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: **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: **BALVERSA®**

COMPANY: Janssen Biotech, Inc.

THERAPEUTIC AREA & INDICATION:
Kinase inhibitor to treat adults with advanced or metastatic urothelial cancers that are susceptible to FGFR2 or FGFR3 mutations or have proven resistant to chemotherapy

ABOUT THE PRODUCT

BALVERSA™ (erdafitinib) is a once-daily, oral fibroblast growth factor receptor (FGFR) kinase inhibitor indicated for the treatment of adults with locally advanced or metastatic urothelial carcinoma (mUC) which has susceptible FGFR3 or FGFR2 genetic alterations and who have progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. About one in five patients with mUC have a FGFR genetic alteration. FGFRs are a family of receptor tyrosine kinases which can be activated by genetic alterations in a variety of tumor types, and these alterations may lead to increased tumor cell growth and survival.

THE GALIEN FOUNDATION

PRODUCT: **ERLEADA®**

COMPANY: Janssen Biotech, Inc.

THERAPEUTIC AREA & INDICATION:

Non-steroidal selective antagonist of the androgen receptor to treat adults with metastatic castration-sensitive prostate cancer and patients with non-metastatic castration-resistant prostate cancer who are at high risk for developing metastasis

ABOUT THE PRODUCT

ERLEADA® (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC) and patients with metastatic castration-sensitive prostate cancer (mCSPC). The term nmCRPC refers to a disease stage in which the prostate cancer no longer responds to treatments that lower testosterone but has not yet been discovered in other parts of the body using a total body bone scan and/or CT/MRI scan. The term mCSPC, also known as metastatic hormone-sensitive prostate cancer (mHSPC), refers to prostate cancer that still responds to ADT and has spread to other parts of the body.

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

Second-generation, anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitors (TKI) exhibit clinical efficacy in ALK-positive, advanced non-small cell lung cancer (NSCLC). However, many patients relapse due to the occurrence of resistance mechanisms, with brain metastases representing a major clinical challenge.

LORBRENA, a third-generation highly brain-penetrant ALK TKI, was specifically developed to inhibit the most common tumor mutations that drive resistance and to address brain metastases. LORBRENA is the first and only ALK TKI specifically approved for use after second-generation ALK TKIs.

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: **Lutathera® (lutetium Lu 177 dotatate)**

COMPANY: Advanced Accelerator Applications, a Novartis company

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