

Compound	Areas of Interest and Areas of Non-Interest
avacincaptad pegol intravitreal solution (ACP)	<ul style="list-style-type: none"> <input type="checkbox"/> Natural history of geographic atrophy (GA) in patients. <input type="checkbox"/> Functional and patient-centric outcomes, especially those correlated with structure changes and/or biomarkers. <input type="checkbox"/> Patient reported outcomes and QoL in response to ACP treatment. <input type="checkbox"/> Use of artificial intelligence (AI) and other technologies in prediction, diagnosis, and management of GA. <input type="checkbox"/> Biomarkers for the identification of high-risk patients, disease progression, or treatment outcome. <input type="checkbox"/> Genetic and epidemiological data of GA patients. <input type="checkbox"/> Treatment of GA in patients with other ocular and relevant comorbidities. <input type="checkbox"/> Real world data studies on treatment patterns and outcomes. <input type="checkbox"/> Behavioral science and attitudinal research on clinical decision making, patient choice, and adherence. <input type="checkbox"/> Role of complement system in GA pathogenesis. <p>The following proposal types will not be considered at this time:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Head-to-head studies vs other complement-inhibitors or GA treatments. <input type="checkbox"/> Switching patients between complement-inhibitors therapies. <input type="checkbox"/> Use of ACP for conditions/diseases other than GA. <input type="checkbox"/> Same eye injections of ACP and anti-VEGF therapy.

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enfortumab vedotin (EV)	<p>Practice Informing:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Adverse Event prevention, treatment and mitigation. <input type="checkbox"/> Retreatment <ul style="list-style-type: none"> • In patients previously exposed to enfortumab vedotin in muscle invasive bladder cancer (MIBC), locally advanced/metastatic urothelial cancer (la/mUC). <input type="checkbox"/> Clinical resistance <ul style="list-style-type: none"> • In patients previously exposed to enfortumab vedotin. <p>Proof of Concept:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Combinations/sequences with targeted therapies <ul style="list-style-type: none"> • Evidence of monotherapy activity and safety in the relevant tumor type for one or both agents is required. <input type="checkbox"/> Nectin-4* expressing tumors with scientific rationale/ unmet need. <p>HEOR:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Patterns and outcomes of retreatment in urothelial cancer (UC). <p>The following proposal types will not be considered at this time:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Research for EV duplicative with: clinical development program (CDP) including EV-202**, ongoing ISR program, or ongoing/planned HEOR studies. <input type="checkbox"/> Evaluation of altered route, dose or schedule of EV that are inconsistent approved local label. <input type="checkbox"/> Combinations of EV with investigational/unapproved agents. <input type="checkbox"/> Economic models and outputs with EV. <input type="checkbox"/> Preclinical models of resistance with EV. <input type="checkbox"/> Nectin-4 as a predictive biomarker that is duplicative with the development program. <p><i>* 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</i></p> <p><i>** 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.</i></p>

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enzalutamide	<ul style="list-style-type: none"> <input type="checkbox"/> Novel Hormonal Therapy (NHT) Rechallenge post NHT use in earlier stage of prostate cancer. <input type="checkbox"/> Treatment approaches utilizing enzalutamide as backbone therapy, including treatment with new combinations. <input type="checkbox"/> AE management under standard enzalutamide dosing. <input type="checkbox"/> Biomarkers to inform response, resistance and treatment decisions. <input type="checkbox"/> Patient reported outcomes and QoL in Prostate Cancer. <input type="checkbox"/> New screening, artificial intelligence (AI), and diagnosis technology in conjunction with Prostate Cancer treatment. <input type="checkbox"/> Understanding mechanisms of AR inhibitor action and resistance. <input type="checkbox"/> Treatment of oligometastatic disease. <p>The following proposal types will not be considered at this time:</p> <ul style="list-style-type: none"> <input type="checkbox"/> All tumor types other than prostate cancer. <input type="checkbox"/> Country-specific studies where there is no rationale for data generation in sub-populations. <input type="checkbox"/> Healthcare Resource Utilization (Cost Analysis). <input type="checkbox"/> Unapproved enzalutamide dosing.

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fezolinetant	<ul style="list-style-type: none"> <input type="checkbox"/> Combination treatment (drug-drug or drug-device combinations, Traditional Chinese Medicine (TCM). <input type="checkbox"/> Antidepressants, combination with vaginal oestrogen, Selective Estrogen Receptor Modulator (SERM), osteoporosis medication). <input type="checkbox"/> Vasomotor symptoms (VMS) in the perimenopause population. <input type="checkbox"/> Night sweats. <input type="checkbox"/> VMS associated sleep disturbance. <input type="checkbox"/> Breast cancer treatment induced VMS in women. <input type="checkbox"/> Prostate cancer treatment induced VMS in men. <input type="checkbox"/> Quality of Life and other patient reported outcomes (e.g. mood, sexual wellbeing, cognition, work productivity). <input type="checkbox"/> Sub-populations (e.g. >60 years old, women with comorbidities). <input type="checkbox"/> 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). <input type="checkbox"/> Weight regulation e.g. weight change and redistribution of body fat associated with menopause. <input type="checkbox"/> Previous or current hormone therapy users dissatisfied with their treatment outcome. <input type="checkbox"/> Appropriate and relevant basic science and pre-clinical studies. <input type="checkbox"/> Digital therapeutics in VMS in association with fezolinetant. <p>The following proposal types will not be considered at this time:</p> <ul style="list-style-type: none"> <input type="checkbox"/> High dose fezolinetant. <input type="checkbox"/> Drug-drug interactions. <input type="checkbox"/> Head-to-head studies vs. hormonal treatment and Neurokinin 3 (NK3) antagonists. <input type="checkbox"/> Special populations (precocious puberty and studies in children). <input type="checkbox"/> Toxicity studies in male animals. <input type="checkbox"/> Toxicity studies in juvenile animals.

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gilteritinib	<ul style="list-style-type: none"> <input type="checkbox"/> FLT3 mutation positive (FLT3 m+) malignancies, acute myeloid leukemia (AML) and other (high risk myelodysplastic syndromes (HR-MDS)). <input type="checkbox"/> Targeted drug combinations with gilteritinib in FLT3 m+ AML, sequencing with FLT3 inhibitors. <input type="checkbox"/> Maintenance therapy in FLT3 m+ AML. <input type="checkbox"/> Minimal residual disease (MRD) and impact on treatment outcomes in gilteritinib treated AML patients, mechanisms of resistance and allelic ratio. <input type="checkbox"/> Wild type FLT3 AML. <p>The following proposal types will not be considered at this time:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Pediatric studies. <input type="checkbox"/> Bridge to transplant. <input type="checkbox"/> Combination with other FLT3 inhibitors and head-to-head studies with other FLT3 inhibitors.
ipragliflozin	<ul style="list-style-type: none"> <input type="checkbox"/> Clinical and mechanistic studies regarding the effects of sodium-glucose co-transporter 2 (SGLT-2) inhibition with ipragliflozin associated type 1 diabetes mellitus (T1DM). <input type="checkbox"/> 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). <p>The following proposal types are not being considered at this time:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Safety studies of Ipragliflozin, comparator studies with other SGLT- 2 inhibitors.

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mirabegron	<ul style="list-style-type: none"> <input type="checkbox"/> 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. <input type="checkbox"/> Patient centric outcomes, novel associated PROs, caregivers' QoL etc. with mirabegron use. <input type="checkbox"/> Combination treatment with mirabegron e.g., botulinum toxin A (Botox), percutaneous tibial nerve stimulation (PTNS) or sacral nerve stimulation (SNS). <input type="checkbox"/> Differentiation with antimuscarinics in relation to anti-cholinergic burden in vulnerable patients e.g., elderly with comorbidities and polypharmacy. <input type="checkbox"/> Mirabegron efficacy and safety post-urological surgical procedures. <p>The following proposal types are not being considered at this time:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Paediatric OAB and NDO. <input type="checkbox"/> General OAB disease research e.g., epidemiology, diagnosis and treatment, biomarkers etc. <input type="checkbox"/> Alternate mirabegron dosing, head-head comparisons to Vibegron and small safety-only studies, CV outcomes.
peficitinib	<ul style="list-style-type: none"> <input type="checkbox"/> Efficacy of peficitinib in patients with rheumatoid arthritis. <input type="checkbox"/> Evaluation of peficitinib using biomarkers for rheumatoid arthritis. <input type="checkbox"/> Evaluation of arthritis, synovitis or joint destruction in rheumatoid arthritis patients treated with peficitinib. <input type="checkbox"/> Elucidation of pathophysiology of synovitis or joint destruction in rheumatoid arthritis patients treated with peficitinib.

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roxadustat	<ul style="list-style-type: none"> <input type="checkbox"/> Clinical efficacy outcomes. <input type="checkbox"/> Special populations: <ul style="list-style-type: none"> • Patients with CKD anaemia with a functioning renal transplant • HIV+ patients with anaemia of CKD (South Africa) <input type="checkbox"/> Iron metabolism. <input type="checkbox"/> Patient Reported Outcomes (PROs) adherence and persistence. <input type="checkbox"/> Mechanistic and biomarker studies. <input type="checkbox"/> Renal anaemia / anaemia of CKD epidemiology. <p>The following proposal types are not being considered at this time:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Off-label use studies. <input type="checkbox"/> Studies with Roxadustat with safety as the primary endpoint (due to required size and length of such study). <input type="checkbox"/> CKD progression. <input type="checkbox"/> Single-arm interventional studies.

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tacrolimus	<p>ADVAGRAF: Real World Evidence research including:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Database, registries, networks of treatment pattern of long-term clinical outcomes in liver/kidney transplantation (non-interventional and retrospective data). <input type="checkbox"/> Conversion from Prograf to Advagraf, de novo use of Advagraf (e.g. dose, trough level, renal function). <input type="checkbox"/> Risk factors evaluation related to treatment outcomes, (e.g. inpatient variability, adherence). <input type="checkbox"/> COVID-19 related. <p>PROGRAF:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Epidemiological studies in those countries who have launched/pre-launch autoimmune disease indication. <input type="checkbox"/> Efficacy and safety outcome of Prograf treatment on auto-immune (AI) patients. <p>The following proposal types are not being considered at this time:</p> <ul style="list-style-type: none"> <input type="checkbox"/> 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). <input type="checkbox"/> Comparison studies between generics with Prograf or Advagraf in terms of purity, pharmacokinetic (PK) or bioequivalence (BE) analysis. <input type="checkbox"/> Comparison studies between Prograf and Advagraf.

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zolbetuximab	<p>Practice informing*</p> <ul style="list-style-type: none"> <input type="checkbox"/> Chemotherapy regimens not evaluated in zolbetuximab gastric cancer (GC)/gastroesophageal junction cancer (GEJC) development studies. <input type="checkbox"/> HER2-ve, CLDN 18.2+ LA unresectable mGC/GEJC patient sub-segments. <input type="checkbox"/> Adverse event management (prevention and treatment). <input type="checkbox"/> Second line+ or treatment and continued treatment beyond progression in patients expressing CLDN 18.2. <p>Proof of Concept*</p> <ul style="list-style-type: none"> <input type="checkbox"/> First line HER2ve+, CLDN 18,2+ LA unresectable or mGC/GEJC patients. <input type="checkbox"/> CLDN 18.2 co-expressing tumors for combination with respective targeted therapies for G/GEJ. <input type="checkbox"/> CLDN 18.2 expressing tumors with unmet need and scientific rationale. <p>Biomarkers*</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biology of Resistance pathway/overcoming resistance pathway. <input type="checkbox"/> Biomarker co-expression and testing practices in GC/GEJC. <p>The following proposal types will not be considered at this time:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Duplicative with zolbetuximab development program/ISRs**. <input type="checkbox"/> Evaluation of altered route, dose or administration methodology or schedule or any deviation from prescribing information. <input type="checkbox"/> Combinations with investigational therapies. <input type="checkbox"/> Low CLDN 18.2 expressing (<50% of tumor cells with moderate to strong membranous staining) G/GEJ and other tumors. <p><i>* CLDN 18.2 testing in ISR studies is recommended to be conducted with the Ventana assay</i></p> <p><i>**HER2-ve, CLDN 18.2+ve resectable GC/GEJC and CLDN18.2+ve pancreatic cancer out of scope due to ongoing development program</i></p>