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: **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

Novartis researchers reimagined medicine with Entresto®, the first breakthrough treatment for heart failure with reduced ejection fraction in over a decade, by combining a neprilysin inhibitor (sacubitril) with an angiotensin receptor blocker (valsartan). Entresto was developed with the goal of improving patients' lives by reducing heart failure (HF) hospitalization and mortality. HF patients with all forms of the condition have a 50% risk of death within 5 years of diagnosis. By 2030, 1 in 33 people will have HF. Patients treated with Entresto are less likely to be hospitalized and incur lower total healthcare costs versus those treated with ACEis. Company's literature for the application for the Prix Galien USA 2020. Please refer to complete submission package for references. 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:

VYNDAQEL® (tafamidis meglumine)

COMPANY: Pfizer Inc.

THERAPEUTIC AREA & INDICATION:

For cardiomyopathy associated with transthyretin-mediated amyloidosis (ATTR-CM) to reduce cardiovascular mortality and related hospitalizations

ABOUT THE PRODUCT

VYNDAQEL and VYNDAMAX are transthyretin stabilizers indicated for the treatment of the cardiomyopathy associated with wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.
Prior to tafamidis, the only disease-modifying treatment available to patients with (ATTR-CM) was liver transplantation in selected patients with the hereditary form.
In a pivotal trial, tafamidis meglumine demonstrated significant reduction in the hierarchical combination of all-cause mortality and frequency of cardiovascular-related hospitalizations. Since tafamidis was approved for this indication in 2019, we estimate that approximately 15,000 patients have been diagnosed with ATTR-CM.

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: **YUPELRI® (revefenacin) Inhalation Solution**

COMPANY: Theravance Biopharma, Inc.

THERAPEUTIC AREA & INDICATION:
Anticholinergic to treat chronic obstructive pulmonary disease (COPD), including emphysema and chronic bronchitis

ABOUT THE PRODUCT

YUPELRI® (revefenacin) inhalation solution is a once-daily nebulized LAMA approved for the maintenance treatment of COPD in the US.

Market research by Theravance Biopharma indicates approximately 9% of the treated COPD patients in the US use nebulizers for ongoing maintenance therapy. LAMAs are a cornerstone of maintenance therapy for COPD and YUPELRI® is positioned as the first once-daily single-agent bronchodilator product for COPD patients who require, or prefer, nebulized therapy.

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.