THE GALIEN FOUNDATION

PRODUCT: **Adakveo® (crizanlizumab-tmca)**

COMPANY: Novartis Pharmaceuticals Corporation

THERAPEUTIC AREA & INDICATION:
Treatment to lower frequency of recurrent vaso-occlusive crises associated with severe vascular system pain for conditions like sickle cell anemia

ABOUT THE PRODUCT

Adakveo is the first and only FDA-approved, monthly targeted medicine that has been shown to reduce the annual rate of sickle cell pain crises to 1.63 vs 2.98 (equivalent to -45%) and the annual rate of days hospitalized to 4 vs 6.87 (-42%). In the SUSTAIN trial, IRRs (occurring during/within 24 hours of infusion) were observed in two (3%) patients treated with Adakveo 5 mg/kg. Post-marketing cases of IRRs, including severe pain events requiring hospitalization, have been reported. The most common side effects (incidence ?10%) include nausea, joint pain, back pain, stomach-area (abdominal) pain or tenderness, and fever.

THE GALIEN FOUNDATION

PRODUCT: **Adhansia XR®**

COMPANY: Adlon Therapeutics L.P.,
a subsidiary of Purdue Pharma L.P.

THERAPEUTIC AREA & INDICATION:
Central nervous system stimulant to treat attention deficit hyperactivity disorder (ADHD) in people age six and older

ABOUT THE PRODUCT

Adhansia XR contains methylphenidate (MPH) and is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older. Adhansia XR capsules contain identical beads which are formulated using the proprietary smart design MLR™ (Multi-Layer Release) technology. Each bead has an immediate-release component (containing 20% of the dose) and a controlled-release component (containing 80% of the dose). Adhansia XR is the first and only single daily dose MPH medication that demonstrates efficacy starting at 1 hour and continuing throughout the day up to, and including, 16 hours post-dose in adults.

THE GALIEN FOUNDATION

PRODUCT: **Annovera™**

COMPANY: Population Council and TherapeuticsMD

THERAPEUTIC AREA & INDICATION:
Novel hormonal contraceptive vaginal ring that prevents ovulation and pregnancy over a full-year cycle of use

ABOUT THE PRODUCT

Stay tund

THE GALIEN FOUNDATION

PRODUCT: **ASPARLAS®**

COMPANY: Servier Pharmaceuticals

THERAPEUTIC AREA & INDICATION:
Component therapy of a multi-agent chemotherapy regimen for treatment of acute lymphoblastic leukemia (ALL) in patients 21 years of age or younger

ABOUT THE PRODUCT

ASPARLAS, a newer form of PEGylated asparaginase, is a component of multi-agent chemotherapeutic regimen to treat acute lymphoblastic leukemia (ALL) in pediatric and young adult patients. No chemotherapy drug has made a greater impact to patients with ALL than asparaginase. ASPARLAS decreases the dosing schedule for patients and improves the stability of the shelf life to 36-months. The extended shelf life allows for an improved supply chain allowing hospitals to ensure they always have ASPARLAS on hand when a patient is diagnosed or scheduled for treatment. In numerous clinical studies survival rates for patients with ALL are 34-53% higher when asparaginase is added to the standard ALL backbone treatment regimen.

THE GALIEN FOUNDATION

PRODUCT: **Entresto® (sacubitril/valsartan)**

COMPANY: Novartis Pharmaceuticals Corporation

THERAPEUTIC AREA & INDICATION:
Reduce hospitalizations and deaths in adults with chronic heart failure through improvement in the heart's ability to pump blood to the body

ABOUT THE PRODUCT

Entresto® is a first-in-class ARNI* and first breakthrough in Heart Failure (HF) treatment in over a decade. Novartis researchers reimagined medicine by combining a neprilysin inhibitor (sacubitril) with an angiotensin receptor blocker (valsartan) to create Entresto®. By 2030, 1 in 33 individuals will have HF. Patients with HF have a 50% risk of death within 5 years of disease onset. Entresto® was developed with the goal of improving patients' lives by reducing HF hospitalization and mortality. Patients treated with Entresto® are less likely to be hospitalized and incur lower total healthcare costs versus those treated with ACEis** a standard of care. Company's literature for the application for the Prix Galien USA 2021. Please refer to complete submission package for references.

*Angiotensin Receptor-Neprilysin inhibitor (ARNI).

**Angiotensin Converting enzyme inhibitor (ACEi)For side effect information, please refer to the company website: https://www.novartis.us/sites/www.novartis.us/files/entresto.pdf

THE GALIEN FOUNDATION

PRODUCT: **Gamifant®**

COMPANY: Sobi

THERAPEUTIC AREA & INDICATION:

First treatment for infants/adults with primary haemophagocytic lymphohistiocytosis (HLH), an ultra-rare immune disorder that leads to severe inflammation, infections, bleeding, organ failures and early death

ABOUT THE PRODUCT

Gamifant® (emapalumab-lzsg) is the first and only medicine approved by the FDA for primary haemophagocytic lymphohistiocytosis (HLH), an ultra-rare syndrome of hyperinflammation that can rapidly become fatal unless diagnosed and treated. Gamifant is indicated for paediatric and adult primary HLH patients with refractory, recurrent or progressive disease, or intolerance to conventional HLH therapy.

Visit www.gamifant.com for more information, including full Prescribing Information.

THE GALIEN FOUNDATION

PRODUCT: **LORBRENA®**

COMPANY: Pfizer Inc.

THERAPEUTIC AREA & INDICATION:
For patients with anaplastic lymphoma kinase (ALK) positive metastatic non-small cell lung cancer (NSCLC) in cases where previous ALK inhibitors have failed

ABOUT THE PRODUCT

LORBRENA is a third-generation ALK inhibitor specifically designed to inhibit the most common tumor mutations that drive resistance to current medications and to address metastases in the brain.

LORBRENA was first approved in 2018 – just four years from its discovery – for people with previously-treated ALK-positive NSCLC, and in 2021 received an expanded approval for those newly diagnosed with the disease.

During this time, LORBRENA has become an important treatment option for people with this rare type of lung cancer.

THE GALIEN FOUNDATION

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PRODUCT: **Lutathera®**

COMPANY: Advanced Accelerator Applications

THERAPEUTIC AREA & INDICATION:
Radioactive isotope treatment for cancerous neuroendocrine tumors affecting the pancreas or gastrointestinal tract

ABOUT THE PRODUCT

LUTATHERA® (lutetium Lu 177 dotatate) is precision targeted therapy approved in the United States for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut and hindgut neuroendocrine tumors in adults[1]. LUTATHERA® belongs to a class of treatments called Peptide Receptor Radionuclide Therapy (PRRT), a type of radioligand therapy (RLT) that combines a radioactive particle with a targeting molecule that binds to a particular type of receptor (somatostatin) over-expressed by neuroendocrine tumors, inhibiting tumor growth and replication. The most common Grade 3-4 adverse reactions observed in LUTATHERA® clinical trials were lymphopenia (44%), increased GGT (20%), vomiting (7%), nausea (5%), elevated AST (5%), increased ALT (4%), hyperglycemia (4%), and hypokalemia (4%).1 Please see important Safety Information and Full Prescribing information at: LUTATHERA.US

1. LUTATHERA Prescribing Information: www.accessdata.fda.gov/drugsatfda_docs/label/2018/208700s000lbl.pdf

THE GALIEN FOUNDATION

PRODUCT: **Moxidectin**

COMPANY: Medicines Development for Global Health & TDR

THERAPEUTIC AREA & INDICATION:
New treatment for onchocerciasis (river blindness) demonstrating superiority over ivermectin, the current standard of care against this major neglected infectious disease prevalent in developing countries

ABOUT THE PRODUCT

Moxidectin is the first new medicine to be approved for river blindness (onchocerciasis) in over 30 years. In Phase 3, a single dose of moxidectin reduced skin microfilariae (parasite) levels to undetectable levels one year after treatment in 45.9% of recipients, vs 5.4% in those who received ivermectin. Moxidectin should accelerate elimination of river blindness, and its broad antiparasitic activity make it potentially one of the most important global health medicines in history. Additional Phase 2 and 3 trials are underway in several other important neglected tropical diseases including scabies, lymphatic filariasis, and soil-transmitted helminths.

THE GALIEN FOUNDATION

PRODUCT: **Nubeqa®**

COMPANY: Bayer

THERAPEUTIC AREA & INDICATION:
For patients with non-metastatic castration-resistant prostate cancer

ABOUT THE PRODUCT

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. We support efforts to overcome the major challenges presented by a growing and aging global population. In prostate cancer, the second most common cancer in men, we are transforming the standard of care with products that focus on delaying metastases, survival, and tolerability. In precision oncology, Bayer is paving the way with the global introduction of a first-in-class oral TRK inhibitor exclusively designed to treat the driver that causes the cancer to spread and grow, rather than treat where the tumor originates in the body, in adults and children.

THE GALIEN FOUNDATION

PRODUCT: **Olumiant®**

COMPANY: Eli Lilly and Company

THERAPEUTIC AREA & INDICATION:
JAK inhibitor for treatment of Rheumatoid Arthritis in patients who fail to benefit from existing TNF alpha inhibitor therapies

ABOUT THE PRODUCT

Baricitinib is a novel orally-administered Janus kinase (JAK) inhibitor developed for the treatment of patients with rheumatoid arthritis (RA). The unmet medical need remains high in rheumatology despite other available treatment options such as TNFi.

Innovative features of Baricitinib include:

- First JAK1/JAK2 inhibitor developed for RA. Pioneering Phase 3 programs in high unmet need diseases like atopic dermatitis, lupus, pediatric interferonopathies, alopecia areata and COVID-19 infection.
- Tablet specifically engineered to rock and facilitate grasping with fingers through its shape and coating. Bottle shape and cap engineered to provide ease of opening and to conform to an arthritic hand.

THE GALIEN FOUNDATION

PRODUCT: **Piqray® (alpelisib)**

COMPANY: Novartis Pharmaceuticals Corporation

THERAPEUTIC AREA & INDICATION:
Treatment of advanced or metastatic breast cancer with PIK3CA gene mutation

ABOUT THE PRODUCT

Approved in May 2019, PIQRAY was discovered at NIBR (Novartis Institutes for BioMedical Research) and was the first new drug application approved under the FDA Oncology Center of Excellence Real-Time Oncology Review pilot program. PIQRAY is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with HR+/HER2-, PIK3CA-mutated, metastatic breast cancer, detected by an FDA-approved test following progression on or after an endocrine-based regimen. The first and only treatment specifically developed to target PI3Ka, PIQRAY delivers hope for patients facing aggressive disease and offers patients individualized therapy for their tumor harboring a PIK3CA mutation.

THE GALIEN FOUNDATION

PRODUCT: **RECARBRIO™**

COMPANY: Merck & Co., Inc.

THERAPEUTIC AREA & INDICATION:
Combination anti-bacterial for adults with complicated urinary tract infections and complicated intra-abdominal infections

ABOUT THE PRODUCT

RECARBRIO™ is the only carbapenem/BLI combination addressing two of the three most critical antimicrobial-resistant bacteria on the WHO's priority list (carbapenem-resistant Enterobacteriaceae and *P. aeruginosa*). RECARBRIO™ is not subject to efflux from bacterial cells and provides a monotherapy treatment option for complex infections due to its unique coverage of gram-negative, gram-positive and anerobic organisms. Innovative development of RECARBRIO™ with these novel attributes suggest it will be an important addition for the treatment of multidrug-resistant infections and will improve patient outcomes. The development of RECARBRIO™ demonstrates Merck's commitment to the fight against antimicrobial resistance a critical area of global public health.

THE GALIEN FOUNDATION

PRODUCT: **REYVOW®**

COMPANY: Eli Lilly and Company

THERAPEUTIC AREA & INDICATION:
A serotonin (5-HT) 1F receptor agonist indicated for the acute treatment of migraine with or without aura in adults

ABOUT THE PRODUCT

REYVOW is a 5-HT1F receptor agonist specifically designed to treat the underlying pathophysiology of migraine through a neurological mechanism of action. Innovations of REYVOW include:

- Highly specific agonist for the 5-HT1F receptor with >440-fold selectivity relative to other serotonin receptors, without vasoconstrictive properties.
- Demonstrated complete elimination of moderate to severe migraine pain and most bothersome symptoms of migraine attacks in population including patients with significant migraine disability and medical comorbidities.
- Provides clinical support for a revised understanding of migraine as a neurological rather than vascular disease.
- Offers a novel and effective option for patients with migraine.

THE GALIEN FOUNDATION

PRODUCT: **RINVOQ™**

COMPANY: AbbVie

THERAPEUTIC AREA & INDICATION:
JAK (janus kinase) inhibitor that blocks inflammation of moderate to severe rheumatoid arthritis (RA) in patients who don't benefit from existing treatments

ABOUT THE PRODUCT

RINVOQ (upadacitinib) is a once-daily oral Janus kinase (JAK) inhibitor approved for the treatment of moderate to severe rheumatoid arthritis (RA) by the U.S. Food and Drug Administration as well as regulatory agencies in many other countries. Discovered and developed by AbbVie scientists, RINVOQ is a selective and reversible JAK inhibitor that is being studied in several immune-mediated inflammatory diseases. Previously, JAK inhibition was not a widely accepted area of study in immunology, but AbbVie's team designed, synthesized and tested more than 3,000 molecules to find RINVOQ — the best combination of affinity, selectivity and desirable pharmacokinetic properties.

THE GALIEN FOUNDATION

PRODUCT: **Rozlytrek™**

COMPANY: Genentech, Inc.

THERAPEUTIC AREA & INDICATION:
First "tumor agnostic" treatment with biomarkers to specifically target ROS-1 positive metastatic non-small cell lung cancer (NSCLC) as well as other NTRK gene fusion positive solid tumors

ABOUT THE PRODUCT

ROZLYTREK is a small molecule inhibitor of ROS1 and TRK1, 2, and 3, which is indicated for patients with ROS1-positive NSCLC and NTRK fusion-positive solid tumors. ROZLYTREK has demonstrated the ability to penetrate the blood-brain barrier and exert CNS antitumor activity in intracranial models and clinical trials. Strong and durable responses have been observed in patients with and without CNS metastases with both ROS1-positive NSCLC and across various tumor types in patients with NTRK fusion-positive solid tumors. ROZLYTREK represents a valuable precision oncology medicine and an advance for rare and underserved patient populations.

THE GALIEN FOUNDATION

PRODUCT: **TPOXX®**

COMPANY: SIGA Technologies, Inc.

THERAPEUTIC AREA & INDICATION:
First drug with an indication for treatment of smallpox in humans in the event of its use as a bioweapon and public health emergency

ABOUT THE PRODUCT

TPOXX is indicated for the treatment of smallpox disease in adults and pediatric patients (>13kg). Tecovirimat targets and inhibits the exit of the variola virus that causes smallpox from infected cells, preventing its spread and infection of other cells. TPOXX was approved by the FDA using the "Animal Rule," and is intended to treat humans with dosing of 600 mg twice daily for 14 days. TPOXX is among the first novel small molecule therapies delivered to the Strategic National Stockpile and would play a critical role in responding to a smallpox bioterror attack.

THE GALIEN FOUNDATION

PRODUCT: **VITRAKVI®**

COMPANY: Bayer

ABOUT THE PRODUCT

Larotrectinib (trade name: VITRAKVI®) is a first-in-class tropomyosin receptor kinase (TRK) inhibitor to treat tumors that have a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion. This is the first small molecule treatment to receive a tumor-agnostic indication at the time of initial United States Food and Drug Administration (FDA) approval. Larotrectinib was granted a breakthrough therapy designation by the FDA.

Larotrectinib is indicated for the treatment of adult and pediatric patients with solid tumors that:
- have a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation;
- are metastatic or where surgical resection is likely to result in severe morbidity; and
- have no satisfactory alternative treatments or that have progressed following treatment.

THE GALIEN FOUNDATION

PRODUCT: **XPOVIO®**

COMPANY: Karyopharm Therapeutics Inc.

THERAPEUTIC AREA & INDICATION:
Treatment of relapsed/refractory (RR) multiple myeloma and RR diffuse large B-cell lymphoma

ABOUT THE PRODUCT

XPOVIO® (selinexor) is a first-in-class, oral Selective Inhibitor of Nuclear Export (SINE) compound. XPOVIO blocks the nuclear export of tumor suppressor, growth regulatory and anti-inflammatory proteins. XPOVIO received accelerated FDA approval in July 2019 in combination with dexamethasone for the treatment of adult patients with penta-refractory multiple myeloma. Karyopharm's sNDA requesting an expansion of its current indication to include the treatment for patients with multiple myeloma after at least one prior line of therapy has also been accepted for filing by the FDA. In June 2020, XPOVIO received accelerated FDA approval for its second indication in adult patients with relapsed or refractory diffuse large B-cell lymphoma after at least 2 lines of systemic therapy.

THE GALIEN FOUNDATION

PRODUCT: **XOSPATA®**

COMPANY: Astellas Pharma Inc.

THERAPEUTIC AREA & INDICATION:
Tyrosine kinase inhibitor for adults with relapsed or refractory acute myeloid leukemia (AML) with the tyrosine kinase-3 gene mutation

ABOUT THE PRODUCT

Gilteritinib was discovered through a research collaboration with Kotobuki Pharmaceutical Co., Ltd., and Astellas has exclusive global rights to develop, manufacture and commercialize gilteritinib. XOSPATA® is approved in the U.S., Japan, Europe, Canada, Korea, Brazil and Australia for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with an FMS-like tyrosine kinase 3 (FLT3) mutation, and is currently undergoing regulatory review in China.

Gilteritinib has demonstrated inhibitory activity against FLT3-ITD, a type of FLT3mut+ that is seen in approximately one-third of patients with AML, as well as FLT3-TKD mutation.

THE GALIEN FOUNDATION

PRODUCT: **Nurtec® ODT**

COMPANY: Biohaven Pharmaceuticals

THERAPEUTIC AREA & INDICATION:
Acute treatment of migraine

ABOUT THE PRODUCT

Nurtec® ODT (rimegepant) is the first and only calcitonin gene-related peptide (CGRP) receptor antagonist available in a quick-dissolve ODT formulation that is approved by the U.S. Food and Drug Administration for the acute treatment of migraine with or without aura and the preventive treatment of episodic migraine in adults. Nurtec ODT allows a patient to manage their migraine with a single medication with a simple dose of 75 mg, taken as needed, up to once daily to treat or every other day to help prevent migraine attacks.

THE GALIEN FOUNDATION

PRODUCT: **AYVAKIT™ (avapritinib)**

COMPANY: Blueprint Medicines

THERAPEUTIC AREA & INDICATION:
Treatment of gastrointestinal stromal tumor

ABOUT THE PRODUCT

N

THE GALIEN FOUNDATION

PRODUCT: **GAVRETO® (pralsetinib)**

COMPANY: Blueprint Medicines

THERAPEUTIC AREA & INDICATION:
Treatment of lung cancer

ABOUT THE PRODUCT

N

THE GALIEN FOUNDATION

PRODUCT: **QINLOCK®**

COMPANY: Deciphera Pharmaceuticals

THERAPEUTIC AREA & INDICATION:
Treatment of gastrointestinal stromal tumor

ABOUT THE PRODUCT

QINLOCK®, a novel switch control tyrosine kinase inhibitor, was specifically designed to broadly inhibit KIT and PDGFRA mutated kinases with a unique dual mechanism of action. QINLOCK binds to both the switch pocket region and the activation switch securing the target kinase into an inactive conformation, resulting in the inhibition of downstream signaling and cell proliferation.

In INVICTUS, QINLOCK provided a powerful PFS benefit and reduced the risk of progression or death by 85% in patients with ≥4th-line advanced GIST. Patients received a clinically meaningful survival benefit when treated with QINLOCK versus placebo (median OS – 15.1 months versus 6.6 months).

THE GALIEN FOUNDATION

PRODUCT: **ELYXYB**

COMPANY: Dr. Reddy's Laboratories Ltd

THERAPEUTIC AREA & INDICATION:
Treatment of migraine

ABOUT THE PRODUCT

N

THE GALIEN FOUNDATION

PRODUCT: **ZOKINVY®**

COMPANY: Eiger BioPharmaceuticals, Inc.

THERAPEUTIC AREA & INDICATION:
Treatment of genetic diseases of premature aging in children and young adults

ABOUT THE PRODUCT

N

THE GALIEN FOUNDATION

PRODUCT: **TAZVERIK®**

COMPANY: Epizyme Inc.

THERAPEUTIC AREA & INDICATION:
Treatment of sarcoma or refractory follicular lymphoma

ABOUT THE PRODUCT

N

THE GALIEN FOUNDATION

PRODUCT: **NEXLETOL**

COMPANY: Esperion Therapeutics Inc.

THERAPEUTIC AREA & INDICATION:
Treatment of hypercholesterolemia

ABOUT THE PRODUCT

NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. In spite of advances in lipid management, hyperlipidemia remains a dire epidemic worldwide. It's why ESPERION Therapeutics, Inc., the Lipid Management Company, developed oral, once-daily NEXLETOL® (bempedoic acid). Its active ingredient is bempedoic acid, the first adenosine triphosphate citrate lyase (ACL) inhibitor, which lowers LDL-C by working 2 steps upstream from statins in the cholesterol biosynthesis pathway in the liver. When added to maximally tolerated statin therapy, NEXLETOL delivered significant mean LDL-C reduction of up to 18% vs placebo, with incidence of most common adverse reactions generally comparable to placebo. See NEXLETOLHCP.com for product information, including side effects.

THE GALIEN FOUNDATION

PRODUCT: **NEXLIZET**

COMPANY: Esperion Therapeutics Inc.

THERAPEUTIC AREA & INDICATION:
Treatment of hypercholesterolemia

ABOUT THE PRODUCT

NEXLIZET is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. Despite advances in lipid management, millions struggle to reach LDL-C goals. It's why ESPERION Therapeutics, Inc., the Lipid Management Company, developed NEXLIZET® (bempedoic acid and ezetimibe), the first oral nonstatin LDL-C lowering therapy with the dual mechanisms of bempedoic acid, the first adenosine triphosphate citrate lyase (ACL) inhibitor to reduce cholesterol biosynthesis in the liver, and ezetimibe, which reduces cholesterol absorption in the intestine. When added to maximally tolerated statin therapy, NEXLIZET delivered a significant mean 38% LDL-C reduction vs placebo, with incidence of most common adverse reactions generally comparable to placebo. See NEXLIZETHCP.com for product information, including side effects.

THE GALIEN FOUNDATION

PRODUCT: **Veklury®**

COMPANY: Gilead Sciences, Inc.

THERAPEUTIC AREA & INDICATION:
For the treatment of coronavirus disease 2019 (COVID-19)

ABOUT THE PRODUCT

When the world first heard about the novel coronavirus, little was known about this virus other than its pneumonia-like symptoms, which could be fatal. This limited information set into motion a herculean effort by Gilead to evaluate Veklury as a potential treatment. Within months, the FDA granted Veklury an EUA to treat hospitalized COVID-19 patients and six months later granted full marketing approval.

Veklury® is the antiviral standard of care for COVID-19 and is playing a critical role in the pandemic by reducing disease progression and enabling hospitalized patients to recover faster. Around half of people hospitalized by COVID-19 in the U.S. are treated with Veklury.

THE GALIEN FOUNDATION

PRODUCT: **Pemazyre® (pemigatinib)**

COMPANY: Incyte

THERAPEUTIC AREA & INDICATION:
Treatment of cholangiocarcinoma

ABOUT THE PRODUCT

Pemazyre® (pemigatinib) is a small molecule inhibitor of FGFR 1, 2 and 3 kinases that blocks FGFR phosphorylation and signaling and decreases the viability of cells expressing FGFR gene alterations in preclinical models. Pemazyre is indicated in the U.S. for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma (CCA) with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. It is the first and only FDA-approved, individualized treatment option for these patients.

THE GALIEN FOUNDATION

PRODUCT: **ORGOVYX® (Relugolix)**

COMPANY: Myovant Sciences, Inc.

THERAPEUTIC AREA & INDICATION:
Treatment of advanced prostate cancer

ABOUT THE PRODUCT

At Myovant, we believe men should be empowered with treatment options. ORGOVYX® (relugolix) is the only oral gonadotropin-releasing hormone (GnRH) antagonist approved for the treatment of advanced prostate cancer. As a GnRH antagonist, ORGOVYX blocks the GnRH receptor and reduces production of testosterone, a hormone known to stimulate the growth of prostate cancer. The Phase 3 HERO study demonstrated the efficacy and safety of ORGOVYX, including a 96.7% response rate in testosterone suppression to castrate levels (<50 ng/dL) through 48 weeks. Safety warnings and precautions include QT /QTc interval prolongation, embryo-fetal toxicity, and laboratory testing.

THE GALIEN FOUNDATION

PRODUCT: **Braftovi® Mektovi®**

COMPANY: Pfizer Inc.

THERAPEUTIC AREA & INDICATION:
Treatment of metastatic melanoma

ABOUT THE PRODUCT

Metastatic melanoma is one of the most serious and life-threatening types of skin cancer. There are a variety of gene mutations that can lead to metastatic melanoma, the most common being *BRAF*, which occurs in approximately half of patients with unresectable or metastatic disease. BRAFTOVI® (encorafenib) and MEKTOVI® (binimetinib) are kinase inhibitors indicated for use in combination for the treatment of patients with unresectable or metastatic melanoma with a *BRAF* V600E or V600K mutation as detected by an FDA-approved test. BRAFTOVI is not indicated for treatment of patients with wild type *BRAF* melanoma.

THE GALIEN FOUNDATION

PRODUCT: **TUKYSA**

COMPANY: Seagen

THERAPEUTIC AREA & INDICATION:
Treatment of breast cancer

ABOUT THE PRODUCT

TUKYSA® (tucatinib) is an oral medicine approved by the U.S. Food and Drug Administration (FDA) for use in combination with trastuzumab and capecitabine, for adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.

TUKYSA became the first new therapy approved under the FDA's Project Orbis, which facilitates concurrent international regulatory review of oncology therapies to expedite access for patients. TUKYSA is now approved in 37 countries.