraf when tacrolimus levels are already low (e.g. <5ng/mL). ❑ Comparison studies between generics with Prograf or Advagraf in terms of purity, pharmacokinetic (PK) or bioequivalence (BE) analysis. ❑ Comparison studies between Prograf and Advagraf.
zolbetuximab	**Practice informing*** ❑ Chemotherapy regimens not evaluated in zolbetuximab gastric cancer (GC)/gastroesophageal junction cancer (GEJC) development studies. ❑ HER2-ve, CLDN 18.2+ LA unresectable mGC/GEJC patient sub-segments. ❑ Adverse event management (prevention and treatment). ❑ Second line+ or treatment and continued treatment beyond progression in patients expressing CLDN 18.2. **Proof of Concept*** ❑ First line HER2ve+, CLDN 18,2+ LA unresectable or mGC/GEJC patients. ❑ CLDN 18.2 co-expressing tumors for combination with respective targeted therapies for G/GEJ. ❑ CLDN 18.2 expressing tumors with unmet need and scientific rationale. **Biomarkers*** ❑ Biology of Resistance pathway/overcoming resistance pathway. ❑ Biomarker co-expression and testing practices in GC/GEJC. **The following proposal types will not be considered at this time:** ❑ Duplicative with zolbetuximab development program/ISRs**. ❑ Evaluation of altered route, does or administration methodology or schedule or any deviation from prescribing information. ❑ Combinations with investigational therapies. ❑ Low CLDN 18.2 expressing (<50% of tumor cells with moderate to strong membranous staining) G/GEJ and other tumors. ** CLDN 18.2 testing in ISR studies is recommended to be conducted with the Ventana assay* ***HER2-ve, CLDN 18.2+ve resectable GC/GEJC and CLDN18.2+ve pancreatic cancer out of scope due to ongoing development program.*