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 an endectocide approved by the US FDA in 2018 for treatment of the neglected tropical disease onchocerciasis, also known as "river blindness". In pivotal studies, moxidectin was superior to ivermectin, becoming the first advance for this disease in 30 years. Medicines Development for Global Health who licensed moxidectin from WHO TDR in 2014, is now undertaking further development to support inclusion of moxidectin in WHO Treatment Guidelines with the goal of accelerating elimination of this devastating disease. Moxidectin is also being clinically evaluated as a potential therapy for scabies, lymphatic filariasis and the soil-transmitted helminths.

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: **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: **Pretomanid**

COMPANY: TB Alliance

THERAPEUTIC AREA & INDICATION:

A nitroimidazole drug, one of a class of novel anti-bacterials and approved as a combination with two other drugs for use in patients with highly drug-resistant pulmonary tuberculosis (TB)

ABOUT THE PRODUCT

Patients with highly drug-resistant forms of tuberculosis (TB) have historically been treated with long, complex, toxic and inadequate treatments due to a scarcity of effective medicines. In 2019, TB Alliance's anti-TB drug pretomanid received FDA approval as part of a three-drug, six-month, all-oral regimen for people with highly resistant forms of TB. This regimen (known as "BPaL" and comprised of the drugs bedaquiline, pretomanid and linezolid) has cured nine of out ten patients in the pivotal Nix-TB trial, which is comparable to outcomes with optimal therapy in drug-susceptible TB. Pretomanid is only the third new medicine for drug-resistant tuberculosis to be approved by a stringent regulatory authority in the past 40 years.