Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2024

Number of Requests: 54

Technology Name

Generic Name: Ankle Truss System

Trade Name: 4WEB Medical Ankle Truss System

Applicant Name: 4WEB Medical

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The 4WEB Ankle Truss System (ATS) has an advanced structural design that incorporates proprietary Truss Implant Technology. Under normal loading conditions the struts in the truss implant transfer strain to adjacent cellular material, which stimulates a mechanobiologic response. The Ankle Truss System devices are designed to restore limb height while providing structural integrity for the limb during tibio-talo-calcaneal fusions. The ATS implants leverage an open architecture design and a surface roughness that create an environment for bone ingrowth and fusion. The Ankle Truss System implants come in three general shapes: a spherical implant, a spherical implant with a flat side and a cuboidal implant. The shape utilized is dependent on the size of the bony defect. The ATS implants are intended to be used with supplemental fixation with a premarket authorized tibiotalocalcaneal fusion nail.

Note: The information on this tracking form was provided by the applicant at the time of application submission.

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Technology Name

Generic Name: Transdermal GFR Measurement System utilizing Relmapirazin

Trade Name: Transdermal GFR Measurement System utilizing Lumitrace (Needs FDA confirmation)

Applicant Name: MediBeacon Inc.

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Transdermal GFR (Glomerular Filtration Rate) Measurement System is a three-component system consisting of (1) an optical skin sensor, (2) a monitor and (3) MB-102 (AKA Relmapirazin/Lumitrace), which is a proprietary fluorescent tracer agent that glows in the presence of light and is removed from the blood exclusively by the GFR mechanism of the kidney. The technology is intended to measure Glomerular Filtration Rate (GFR) in patients with impaired or normal renal function.

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Technology Name

Generic Name: not applicable

Trade Name: NUsurface

Applicant Name: Active Implants, LLC

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The FDA Breakthrough-designated NUsurface® Meniscus Implant (NUsurface) is intended for patients with persistent medial knee compartment pain following medial meniscus surgery(ies). The NUsurface comes in 7 sizes and is a flexible, discoid-shaped, composite polymeric medial meniscus replacement implant that is surgically implanted interpositionally between the articular cartilage surfaces of the medial femoral condyle and medial tibial plateau. The lateral border of the implant sits within the femoral intercondylar notch, providing stability of the implant during full range of knee motion and kinematics, and does not require fixation to bone or soft tissue. The NUsurface design mimics that of the native meniscus, replacing the biomechanical characteristics and distributing load (i.e. weight) across the medial compartment to protect the articular cartilage of the knee, alleviating knee pain and restoring normal knee kinematics.

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Technology Name

Generic Name: Ceribell Status Epilepticus Monitor

Trade Name: Ceribell Status Epilepticus Monitor

Applicant Name: Ceribell, Inc

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? No

Brief Description of the Technology:

The Ceribell Status Epilepticus Monitor is a medical device system comprised of proprietary software and proprietary signal acquisition headbands and recorder. The software utilizes a machine learning model to analyze EEG signals to detect features indicative of electrographic status epilepticus (ESE) in order to provide more effective diagnosis of ESE. The software requires and interfaces with two proprietary cleared Ceribell products: the EEG Headband for EEG signal acquisition, and the Ceribell EEG recorder for obtaining signals from the headband, displaying signals, and displaying results or triggering alarms based on the output of the Status Epilepticus Monitor.

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Technology Name

Generic Name: Not applicable

Trade Name: Nelli Seizure Monitoring System

Applicant Name: Neuro Event Labs, Inc.

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Nelli is a prescription-only device that is designed to be used as an adjunct to seizure monitoring in a hospital inpatient or home setting for adults and children 6 years of age and older. Nelli's software is designed to automate the analysis of audio and video data to identify seizure events with a positive motor component.

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Technology Name

Generic Name: Wireless Thermal Anisotropy Flow Sensor

Trade Name: FlowSense

Applicant Name: Rhaeos, Inc.

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The technology is a single-use, non-invasive and wireless sensor device for the detection of flow in cerebrospinal fluid (CSF) shunts. The device transmits thermal measurement information wirelessly to a tablet application where the flow results are displayed. The device is used by clinicians including neurosurgeons, emergency room physicians, and advanced practice clinicians, on hydrocephalus patients with an existing implanted CSF shunt. The device can be used to assist in the decision to perform surgery to revise an existing implanted shunt or after surgery to confirm flow in a newly placed shunt. The clinician adheres the device to the skin overlying the shunt catheter (on or near the clavicle) and analyzes the results displayed on the tablet application.

Technology Name

> ***Generic Name:*** MOSUNETUZUMAB is the international, non-proprietary name for the technology under consideration.
>
> ***Trade Name:*** Subject to U.S. Food and Drug Administration (FDA) approval, the trade name for the product MOSUNETUZUMAB will be finalized.

Applicant Name: Genentech, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

MOSUNETUZUMAB is a novel, full-length, humanized, immunoglobulin G1 (IgG1) bispecific antibody that is designed to concomitantly bind CD3 on T cells and CD20 on B cells, including those that cause malignant disease (1). United States Food and Drug Administration (US FDA) approval of MOSUNETUZUMAB is being sought for the proposed indication of treatment of adults with relapsed/refractory (R/R) follicular lymphoma (FL) who have received at least 2 (≥2) prior systemic therapies (also referred to herein as 3L+FL). The FDA granted MOSUNETUZUMAB Breakthrough Therapy Designation for 3L+ FL on July 14, 2020. MOSUNETUZUMAB is currently under priority review with the FDA with a Prescription Drug Use Fee Act (PDUFA) date of December 29, 2022.

Technology Name

Generic Name: omidubicel

Trade Name: Not yet established

Applicant Name: Gamida Cell, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Omidubicel is currently under review by the US Food and Drug Administration (FDA) and, when approved, it will be the first, patient-specific advanced cellular therapy donor source for potential life-saving allogeneic hematopoietic cell transplant (HCT) for patients with hematologic malignancies. Gamida Cell is the leader in pioneering proprietary nicotinamide (NAM)-based cellular therapies designed as a curative approach for patients with cancers and other serious diseases. Omidubicel is a first-in-class, one-time, patient-specific advanced cellular therapy donor source consisting of a cultured and non-cultured fraction from a single umbilical cord blood unit, utilizing the proprietary NAM technology that inhibits differentiation and enhances the functionality of cultured hematopoietic stem and progenitor cells. Hematopoietic progenitor cells (HPCs) manufactured using NAM-based proprietary technology are able to preserve stem cell functions, including migration, homing, ability for long term self-renewal and reconstitution of the full immune cell repertoire. The resulting number of CD34+ HPCs in omidubicel and their functional fitness led to the long-term engraftment efficacy and rapid and broad immune reconstitution observed post-infusion. Omidubicel is the first stem cell transplant cellular therapy donor source to receive Breakthrough Therapy Designation from the FDA and has also received Orphan Drug Designation in the United States (US) and European Union (EU).

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Technology Name

Generic Name: lifileucel

Trade Name: Not yet established

Applicant Name: Iovance Biotherapeutics

Application Pathway: Traditional

Brief Description of the Technology:

Lifileucel is an investigational one-time, autologous tumor-infiltrating lymphocyte (TIL) immunotherapy for the proposed indication for the treatment of adult patients with unresectable or metastatic melanoma and previously treated with a PD-1 blocking antibody, if BRAF V600 mutation positive, a BRAF inhibitor or a BRAF inhibitor with a MEK inhibitor. Upon FDA approval, lifileucel will be the first and only FDA-approved post-ICI and post-BRAF/MEK therapy across all classes of medicines for this challenging-to-treat population and is expected to be the only one-time cell therapy for treatment of a solid tumor. TIL cell therapy with lifileucel involves the adoptive cell transfer (ACT) of autologous T-cells isolated from the tumor tissue and expanded ex vivo using a centralized manufacturing process, maintaining the heterogeneous repertoire of T-cells without any prior selection or genetic modification. Tumor antigen-specific T-cells are located within tumor lesions, where a dysfunctional state, low numbers, and a hostile microenvironment prevent them from effectively eradicating the tumor. By isolating autologous TIL from the tumor microenvironment and expanding them ex vivo in the presence of growth factors, the lifileucel manufacturing process produces large numbers of reinvigorated T-cells. Following one-time infusion of the personalized lifileucel TIL cell therapy, the TIL migrate back into primary and metastatic tumors, where they amplify and rejuvenate the patient's own immune system triggering specific tumor cell killing upon recognition of tumor antigens. Lifileucel has been granted Regenerative Medicine Advanced Therapy (RMAT), Orphan Drug and Fast Track designations in metastatic melanoma.

Technology Name

Generic Name: LimFlow System

Trade Name: LimFlow System

Applicant Name: LimFlow

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The LimFlow System is a single-use, medical device system designed to treat patients with no-option chronic limb-threatening ischemia (CLTI) of the lower extremities and who are at risk of major amputation. The LimFlow System aims to restore blood flow by diverting a stream of oxygenated blood around diseased arteries, through tibial veins and into the ischemic foot. This minimally invasive procedure is called transcatheter arterialization of the deep veins (TADV) and represents a significant technological advancement for no-option CLTI patients. The LimFlow System received Breakthrough Device Designation from the FDA on October 3, 2017.

Technology Name

Generic Name: spesolimab-sbzo

Trade Name: Spevigo

Applicant Name: Boehringer Ingelheim

Application Pathway: Traditional

Brief Description of the Technology:

SPEVIGO® is a humanized monoclonal immunoglobulin G1 antibody that inhibits interleukin-36 (IL-36) signaling by specifically binding to the IL36 receptor (IL36R). Binding of SPEVIGO to IL36R prevents the subsequent activation of IL36R by cognate ligands (IL-36 α, β and γ) and downstream activation of pro-inflammatory and pro-fibrotic pathways. SPEVIGO was granted FDA approval on September 1, 2022. SPEVIGO is FDA approved for the treatment of generalized pustular psoriasis (GPP) flares in adults. GPP is a heterogenous and potentially life-threatening neutrophilic skin disease, with a considerable burden for patients. GPP is a rare disease, with US prevalence estimated to be less than 1/10,000 (Stober 2021) and it is characterized by episodes of flares with widespread eruption of sterile, macroscopic pustules that can occur with or without systemic inflammation. Overactivation of the IL-36 pathway results in secretion of inflammatory mediators that promote infiltration of neutrophils to the skin, leading to the formation of sterile pustules. The clinical, pathological and genetic features associated with GPP establish it as a distinct disease entity from plaque psoriasis (Furue, et al., 2018; Johnston, et al., 2017; Navarini, et al., 2017; Twelves, et al., 2019). Although there are shared pathways between GPP and plaque psoriasis, the IL-36 pathway is predominantly involved in the pathogenesis of GPP, while the IL-23 axis drives plaque psoriasis (Furue, et al., 2018; Gooderham, et al., 2019; Liang, et al., 2017).

Technology Name

Generic Name: afamitresgene autoleucel

Trade Name: The trade name for afamitresgene autoleucel (afami-cel) will not be finalized until the therapy receives FDA approval.

Applicant Name: Adaptimmune LLC

Application Pathway: Traditional

Brief Description of the Technology:

Afami-cel is a genetically modified autologous T-cell immunotherapy consisting of CD4 and CD8 positive T-cells transduced with a self-inactivating LV expressing an enhanced-affinity TCR specific for MAGE-A4. It is anticipated to be indicated for patients with unresectable or metastatic SS who have received prior systemic therapy, are positive for HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P, and negative for HLA-A*02:05P, and whose tumor expresses the MAGE-A4 antigen as detected by a FDA-approved test. STS is a condition consisting of approximately 50 different histological subtypes. (Doyle 2014). SS is one type of STS representing approximately 10% of all STS in the overall population. (Raney 2005; Stacchioti 2018). SS is a rare disease, with an estimated US annual incidence 1,300 cases per year (SEER 2022), and a 5-year prevalence of 0.65 per 100,000. (Joseph 2019). SS is a serious, life-threatening disease, with a 5-year overall and cancer-specific survival of approximately 52% and 66% respectively. (Corey 2014; Sultan 2009). Outcomes are particularly poor in the metastatic setting, with a median OS from diagnosis of approximately 22 months (Spurrell 2005; Moreau-Bachelard 2022) and a 5-year OS from diagnosis under 15%. (Moreau-Bachelard 2022; Riedel 2018). For many types of advanced or metastatic STS, including SS, cytotoxic therapies remain the cornerstone of first line treatment, as well as forming the basis for the majority of second-line treatment regimens used in the real-world setting but which have limited demonstrable prognostic benefit. (Casali 2018; NCCN 2022). Patients who relapse after first-line therapy have very few treatment options with time-to-next-treatment and OS progressively worsening with each subsequent line of treatment. (Savina 2017). Beyond first-line (for which afami-cel is anticipated to be indicated), there are no therapies that specifically target the biology of SS, and real-world evidence indicates that there is no SoC with only approximately 12% of patients receiving licensed second-line metastatic therapies (e.g., pazopanib). (Pollack 2020). NCCN guidelines recommend systemic therapies as palliative therapies for patients with unresectable recurrent or metastatic disease and clinical trials as the preferred treatment option for patients with metastatic disease. (NCCN 2022). Real-world evidence suggests most second-line metastatic patients are treated with repeat administration of ifosfamide, administered off-label, use of single agent or combination therapies, or enrolled into clinical trials. (NCCN 2022). Thus, there is a significant treatment gap for metastatic SS patients, and afami-cel will fill that gap.

Technology Name

Generic Name: Vascular Conduit Solution

Trade Name: DuraGraft

Applicant Name: Marizyme, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

DuraGraft is an intraoperative vein-graft treatment and endothelial damage inhibitor used during CABG surgery that protects the vascular endothelium of harvested vascular grafts against ischemic injury that occurs following graft harvesting. Intraoperative Ischemic injury to the endothelial layer of free vascular grafts forms the basis of post-CABG vein graft disease and graft failure: clinical manifestations of graft ischemia reperfusion injury (IRI). DuraGraft treatment is associated with a reduction in both vein graft disease and clinical complications associated with vein graft failure post-CABG; repeat revascularization and myocardial infarction. Recent published clinical data (Szalkiewicz, et. al.) have demonstrated that DuraGraft also confers myocardial protection during CABG. There are currently no commercial products that prevent ischemic injury of vein grafts during CABG surgery and no products that reduce vein graft disease or its complications following CABG surgery.

Technology Name

Generic Name: Terlipressin

Trade Name: TERLIVAZ

Applicant Name: Mallinckrodt Hospital Products Inc.

Application Pathway: Traditional

Brief Description of the Technology:

TERLIVAZ (terlipressin) is a V1 receptor agonist that is thought to increase renal blood flow in patients with hepatorenal syndrome (HRS). It is a pharmacologic therapy that acts as a prodrug for lysine-vasopressin while having activity on its own. As a synthetic vasopressin analogue, TERLIVAZ has twice the selectivity for V1 receptors in the splanchnic area as V2 receptors, allowing for targeting of splanchnic vessels, reduction of portal hypertension, improvement in effective circulatory volume, and restoration of renal perfusion. TERLIVAZ is the first and only FDA-approved treatment indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function. Terlipressin is also listed as the preferred treatment for HRS-acute kidney injury (AKI) by the American Association for the Study of Liver Diseases (AASLD) 2021 guidance, the American College of Gastroenterology (ACG) 2022 guidelines, the American Gastroenterological Association (AGA) 2022 clinical practice update, and in international guidelines. It is one of the most studied pharmacologic treatments for HRS with more than 70 published manuscripts and presented abstracts on clinical data to date. TERLIVAZ is administered as a slow intravenous (IV) bolus injection every 6 hours. It is intended to be used in the inpatient hospital setting, with the vast majority (84.4%) of patients in the pivotal CONFIRM trial treated outside of the intensive care unit (ICU). TERLIVAZ may be administered through a peripheral line and does not require invasive cardiac monitoring, per the approved Prescribing Information.

Technology Name

Generic Name: LigaPASS 2.0 Ligament Augmentation System

Trade Name: LigaPASS 2.0 Ligament Augmentation System

Applicant Name: Medtronic

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The LigaPASS™ 2.0 Ligament Augmentation System consists of a polyester (PET) band and titanium alloy medial open connector with 2 set screws. LigaPASS™ bands allow the surgeon to create a posterior vertebra anchorage without the use of a pedicle screw or hook. Instead of a pedicle screw or hook, the LigaPASS™ bands are laced around or through the vertebra independently of the vertebra anatomy and then connected to a LigaPASS 2.0 medial open connector to make the rod-bone connection. LigaPASS™ 2.0 system family of band connectors is compatible with any rods made of titanium or cobalt chromium alloys between diameters 5.5 mm and 6.0 mm. The technology was granted breakthrough device designation for the mitigation of the risk of post-operative proximal junctional kyphosis (PJK) and proximal junctional failure (PJF). This device is used in patients being surgically treated for adult spinal deformity with rigid instrumentation.

Technology Name

Generic Name: lovotibeglogene autotemcel (lovo-cel)

Trade Name: Not yet established

Applicant Name: bluebird bio, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Lovo-cel is an investigational, one-time, autologous gene therapy being evaluated for the treatment of sickle cell disease (SCD), a serious, progressive and debilitating genetic disease caused by a single mutation in the β-globin subunit of the oxygen-carrying hemoglobin (Hb) molecule expressed in red blood cells (RBCs). Lovo-cel fundamentally impacts the pathophysiology of SCD at the genetic level, with a goal of reducing or eliminating downstream complications. Lovo-cel is designed to add functional copies of a modified form of the β-globin gene (βA-T87Q-globin gene) into a patient's own hematopoietic (blood) stem cells (HSCs). Once patients have the βA-T87Q-globin gene, their RBCs can produce anti-sickling hemoglobin (HbAT87Q) to substantially reduce sickling, with the goal of reducing sickle hemoglobin (HbS), hemolysis, and other complications. Lovo-cel consists of an autologous CD34+ cell-enriched population from patients with SCD that contains HSCs transduced with BB305 LVV encoding the βA-T87Q-globin gene, suspended in a cryopreservation solution. Lovo-cel is administered as a one-time, single dose intravenous infusion.

Technology Name

Generic Name: Elranatamab

Trade Name: Not yet assigned

Applicant Name: Pfizer, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Elranatamab is a heterodimeric humanized full-length bispecific antibody against BCMA and CD3. Bispecific antibodies offer a novel immunotherapeutic approach that allows the direct targeting of cytotoxic T cells to tumor cells. BCMA expression is upregulated during B cell maturation into plasmablasts and plasma cells, but is not expressed on naïve B cells, hematopoietic stem cells, or normal tissues such as heart, lung, kidney, or tonsil. BCMA is, thus, an ideal cell surface target for MM, a disease characterized by the accumulation of malignant plasma cells in the bone marrow. Elranatamab is proposed to act through direct bridging of the BCMA cell-surface antigen and the extracellular CD3 subunit expressed on T cells.

Technology Name

Generic Name: MY01 device

Trade Name: MY01 Continuous Compartmental Pressure Monitor

Applicant Name: MY01 Inc.

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in the diagnosis of Compartment Syndrome (Acute and Chronic). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.

Technology Name

Generic Name: RBX2660

Trade Name: RBX2660

Applicant Name: Ferring Pharmaceuticals Inc., an affiliate of the manufacturer, Rebiotix, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

The product is currently being referred to as RBX2660. A brand name and generic name will be available when the product is approved by the FDA.

Technology Name

Generic Name: none

Trade Name: SeptiCyte RAPID

Applicant Name: Immunexpress

Application Pathway: Traditional

Brief Description of the Technology:

The SeptiCyte® RAPID test is a gene expression assay using reverse transcription polymerase chain reaction to quantify the relative expression levels of host response genes, (PLAC8 and PLA2G7) isolated from whole blood collected in the PAXgene® Blood RNA Tube. The test is performed in a fully integrated cartridge which runs on the Biocartis Idylla system, with sample to answer turnaround time of approximately 60 minutes. The SeptiCyte® RAPID test generates a score (SeptiScore®) ranging from 0-15 that falls within one of four discrete Interpretation bands based on the increasing likelihood of infection-positive systemic inflammation, (sepsis). The SeptiCyte® RAPID test is used in conjunction with clinical assessments and other laboratory findings as an aid to differentiate infection-positive (sepsis) from infection-negative systemic inflammation in patients suspected of sepsis on their first day of ICU admission. SeptiCyte® RAPID is intended for in-vitro diagnostic use.

Technology Name

Generic Name: Venous External Support

Trade Name: VEST

Applicant Name: Vascular Graft Solutions (VGS)

Application Pathway: Traditional

Brief Description of the Technology:

VEST is a novel, first of its kind, external support device which can be fitted over the saphenous vein when used as a bypass conduit in coronary artery bypass grafting (CABG) surgery. It is the only technology that has been proven to prevent common vein graft failures as a result of graft kinking and vein graft disease (intimal hyperplasia). In doing so, VEST ultimately improves the outcome of CABG by reducing clinical events associated with vein graft failure such as coronary re-intervention (PCI or re-do CABG), MI, angina, and death.

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Technology Name

Generic Name: Treosulfan injection

Trade Name: Treosulfan

Applicant Name: Medexus Pharma, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Treosulfan is a new chemical entity and a novel prodrug of a bifunctional alkylating agent that is used as a preparative regimen for alloHSCT. It has a unique mechanism of action that permits it to bypass the liver when it metabolizes, resulting in reduced toxicity. Treosulfan received orphan-drug designation from FDA on April 8, 2015, for "conditioning treatment prior to hematopoietic stem cell transplantation (HSCT) in malignant diseases in adults and pediatric patients." Treosulfan is under FDA review through a New Drug Application (NDA) with a proposed indication for: (1) use in combination with fludarabine as a preparative regimen for alloHSCT in adult and pediatric patients older than one year with acute myeloid leukemia (AML); and (2) use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients older than one year with myelodysplastic syndrome (MDS). The proposed indications are not restricted to patients in remission. The proposed indications are not restricted to patients in Both AML and MDS are malignant cancers associated with high relapse rates and low overall survival rates. FDA approval is anticipated by June 30, 2023. alloHSCT is currently used for patients with intermediate or high-risk malignant and certain non-malignant disorders. The goal of alloHSCT is to cure patients of their disease by replacing their hematopoietic stem cells with stem cells from a healthy donor. Conditioning/preparative treatments have traditionally included Myeloablative Conditioning (MAC), which includes high-dose total body irradiation (TBI) and high-dose chemotherapy. Reduced Intensity Conditioning (RIC), in which cytotoxic components of the regimen are reduced or replaced with less toxic agents are an option for some patients. However, MAC regimens are associated high treatment-related toxicity and transplantation-related mortality (TRM), but RIC regimens usually pose a higher risk of relapse. Treosulfan was developed to address the significant unmet medical need for improved conditioning that can reduce toxicity and TRM without increasing the incidence of relapse, particularly for the elderly or compromised patients who are not candidates for MAC. See Exhibit 2. As a pro-drug, Treosulfan has a unique mechanism of action that bypasses metabolism in the liver, reducing toxicity, but still delivers effective treatment. Because of its unique hydroxide (OH) bonds, Treosulfan also has an "entirely different" mechanism of alkylation. See Exhibit 1. With its lower toxicity, its ability to bypass metabolism in the liver, and its different means of alkylation, Treosulfan has demonstrated a statistically significant improvement in the incidence of non-relapse mortality, TRM, improved control of GVHD, improved event-free survival, and overall survival as compared to busulfan, which is the treatment used in 43% of patients, making it the predominant agent used. See Exhibit 10.

Technology Name

Generic Name: EPSB3 Base Station and PNX-1000 catheter

Trade Name: Phagenyx System

Applicant Name: Phagenesis Ltd.

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Phagenyx® System is designed to treat neurogenic dysphagia. Neurogenic dysphagia is dysphagia arising from the disruption of any of the neurological systems or processes involved in the execution of a coordinated safe swallow. A broad range of different underlying diseases (neurological or non-neurological) or care management interventions like mechanical ventilation can give rise to this form of neurological disruption. Phagenyx treatment does not treat the underlying disease that gave rise to the dysphagia–it treats the common neurological symptoms and swallowing deficits that those diseases cause (i.e., neurogenic dysphagia). These deficits can manifest as desensitization or dysfunction of local neurological sensory systems, a disruption of control systems in the swallow motor cortex, or both. Neurogenic dysphagia is commonly seen after stroke, traumatic brain injury or prolonged mechanical ventilation. Phagenyx® uses electrical pulses to stimulate sensory nerves in the oropharynx. Once excited, these nerves send signals to the motor cortex in the brain, increasing cortical activity, promoting neuroplasticity and restoring swallowing control through functional cortical reorganization. In addition, Phagenyx® treatment results in beneficial changes in the local sensory mechanisms of the pharyngeal mucosa linked to swallow and the cough reflex through an increase in the swallow related neurotransmitter. The Phagenyx® product is comprised of two parts, a sterile single patient use Catheter and a Base Station. The Catheter is a two-part fine bore flexible tube that is introduced nasally and extends down as far as the patients' stomach. It incorporates two bipolar ring electrodes on its outer surface to deliver the electrical stimulation. It also incorporates a feeding tube to facilitate delivery of nutrition or hydration. The Base Station is a touch screen user interface that facilitates the optimization of stimulation levels and stores patient and treatment information. Treatment Process 1. The catheter is adjusted prior to insertion to fit the patient anatomy and then inserted nasally until the tip is located in the stomach and electrodes in the oropharynx. 2. The catheter is connected to the Base Station and stimulation incrementally increased to establish the Threshold Level (lowest current patient can detect) and Tolerance Level (highest level they can tolerate). A Stimulation Level is derived from these two values. 3. 10 minutes of treatment are delivered once per day for 3 consecutive days. For the minority of patients that don't respond to 3 treatments, up to a maximum of 3 more treatments are permitted. 4. Only one catheter is used per patient for the whole treatment regimen i.e., it stays in place between treatment sessions. Once all treatments are completed the catheter is removed and disposed of in clinical waste. Alternatively, if required, the catheter can be left in place for up to 2 weeks to facilitate feeding.

Technology Name

Generic Name: Epcoritamab

Trade Name: To be determined prior to U.S. Food & Drug Administration (FDA) approval

Applicant Name: Genmab US, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Lymphomas are a group of neoplasms derived from malignant lymphoid tissue, lymphocytes, and histiocytes. Lymphomas are divided into Hodgkin's and non-Hodgkin's lymphocytes (NHL), which comprises ~90% of all lymphomas based on morphologic and immunologic characteristics.[1,2,3] NHLs are a heterogeneous group of lymphoproliferative disease arising from transformed B-lymphocyte progenitor cells (85-90%) or, more rarely, transformed T-lymphocyte progenitor cells (10-15%).[2] With an estimated 509,000 new cases globally, NHL is the most common form of hematologic malignancy. NHLs can be further divided into aggressive (fast growing) and indolent (slow growing) subtypes.[4] An aggressive subtype, Large B-cell lymphoma (LBCL), is histologically characterized by transformed B-cells greater than 17µm in diameter. [5,6] LBCL is a constellation of B-cell lymphomas, of which Diffuse Large B-cell Lymphoma (DLBCL) is the most common consisting of ~90% of all LBCLs (and 30% of all NHLs more generally), followed by Primary Mediastinal B-cell Lymphoma (PMBCL), High Grade B-cell Lymphoma (HGBCL), and Grade 3B Follicular Lymphoma (G3b FL) making up less than 5% of LBCL.[2,3,5,7,8] Epcoritamab is an investigational biologic for which Genmab US, Inc. (Genmab) and AbbVie, Inc. (AbbVie) are seeking FDA approval for the treatment of adult patients with relapse or refractory (R/R) LBCL, after two or more lines of systemic therapy. FDA approval is anticipated by May 20, 2023. Epcoritamab is a full-length cluster of differentiation (CD)3 x CD20 bispecific antibody, allowing the direct binding of a CD3+ T-cell and a CD20 expressing B-cell, which may induce T-cell mediated cytotoxicity of the CD20 expressing B-cell.[9] In LBCL patients, it results in the anti-tumor activity against the transformed B-cells.[10]

Technology Name

Generic Name: Solution Taurolidine (13.5 mg mL) and Heparin (1000 USP U mL)

Trade Name: DefenCath (will likely have a different trade name upon FDA request for approval)

Applicant Name: CorMedix

Application Pathway: Alternative (QIDP/LPAD)

Has the technology received a QIDP designation or approval under the LPAD pathway from FDA for the indication relevant to this application? QIDP Designation

Brief Description of the Technology:

DefenCath™ is a proprietary formulation of taurolidine and heparin that is under development for use as a catheter lock solution, with the aim of reducing the risk of bloodstream infections from in-dwelling catheters in patients undergoing hemodialysis. Taurolidine, the antimicrobial compound in Defencath™, is a derivative of the amino acid taurine, with in vitro studies indicating broad antimicrobial activity against gram-positive and gram-negative bacteria, including antibiotic resistant strains, as well as mycobacteria and clinically relevant fungi. In the United States, DefenCath™ was designated by FDA as a Qualified Infectious Disease Product (QIDP) in 2015 and has been granted FDA Fast Track status. CorMedix has completed a Phase 3 clinical trial, known as LOCK-IT-100, which demonstrated a highly significant and clinically relevant 71% decrease in catheter-related bloodstream infection (CRBSI) in patients receiving hemodialysis for the treatment of kidney failure when compared with heparin alone, which is the current standard of care for a catheter lock solution.

Technology Name

Generic Name: Canary Tibial Extension (CTE)

Trade Name: Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System

Applicant Name: Zimmer Biomet

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Canary Medical Canturio Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) is a tibial extension implant containing electronics and software. It can only be used with the Zimmer Biomet Persona® IQ The Personalized Knee®. Using internal motion sensors (3-D accelerometers and 3-D gyroscopes), the CTE implant collects kinematic data pertaining to a patient's gait and activity level following total knee arthroplasty (TKA). The kinematic data produced by the CTE implant is intended as an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-TKA surgery. The CTE implant also provides stability to the knee implant in the same manner as a traditional tibial extension. The CTE with CHIRP is designed to provide granular assessment of patient TKA functionality passively through remote collection of their kinematic data with high levels of compliance during the acute 90-day episode of care and continuously for up to 20 years. The kinematic data generated from the CTE implant will afford the doctor and the patient the opportunity to monitor their TKA's function, potentially improving the delivery and quality of healthcare for the patient.

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Technology Name

Generic Name: Functional connectivity guided, rapidly acting iTBS treatment

Trade Name: SAINT Neuromodulation System

Applicant Name: Magnus Medical, Inc

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The SAINT Neuromodulation System is a non-invasive repetitive transcranial magnetic stimulation (rTMS) system that identifies an individualized target and delivers navigationally directed repetitive magnetic pulses to that individualized target located within the left dorsolateral prefrontal cortex (L-DLPFC) to treat Major Depressive Disorder (MDD) in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. The SAINT Neuromodulation System consists of hardware devices (e.g., stimulator with treatment coil and neuronavigation) designed to deliver SAINT Therapy to a targeted area within the L-DLPFC, as well as cloud software that identifies the personalized target. The personalized target is identified using a proprietary analysis of structural and functional MRI data to determine the subregion within the L-DLPFC that is most strongly connected to deeper brain structures responsible for the symptoms of depression. The system also enables motor threshold determination, which is used to inform patient-specific stimulation settings. SAINT Technology is the combination of using the specific, individualized target for treatment along with a proprietary accelerated treatment protocol that optimizes the pulse dose, pattern, and session spacing resulting in a condensed treatment of five days. SAINT Therapy has demonstrated remission rates of approximately 80-90% in patients who have failed to achieve satisfactory improvement from prior antidepressant medication following the 5-day treatment protocol as demonstrated in a double-blinded, randomized, sham-controlled trial and in three open-label clinical studies. By comparison, current TMS treatments show remission rates of ~35% in moderately treatment-resistant depression, falling to 17% in more treatment-resistant depression.

Technology Name

Generic Name: Dual Chamber Leadless Pacemaker

Trade Name: Aveir Leadless Pacemaker

Applicant Name: Abbott Cardiac Rhythm Management

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Abbott's Aveir™ dual-chamber leadless pacemaker system, referred to as the Aveir™ System, is a programmable system comprising of two implanted leadless pacemakers that provide dual-chamber pacing therapy. The Aveir™ leadless system consists of two implanted pacemaker devices that are placed within the myocardium and paces the heart without the need for traditional "wired" leads. The Aveir™ System is the first dual-chamber leadless pacemaker to provide pacing therapy to indicated patients, through a minimally invasive catheter-based procedure. Transvenous or conventional pacemakers include a power supply (generator) placed under the skin in chest region, and pacing is transmitted through one or two electrodes (leads) to the heart. Each leadless pacemaker within the Aveir™ System contains both the generator and electrodes within the device. The Aveir™ System offers patients a less-invasive approach compared to conventional transvenous procedures for patients that are indicated for single or dual-chamber pacing. Potential benefits of a leadless system include reduced lead and pocket complications associated with traditional pacemaker. Each leadless pacemaker provides single-chamber pacing therapy within respective chamber, the right atrium or the right ventricle. Once the respective devices are positioned and fixated in the relevant chambers of the heart, the devices are then programmed so they can communicate and function together as part of a coordinated dual-chamber system. Currently, there are no leadless dual-chamber pacemaker systems available in the market. Most of the U.S. pacemaker population requires dual-chamber pacing because of their clinical presentation. In the U.S., 80% of patients who require permanent pacemakers receive traditional dual-chamber devices while the remaining 20% receive traditional single-chamber devices (Mond H., The 11th world survey of cardiac pacing and implantable cardioverter defibrillators; calendar year 2009 – a world society of arrhythmia's project. PACE. 2011; 34(8): 1013-1027). Any patient indicated for a dual-chamber transvenous pacemaker could receive a dual-chamber leadless pacemaker. Physicians may prefer leadless pacemakers for patients that have a high risk of infection, or previously experienced an infection with conventional pacemaker with leads. Patients may prefer leadless pacemaker as there is no chest scar, and the device is not visible.

Technology Name

Generic Name: sulbactam-durlobactam

Trade Name: SUL-DUR, for injection, for intravenous use

Applicant Name: Entasis Therapeutics, Inc.

Application Pathway: Alternative (QIDP/LPAD)

Has the technology received a QIDP designation or approval under the LPAD pathway from FDA for the indication relevant to this application? QIDP Designation

Brief Description of the Technology:

Sulbactam-durlobactam (SUL-DUR) is a combination of sulbactam, a penicillin derivative β-lactamase inhibitor with intrinsic antibacterial activity against Acinetobacter baumannii-calcoaceticus complex (ABC), and durlobactam, a β-lactamase inhibitor with broad spectrum activity against Classes A, C, and D β-lactamases. Durlobactam effectively restores sulbactam activity in vitro against ABC organisms. Treatment of infections due to ABC is a serious unmet need. Acinetobacter baumannii is a Gram-negative bacterial pathogen and has emerged globally as a major cause of hospital-acquired infections. While pneumonia and bacteremia are the most common infections caused by ABC, these organisms can also cause urinary tract infections, skin and soft tissue infections, wound infections, osteomyelitis, and meningitis. Infections caused by A. baumannii are associated with high morbidity and mortality and have become increasingly difficult to treat due to the emergence of multi-drug resistant (MDR) and carbapenem-resistant Acientobacter baumannii strains (CRAB). Globally, A. baumannii was among the 5 leading pathogens contributing to the most deaths attributable to antimicrobial resistance in 2019. In 2019, an estimated 326,000 deaths globally were associated with carbapenem-resistant A. baumannii. The rise in carbapenem-resistant A. baumannii is of particular concern, leaving no clear "standard of care" antibiotic regimen for these infections. Carbapenem-resistant Acinetobacter is classified by the United States Centers for Disease Control and Prevention as an "urgent threat" pathogen and is ranked as "priority 1, critical" on the World Health Organization (WHO) global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics. The clinical development program for sulbactam-durlobactam consists of 6 Phase 1 studies, one Phase 2 study, and one Phase 3 study. Sulbactam-durlobactam has shown a favorable clinical profile with demonstration of linear PK, minimal drug interactions, and good penetration into the lung. Sulbactam-durlobactam has been generally well-tolerated, with no drug-related serious adverse events or deaths in Phase 1 studies. In the Phase 3 study, sulbactam-durlobactam met the primary efficacy and safety objectives of the study, achieving noninferiority versus colistin in 28-day all-cause mortality and a statistically significant reduction in the incidence of nephrotoxicity. Adverse events in the safety population were comparable between treatment groups.

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Technology Name

Generic Name: Quizartinib tablets

Trade Name: Vanflyta

Applicant Name: Daiichi Sankyo, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Vanflyta (quizartinib) is a kinase inhibitor indicated for use in combination with standard cytarabine and anthracycline induction chemotherapy and standard cytarabine consolidation chemotherapy, and as continuation monotherapy following consolidation, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FMS-like tyrosine kinase 3 internal tandem duplication (FLT3-ITD) positive as detected by an FDA-approved test.

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Technology Name

Generic Name: Pafolacianine

Trade Name: Cytalux

Applicant Name: On Target Laboratories

Application Pathway: Traditional

Brief Description of the Technology:

CYTALUX is the first targeted intraoperative molecular imaging agent that illuminates lung cancer in real time, enabling the detection of more cancer for resection.

Technology Name

Generic Name: narsoplimab-wuug

Trade Name: Will be updated following FDA approval

Applicant Name: Omeros Corporation

Application Pathway: Traditional

Brief Description of the Technology:

Narsoplimab is a fully human monoclonal antibody with a unique mechanism of action targeting mannan-binding lectin serine protease 2 (MASP-2), the effector enzyme of the lectin pathway of the complement system. (Schwaeble et al., 2011; Kozarcanin, et al., 2016; Demopoulos, 2019; Elhadad, 2020.) Narsoplimab inhibits MASP-2 and activation of the lectin pathway. Narsoplimab prevents lectin pathway-mediated inflammation and exhibits anticoagulant effects, while leaving intact the respective functions of the classical and alternative pathways of innate immunity. (Khaled et al., 2022.)

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Technology Name

Generic Name: Concentrate of proteolytic enzymes enriched in bromelain-bcdb

Trade Name: NexoBrid

Applicant Name: Vericel Corporation

Application Pathway: Traditional

Brief Description of the Technology:

NexoBrid is a novel, non-surgical option for eschar removal (debridement) in adult patients with deep partial thickness (DPT) and/or full thickness (FT) thermal burns. Eschar is the dead tissue and dried secretions following a burn, and its removal is essential for wound healing. When eschar is left in place, tissue death usually extends into the neighboring undamaged tissues, further deepening the wound. The eschar acts as a medium for bacterial growth and a source of infection, contamination, sepsis, and severe local and systemic complications which may ultimately lead to death. (Atiyeh et al, 2005; Barret et al, 1999; Barret and Herndon, 2003; Ong et al, 2006; Xiao-Wu et al, 2002; Young, 2006). NexoBrid is a concentrate of proteolytic enzymes (enriched in bromelain). It is a botanical and biologic product for topical use and is comprised of 2 components: the NexoBrid powder that contains the active pharmaceutical ingredient (API) and a Gel Vehicle. The NexoBrid API is a concentration of proteolytic enzymes enriched in Bromelain extracted from pineapple stems. The mechanism of action of NexoBrid is mediated by the proteolytic activity of its enzymes and is associated with selective degradation of eschar and denatured collagen while sparing healthy tissue. In comparison to standard of care, NexoBrid has been shown in two Phase 3 clinical trials ("DETECT" NCT04040660, NCT00324311) to have a statistically lower rate of surgical excision and lower rate of blood loss than the standard of care (SOC). Additionally, NexoBrid is associated with shorter average time to complete eschar removal than SOC (1.0 days for NexoBrid-treated patients vs. SOC's 3.8 days). Shorter time to complete eschar removal is associated with decreased burn depth conversion and reduced need for subsequent surgery (Loo et al, 2018). NexoBrid was developed by MediWound Ltd. (Yavne, Israel) and is being commercialized in the U.S. by Vericel Corporation (Cambridge, MA). A NexoBrid Biologic License Application (BLA) was submitted for FDA approval on June 30, 2020. The FDA sent a complete response letter (CRL) for that submission in June 2021, in part identifying inability to inspect NexoBrid manufacturing sites in Taiwan and Israel due to COVID-related travel restrictions. NexoBrid's BLA was resubmitted on July 1, 2022 and has a Prescription Drug User Fee Act (PDUFA) date of January 1, 2023. Out of the approximately 40,000 individuals hospitalized for burns in the U.S, ~75%, or ~30,000, are estimated to be treated at one of ~140 dedicated hospital burn centers. Initial NexoBrid use will be primarily in these specialized inpatient burn centers.

Technology Name

Generic Name: GLOFITIMAB is the international, non-proprietary name. Upon FDA approval, the final USPI will be submitted.

Trade Name: Subject to U.S. Food and Drug Administration (FDA) approval, the trade name for the product GLOFITIMAB will be finalized.

Applicant Name: Genentech, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

GLOFITAMAB is a novel full-length, fully humanized, T-cell engaging bispecific antibody with a novel 2:1 structure. U.S. FDA approval of GLOFITIMAB is being sought for the proposed indication of treatment of adults with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) after 2 or more prior therapies. We have provided a description of the technology, what it does, and how it is used in response to subsequent questions. Note that the figures and tables referenced throughout this section of the application appear in the graphical appendix (Appendix 1) attached to this section of the application. We have also included a list of references cited in-line throughout this application in MEARIS as Appendix 2.

Technology Name

Generic Name: TOPS System

Trade Name: TOPS System

Applicant Name: Premia Spine, Inc.

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The TOPS System is a motion preserving device comprised of a titanium construct with an interlocking polycarbonate urethane (PcU) articulating core. After open posterior decompression, it is inserted and affixed using pedicle screws preserving normal spinal motion and providing stabilization of the lumbar intervertebral segment. The TOPS System replaces anatomical structures, such as the lamina and the facet joints, that are removed during spinal decompression treatment to alleviate pain. The internal stoppers replace the natural bony elements of the articular facet joint stabilizing the segment while allowing normal motion . The boot and internal components take the place of the supraspinous ligament, interspinous ligament, and ligamentum flavum in their ability to help control flexion and lateral bending.

Technology Name

Generic Name: Previously referred to as the PQ Bypass System

Trade Name: The DETOUR System

Applicant Name: Endologix

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The DETOUR System is an approach to fully percutaneous femoral-popliteal bypass. Under fluoroscopic guidance a proprietary Torus Stent Graft System is deployed from the popliteal artery into the femoral vein, and from the femoral vein into the superficial femoral artery (SFA) in a continuous, overlapping fashion through two independent anastomoses. The intended result is a large lumen endograft bypass, that delivers unobstructed, pulsatile flow from the SFA ostium to the popliteal artery.

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Technology Name

Generic Name: Not Applicable

Trade Name: NCCT Stroke

Applicant Name: Ischemaview

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

NCCT Stroke integrates information from three algorithms that analyze NCCT images to improve the workflow process for evaluating patients with suspected stroke. The product assesses the NCCT scan for both the suspicion of hemorrhagic stroke (ICH) as well as an ischemic stroke with a large vessel occlusion (LVO). This workflow improvement allows for a single scan to accelerate the workflow prioritizing patients with suspected of LVO for urgent evaluation for thrombectomy and/or other reperfusion therapies. The product also identifies suspected ICH patients for evaluation of the use of urgent surgical or medical therapies

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Technology Name

Generic Name: Rezafungin

Trade Name: REZZAYO

Applicant Name: Melinta Therapeutics

Application Pathway: Alternative (QIDP/LPAD)

Has the technology received a QIDP designation or approval under the LPAD pathway from FDA for the indication relevant to this application? QIDP Designation

Brief Description of the Technology:

REZZAYO (rezafungin) is an echinocandin antifungal drug. An Investigational New Drug application has been filed for approval of REZZAYO for the treatment of candidemia and invasive candidiasis in patients 18 years of age or older. REZZAYO is a sterile, lyophilized product that contains rezafungin acetate. Rezafungin acetate is a semisynthetic lipopeptide synthesized from a fermentation product of Aspergillus nidulans. REZZAYO is an echinocandin, a class of antifungal drugs that inhibits the synthesis of 1,3-beta-D-glucan, an essential component of fungal cell walls. REZZAYO contains rezafungin acetate equivalent to 200 mg of rezafungin. REZZAYO also contains 500 mg mannitol, 450 mg polysorbate 80, 47 mg histidine, and hydrochloric acid and/or sodium hydroxide for pH adjustment. Rezafungin acetate is a hygroscopic, white to off-white powder. It is freely soluble in water, soluble in methanol, and sparingly soluble in ethanol. Rezafungin has been shown to be active against most isolates of the following microorganisms both in vitro and in clinical infections: Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis. The recommended dose of REZZAYO is to be administered once weekly by intravenous (IV) infusion, with an initial 400 mg loading dose, followed by a 200 mg dose once weekly thereafter. At earlier stages of its development, REZZAYO was known as CD101.

Technology Name

Generic Name: SER-109 is currently under review by the FDA. Seres will submit additional information regarding SER-109 as available.

Trade Name: SER-109 is currently under review by the FDA. Seres will submit additional information regarding SER-109 as available.

Applicant Name: Seres Therapeutics

Application Pathway: Traditional

Brief Description of the Technology:

SER-109 is an oral microbiome therapeutic candidate under review by the FDA. The FDA granted SER-109 Breakthrough Therapy designation and Orphan Drug designation for the treatment of recurrent Clostridioides difficile (C. diff) infection (rCDI). The Centers for Disease Control and Prevention (CDC) classifies C. diff as one of the most significant threats to human health.[1] C. diff is the leading cause of hospital-acquired infections (HAIs) in the United States, and CDI is connected with over 20,000 fatalities in the U.S. annually.[2][4] CDI causes colonic inflammation and debilitating diarrhea, which negatively affect quality of life and cause further health complications, such as severe dehydration.[3][6] Patients at increased risk for CDI include those with current or recent antibiotic use, current or recent hospitalization, older than 65 years, and who are immunocompromised.[4][6] Patients in the Medicare population, particularly those receiving treatment in an inpatient hospital setting, are therefore at elevated risk for CDI. The primary risk factor for CDI is exposure to broad-spectrum antibiotics, which leads to compositional and functional changes in the gastrointestinal microbiome and renders patients susceptible to increased germination of C. diff spores, thereby causing recurring infections.[5] In healthy microbial communities, spore-forming Firmicutes bacteria modulate production and consumption of metabolites, which are important to host defense and colonization resistance. For example, greater concentrations of secondary bile acids over primary bile acids inhibit C. diff spore germination. However, antibiotic-induced loss of these beneficial Firmicutes bacteria leads to increases in primary bile-acid concentrations, which then enables C. diff spore germination and launches a cycle of recurrent disease [Figure 1]. According to the CDC, approximately one in six patients infected with C. diff will be infected again in 2-8 weeks, and one in eleven adults over the age of 65 who are diagnosed with CDI will die within one month.[6] Most recurrences occur within 3 weeks of antibiotic discontinuation.[7][8] Despite its prevalence, there are few treatment options for CDI, and currently approved treatments do not have robust efficacy for rCDI because they do not target patients' disrupted microbiomes. Microbiome resilience is key to ensuring recovery of beneficial Firmicutes bacteria following discontinuation of antibiotic treatment. Most CDI recurrences occur within the days and weeks after completion of an antibiotic regimen, as the disrupted microbiome facilitates increased C. diff spore germination.[8] While antibiotics are necessary to treat CDI, they are insufficient to achieve a sustained clinical response. Therefore, the two-pronged treatment approach of (1) antibiotics to kill vegetative C. diff bacteria followed by (2) SER-109 to repair the microbiome is key to managing CDI and to preventing its recurrence.[7][9][12][Figure 2].

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Technology Name

Generic Name: Pafolacianine

Trade Name: CYTALUX

Applicant Name: On Target Laboratories

Application Pathway: Traditional

Brief Description of the Technology:

CYTALUX is the first targeted intraoperative molecular imaging agent that illuminates ovarian cancer in real time, enabling the detection of more cancer for resection.

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Technology Name

Generic Name: ASTar System

Trade Name: ASTar System

Applicant Name: Q-linea

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The ASTar® System is a new, fully automated system for rapid antimicrobial susceptibility testing (AST). The proprietary AST technology is based on broth microdilution (BMD), optimized for high sensitivity and short time-to-result, delivering phenotypic AST with true minimum inhibitory concentration (MIC) results in approximately six hours. The first application is focused on Gram-negative bloodstream infections, to provide rapid AST results directly from positive blood cultures. The ASTar® System covers the broadest Gram-negative antimicrobial panel and range of dilutions to date. With this ideal testing capacity, ASTar abolishes the need for extrapolated values, allowing all required antimicrobial dilutions to be tested simultaneously. Major advantages of the ASTar Instrument and BC G- Kit for the lab, clinicians, and patients are a boosted workflow efficiency, less hands-on labor, faster AST results, and early start of adequate antimicrobial treatment.

Technology Name

Generic Name: HEPZATO KIT (melphalan hydrochloride for injection-hepatic delivery system)

Trade Name: HEPZATO KIT (melphalan hydrochloride for injection-hepatic delivery system)

Applicant Name: Delcath Systems, Inc

Application Pathway: Traditional

Brief Description of the Technology:

The HEPZATO™ KIT (melphalan hydrochloride/Hepatic Delivery System) is a drug/device combination product consisting of melphalan hydrochloride and the HDS. It is intended for the treatment of patients with unresectable primary and metastatic tumors in the liver. The HDS is used to perform Percutaneous Hepatic Perfusion (PHP), an intensive local hepatic chemotherapy procedure in which the alkylating agent melphalan hydrochloride, is delivered intra-arterially to the liver with simultaneous extracorporeal filtration of hepatic venous blood return (hemofiltration).

Technology Name

Generic Name: Sabizabulin

Trade Name: Trade name not yet determined

Applicant Name: Veru

Application Pathway: Traditional

Brief Description of the Technology:

Sabizabulin is an oral, novel microtubule disruptor that will be indicated, upon FDA approval, for treatment of severe SARS-CoV-2 infection in hospitalized patients with moderate to severe COVID-19 at high risk for Acute Respiratory Distress Syndrome (ARDS) and death. ARDS is a primary cause of mortality among patients with COVID-19. ARDS leads to infiltration of immune cells in both lungs, which injures the alveolar-capillary membrane and causes edema. Increased lung permeability leads to exudates filling the air sacs and resulting in hypoxemia. Preclinical studies demonstrate that sabizabulin has both significant antiviral and anti-inflammatory activities by disrupting microtubule dynamics. (Barnette KG, Gordon MS, Rodriguez D, et al. NEJM Evidence. 2022;(20220706).

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Technology Name

Generic Name: Selux Rapid Antimicrobial Susceptibility (AST) System

Trade Name: Selux Next-Generation Phenotyping (NGP) System

Applicant Name: Selux Diagnostics, Inc.

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Selux Rapid AST Platform is a phenotypic antimicrobial susceptibility testing (AST) system, intended to assist medical professionals in the identification of in vitro susceptibility or resistance to specific antimicrobial agents. The technology is intended for use with bacteria separated from monomicrobial positive blood cultures and sterile body fluid culture samples from non-charcoal-containing types of BACTEC, BacT/ALERT, VIRTUO and VersaTREK blood culture bottles. The technology received Breakthrough Designation from the Food and Drug Administration and is awaiting FDA marketing authorization.

Technology Name

Generic Name: Ceribell Delirium Monitor

Trade Name: Ceribell Delirium Monitor

Applicant Name: Ceribell, Inc

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Ceribell Delirium Monitor is a medical device system comprised of proprietary software and proprietary signal acquisition headbands and recorder. The software utilizes a machine learning model to analyze EEG signals to detect features indicative of delirium in order to provide more effective diagnosis of delirium. The software requires and interfaces with two cleared proprietary Ceribell products: the EEG Headband for EEG signal acquisition, and the Ceribell Pocket EEG for obtaining signals from the headband, displaying signals, and displaying results or triggering alarms based on the output of the Delirium Monitor.

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Technology Name

Generic Name: ClearFit Implant

Trade Name: ClearFit Implant

Applicant Name: Longeviti Neuro Solutions

Application Pathway: Traditional

Brief Description of the Technology:

The Longeviti Clear-Fit implant is patient or anatomy specific, implantable prosthetic cranioplasty plates indented to correct and/or restore bony voids and/or defects of the cranium. The implant is manufactured from polymethyl methacrylate materials.

Technology Name

Generic Name: Single Chamber Atrial Leadless Pacemaker

Trade Name: Aveir AR Leadless Pacemaker

Applicant Name: Abbott Cardiac Rhythm Management

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Abbott's Aveir™ single-chamber leadless pacemaker system, referred to as the Aveir™ AR System, is a programmable system comprising of a single implanted leadless pacemaker into the right atrium that provides single-chamber pacing therapy. The Aveir™ AR leadless system consists of an implanted pacemaker device that is placed within the myocardium and paces the heart without the need for traditional "wired" leads. The Aveir™ AR System is the first single-chamber atrial leadless pacemaker to provide pacing therapy to indicated patients, through a minimally invasive catheter-based procedure. Transvenous or conventional pacemakers include a power supply (generator) placed under the skin in chest region, and pacing is transmitted through one or two electrodes (leads) to the heart. The Aveir™ AR System contains both the generator and electrodes within the device. The Aveir™ AR System offers patients a less-invasive approach compared to conventional transvenous procedures for patients that are indicated for single-chamber atrial pacing. Potential benefits of a leadless system include reduced lead and pocket complications associated with traditional pacemaker. The leadless pacemaker provides single-chamber pacing therapy within the right atrium. Physicians may prefer leadless pacemakers for patients that have a high risk of infection, or previously experienced an infection with conventional pacemaker with leads. Patients may prefer leadless pacemaker as there is no chest scar, and the device is not visible. Currently, there are no leadless single-chamber atrial pacemaker systems available in the market.

Technology Name

Generic Name: Tele EMG Biofeedback Device

Trade Name: JOGO-Gx

Applicant Name: JOGO Health Inc.

Application Pathway: Traditional

Brief Description of the Technology:

JOGO-Gx is a Tele EMG-Biofeedback device that could be used by hospitals to provide remote rehabilitation for neurological, pelvic floor, musculoskeletal and chronic pain conditions. JOGO consists of wireless surface electromyography (EMG) sensors and a Tablet PC running the JOGO-Gx Biofeedback software. With JOGO-Gx Cloud , clinicians can also monitor a patient remotely for the therapeutic exercises prescribed for prehab and rehab. JOGO helps hospitals challenged with staff shortages provide clinically superior rehabilitation remotely, by tapping into part-time/retired rehabilitation clinicians, who prefer to work a few hours a week JOGO also helps patients who are unable to travel to outpatient rehab facilities receive clinically superior rehab remotely.

Technology Name

Generic Name: Paradise Ultrasound Renal Denervation System

Trade Name: ParadiseTM Ultrasound Renal Denervation System

Applicant Name: ReCor Medical

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The ParadiseTM Ultrasound Renal Denervation System uses a minimally invasive procedure to lower blood pressure by treating overactive renal nerves with ultrasound energy. The system is indicated to reduce blood pressure in adult (≥22 years of age) patients with uncontrolled hypertension, who may be inadequately responsive to, or who are intolerant to anti-hypertensive medications.

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Technology Name

Generic Name: Hyperpolarized Xenon 129

Trade Name: XENOVIEW

Applicant Name: Leah Amir, MS, MHA

Application Pathway: Traditional

Brief Description of the Technology:

XENOVIEW (xenon (Xe) 129 hyperpolarized (HP)), for oral inhalation use. Initial U.S. XENOVIEW(TM) is prepared using an FDA approved hyperpolarization process from Xenon Xe 129 Gas Blend dose-a safe inert gas. The HP diagnostic signaling agent is indicated for use with magnetic resonance imaging (MRI) for evaluation of lung ventilation in adults and pediatric patients ages 12 years and older. HP Xe 129 is created in a dose equivalent (DE) delivery bag. Five minutes prior to chest MRI the DE is measured to verify the HP active level of Xe 129 administered to the patient. The patient wears a chest coil allowing the signal of the HP Xe 129 nuclei to be captured during the chest MRI. The FDA approved complex process to create radiation free HP Xe 129 and method of oral inhalation of the FDA approved drug, together create an innovative technology used in chest MRI. This imaging signal was specifically created to address the unmet needs to quantitively diagnose early pulmonary oxygen deficiency, at the level of the alveoli oxygen exchange, without exposing the patient to ionizing radiation to inform management of patients with diseases manifested by diminished lung function. HP Xe 129 gas unique biophysical properties prompt rapid distribution throughout the lungs. (Fig. 1). Inhaled HP Xe 129 gas in the presence of a multi-nuclear capable MRI scanner, creates a resulting image displaying novel detail through all regions of the lung-unlike CT imaging. 10-second duration of Inhaled HP Xe 129 provides an MRI signal which is dependent on the number of polarized Xe 129 nuclei. After inhalation, HP Xe 129 freely diffuses from the airspaces through alveolar-capillary barrier (comprised of alveolar epithelial cells, interstitial tissues, and capillary endothelial cells) and subsequently into the RBCs. The radiologist visualizes multiple 3-D slices to then quantify abnormalities across three compartments of alveolar gas-exchange: HP Xe 129 in the airspaces (ventilation), barrier tissue of the lung parenchyma, and transfer to red blood cells (RBCs). Notably, HP Xe 129 exhibits distinct MR frequency shifts in the airspace, barrier, and RBCs, allowing separate imaging of its distribution in all three compartments. Thus, a single inhalation of HP Xe 129 permits 3-D imaging of Xe-129 ventilation, its uptake in interstitial barrier tissues, and its transfer to RBCs. Such imaging has been used to spatially characterize disease burden across a range of pulmonary disorders. For example, defects are commonly seen in all three compartments when assessing chronic obstructive pulmonary disease (COPD) and asthma. Quantitative information regarding pulmonary-vascular hemodynamics informs therapy. No other imaging modality, even ones employing ionizing radiation, have properties able to display this level of functional detail of small airway disease. Thus, it can be used repeatedly on arbitrary timescales, including evaluation of both short and long-term therapy response.

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Technology Name

Generic Name: Total Ankle Talar Replacement

Trade Name: Total Ankle Talar Replacement

Applicant Name: 4WEB Medical, Inc.

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? No

Brief Description of the Technology:

4WEB Medical's Talar Replacement (TR) devices are patient specific, metallic spacers that are solid, polished replicas of a patient's physiologic talus. When implanted, the device allows restoration of function due to losses attributed to talar dysfunction. The technology is designed to mimic a patient's physiologic talar body/head and articulates to the surrounding native bone anatomy (i.e., calcaneus & navicular). However, the dome is mapped so that it matches that of a third-party ankle system. The body and head are patient-specific, while the dome mimics third-party dome specifications. The device is patient-specific and highly polished across the entire surface area.

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Technology Name

Generic Name: Teclistamab-cqyv

Trade Name: TECVAYLI (teclistamab-cqyv)

Applicant Name: Johnson & Johnson Health Care Systems Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Multiple myeloma remains incurable and most patients eventually relapse, even with the advent of new treatments (Rajkumar 2019). Relapsed and refractory multiple myeloma constitutes a specific unmet medical need, especially for patients who have failed multiple drug classes. Patients with relapsed and refractory disease are defined as those who, having achieved a minor response or better, experience return of their myeloma (relapsed) or fail to respond to therapy, progress while on therapy, or experience progression within 60 days of their last therapy (refractory) (Castelli 2014, Nooka 2015). For patients with relapsed and refractory multiple myeloma who have received a PI, an IMiD and an anti-CD38 antibody, there does not exist a standard or consensus for treatment at this time; often best supportive care/palliative care is the only option for these triple class exposed patients (Maples 2020). Novel, innovative therapies are needed to improve long-term survival and outcomes for these patients. TECVAYLI is one such therapy. TECVAYLI is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. Ide-cel and cilta-cel are recently approved CAR-T cell therapies that, like TECVAYLI, target BCMA and induce myeloma cell death via activation of T cells, but CAR-T cell therapies require in-vitro genetic modification of a patient's T cells that are then infused back into the patient. However, TECVAYLI differs significantly from these therapies, as TECVAYLI achieves T cell redirection via simultaneous binding to CD3 on T cells and BCMA on myeloma cells and creates a molecular 'bridge' via the bispecific antibody structure. With this approach, TECVAYLI is available "off-the-shelf" and does not require the complex T cell collection, genetic engineering and cell manufacturing, or lymphodepleting chemotherapy prior to administration of therapy, as is required for ide-cel and cilta-cel. TECVAYLI can also be administered at non-transplant centers via a subcutaneous route, and no IV infusion is required. Lastly, TECVAYLI's "off-the shelf" qualities allow for immediate administration to patients, unlike the complex process involved with CAR-T cell manufacturing that is dependent on lentiviral supply and can often take up to two months from cell collection to product administration.

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Technology Name

Generic Name: EchoGo Heart Failure 1.0

Trade Name: EchoGo Heart Failure 1.0

Applicant Name: Ultromics Limited

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

EchoGo Heart Failure 1.0 is an automated machine learning-based decision support system, indicated as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography. When utilized by an interpreting physician, this device provides information that may be useful in detecting heart failure with preserved ejection fraction (HFpEF). EchoGo Heart Failure is indicated in adult populations. Patient management decisions should not be made solely on the results of the EchoGo Heart Failure analysis.

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Technology Name

Generic Name: MyBloodHealth

Trade Name: MyBloodHealth

Applicant Name: Accumen, Inc

Application Pathway: Alternative (Breakthrough Devices Program)

Has the technology already received a Breakthrough Device designation from FDA for the indication relevant to this application? No

Brief Description of the Technology:

MyBloodHealth is the worlds only web-based, EMR integrated, clinical decision support tool to identify and treat patients with anemia, one of the worlds leading disease states associated with increased perioperative morbidity and mortality. MyBloodHealth is used in both pre-surgical identification of anemia and chronic disease states (CKD/CHF/IBD). MyBloodHealth supports clinicians by simplifying the care coordination of both laboratory data, clinical content and medication care plans by creating a "virtual waiting" of patients triaged by algorithm using scoring factors such as severity of anemia, timeframe to surgery, anticipated blood loss, chronic disease state deploying create patient-centric care plans. MyBloodHealth then aligns all providers of care through integration with the EMR alerting primary care, surgeon and patient. Preoperative anemia is and is the most reliable predictor of significant post-procedure anemia and transfusion requirements. Preoperative anemia is independently associated with increased perioperative morbidity and mortality. MyBloodHealth improves outcomes and provides population health reporting for value based care platforms including measurement of reduced length of stay, improved readmission rates, transfusion avoidance, and per capita cost of health care. The technology is backed by a life science patent in US, CAN and EU.