

# 해외 바이오의약품 임상 현황 (2019.10.29~2019.11.04)

한국바이오의약품협회, 2019.11.5.  
출처: ClinicalTrials.gov

## ○ 미국 74건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04146051	Descartes-08 CAR-T Cells in Generalized Myasthenia Gravis (MG)	Myasthenia Gravis, Generalized	Drug: Descartes-08	Cartesian Therapeutics	Phase 1 Phase 2
NCT04129515	NovoTTF-200A + Pembrolizumab In Melanoma Brain Metastasis	Metastatic Melanoma Melanoma Brain Metastasis	Device: NovoTTF-200A Drug: Pembrolizumab	Eric Wong, MD Dana-Farber Cancer Institute	Phase 1 Phase 2
NCT04081389	Chemokine Modulation Therapy and Standard Chemotherapy Before Surgery for the Treatment of Early Stage Triple Negative Breast Cancer	Anatomic Stage 0 Breast Cancer AJCC v8 Anatomic Stage I Breast Cancer AJCC v8 Anatomic Stage IA Breast Cancer AJCC v8 Anatomic Stage IB Breast Cancer AJCC v8 Anatomic Stage II Breast Cancer AJCC v8 Anatomic Stage IIA Breast Cancer AJCC v8 Anatomic Stage IIB Breast Cancer AJCC v8 Early-Stage Breast Carcinoma Estrogen Receptor Negative HER2/Neu Negative Progesterone Receptor Negative Prognostic Stage 0 Breast Cancer AJCC v8 Prognostic Stage I Breast Cancer AJCC v8 Prognostic Stage IA Breast Cancer AJCC v8 Prognostic Stage IB Breast Cancer AJCC v8 Prognostic Stage II Breast Cancer AJCC v8 Prognostic Stage IIA Breast Cancer AJCC v8 Prognostic Stage IIB Breast Cancer AJCC v8 Triple-Negative Breast Carcinoma	Drug: Celecoxib Drug: Cyclophosphamide Drug: Doxorubicin Drug: Doxorubicin Hydrochloride Drug: Paclitaxel Biological: Recombinant Interferon Alfa-2b Drug: Rintatolimod	Roswell Park Cancer Institute National Cancer Institute (NCI)	Phase 1 Phase 2
NCT04074967	Study of ARRY-614 Plus Either Nivolumab or Ipilimumab	Renal Cell Carcinoma Melanoma Solid Tumor	Drug: Phase Ib ARRY-614 + nivolumab Drug: Phase Ib ARRY-614 + ipilimumab Drug: Phase II ARRY-614 + ipilimumab Drug: Phase II ARRY-614 + nivolumab (melanoma) Drug: Phase II ARRY-614 + nivolumab (RCC)	Jason J. Luke, MD Array BioPharma University of Pittsburgh	Phase 1 Phase 2
NCT04063215	A Clinical Trial to Determine the Safety and Efficacy of Hope Biosciences Autologous Mesenchymal Stem Cell Therapy for the Treatment of Traumatic Brain Injury and Hypoxic-Ischemic Encephalopathy	Traumatic Brain Injury	Drug: HB-adMSC	Hope Biosciences The University of Texas Health Science Center, Houston	Phase 1 Phase 2
NCT04011020	Clinical Application of Stem Cell Educator Therapy in Type 1 Diabetes	Type 1 Diabetes	Combination Product: Stem Cell Educator therapy	Tianhe Stem Cell Biotechnologies Inc. Hackensack Meridian Health	Phase 2 Phase 3
NCT03958383	IT-hu14.18-IL2 With Radiation, Nivolumab and Ipilimumab for Melanoma	Melanoma	Biological: hu14.18-IL2 Radiation: Radiation Therapy Biological: Nivolumab Biological: Ipilimumab	University of Wisconsin, Madison National Cancer Institute (NCI) Bristol-Myers Squibb Apeiron Biologics Provenance Biopharmaceuticals	Phase 1 Phase 2
NCT03851081	Inotuzumab Ozogamicin and Vincristine Sulfate Liposome in Treating Patients With Relapsed or Refractory CD22+ B-cell Acute Lymphoblastic Leukemia	Allogeneic Hematopoietic Stem Cell Transplantation Recipient Blasts 5 Percent or More of Bone Marrow Nucleated Cells Blasts 5 Percent or More of Peripheral Blood White Cells CD22 Positive Lymphoblasts 20 Percent or More of Bone Marrow Nucleated Cells Lymphoblasts 20 Percent or More of Peripheral Blood White Cells Recurrent B Acute Lymphoblastic Leukemia Refractory B Acute Lymphoblastic Leukemia	Biological: Inotuzumab Ozogamicin Other: Quality-of-Life Assessment Drug: Vincristine Sulfate Liposome	Roswell Park Cancer Institute National Cancer Institute (NCI) Pfizer	Phase 1 Phase 2
NCT03767582	Trial of Neoadjuvant and Adjuvant Nivolumab and BMS-813160 With or Without GVAX for Locally Advanced Pancreatic Ductal Adenocarcinomas.	Locally Advanced Pancreatic Ductal Adenocarcinoma (PDAC) Pancreatic Ductal Adenocarcinoma	Radiation: Stereotactic Body Radiation (SBRT) Drug: Nivolumab Drug: CCR2/CCR5 dual antagonist Drug: GVAX	Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Bristol-Myers Squibb	Phase 1 Phase 2
NCT03368729	Niraparib in Combination With Trastuzumab in Metastatic HER2+ Breast Cancer	Metastatic Breast Cancer HER2 Positive Breast Carcinoma	Drug: Niraparib Drug: Trastuzumab	University of Alabama at Birmingham Translational Breast Cancer Research Consortium Tesaro, Inc. Susan G. Komen Breast Cancer Foundation Breast Cancer Research Foundation of Alabama Foundation	Phase 1 Phase 2
NCT03829566	Autologous Transplant To End NMO Spectrum Disorder	Neuromyelitis Optica Devic's Disease NMO Spectrum Disorder	Drug: Rituximab Drug: Cyclophosphamide Drug: Mesna Drug: rATG Drug: Methylprednisolone Drug: G-CSF Biological: IVIg Biological: Autologous Stem Cells	Northwestern University	Phase 2 Phase 3
NCT04149821	Umbralisib Plus Ublituximab (U2) in Progressive CLL After Novel Therapy	Chronic Lymphocytic Leukemia CLL Progression CLL/SLL	Drug: Umbralisib Drug: Ublituximab	Weill Medical College of Cornell University TG Therapeutics, Inc.	Phase 2
NCT04147338	A Study of Subcutaneously-administered Guselkumab Delivered by 3 Different Devices in Healthy Participants	Healthy	Drug: Guselkumab	Janssen Research & Development, LLC	Phase 1
NCT04146129	A Phase 1 Study of CDX-0159	Healthy Subjects	Drug: CDX-0159 Drug: Normal saline	CellDex Therapeutics	Phase 1
NCT04144348	Safety and Immunogenicity of mRNA-1653, a Combined Human Metapneumovirus (hMPV) and Parainfluenza Virus Type 3 (PIV3) Vaccine, in Healthy Adults, and Children 12-36 Months of Age With Serologic Evidence of Prior Exposure	Human Metapneumovirus and Human Parainfluenza Infection	Biological: mRNA-1653 Biological: Placebo	ModernaTX, Inc.	Phase 1
NCT04139577	FMT In High-Risk Acute GVHD After ALLO HCT	Acute Graft-Versus-Host Disease (Gvhd) Grade Hematopoietic Cell Transplantation Fecal Microbiota Transplant	Biological: Fecal Microbiota Transplant	Massachusetts General Hospital American Cancer Society, Inc.	Phase 1
NCT04138056	A Study to Test GlaxoSmithKline's (GSK) Respiratory Syncytial Virus (RSV) Maternal Vaccine's Safety, Ability to Generate an Immune Response and Degree to Which the Vaccine Can Cause Side Effects in Healthy Non-pregnant Women After the Administration of the Vaccine Alone or Together With Boostrix	Respiratory Syncytial Virus Infections	Biological: RSVPreF3 formulation 3 Biological: RSVPreF3 formulation 2 Biological: Boostrix-ex-US Procedure: Boostrix-US Drug: Placebo	GlaxoSmithKline	Phase 2
NCT04137900	Safety, Tolerability and Pharmacokinetics of a Monoclonal Antibody Specific to B- and T-Lymphocyte Attenuator (BTLA) for Injection in Subjects With Advanced Malignancies	Advanced Unresectable Solid Tumor Metastatic Solid Tumor	Drug: TAB004, Recombinant humanized IgG4 $\kappa$ monoclonal antibody specific to BTLA for injection	Shanghai Junshi Bioscience Co., Ltd. CTI Clinical Trial and Consulting Services TopAlliance Biosciences, Inc.	Phase 1

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NCT04136275	CAR-37 T Cells In Hematologic Malignancies	Hematologic Malignancy Leukemia Lymphoma Lymphoma, B-Cell Lymphoma, T-Cell Lymphoma, Non-Hodgkin	Biological: CAR-37 T cells	Marcela V. Maus, M.D.,Ph.D. Massachusetts General Hospital	Phase 1
NCT04134728	Efficacy and Safety of GSK3196165 (Otilimab) Versus Placebo and Sarilumab in Participants With Moderately to Severely Active Rheumatoid Arthritis Who Have an Inadequate Response to Biological Disease-modifying Antirheumatic Drug (DMARDs) and/or Janus Kinase (JAK) Inhibitors	Arthritis, Rheumatoid	Biological: GSK3196165 Biological: Sarilumab Drug: Placebo to GSK3196165/Sarilumab Drug: csDMARDs	GlaxoSmithKline Iqvia Pty Ltd	Phase 3
NCT04134117	Tisagenlecleucel In Primary CNS Lymphoma	Primary CNS Lymphoma Refractory Primary CNS Lymphoma Relapsed Primary CNS Lymphoma	Biological: Tisagenlecleucel	Matthew J. Frigault, M.D. Novartis Massachusetts General Hospital	Phase 1
NCT04123379	Neoadjuvant Nivolumab With CCR2/5-inhibitor or Anti-IL-8) for Non-small Cell Lung Cancer (NSCLC) or Hepatocellular Carcinoma (HCC)	Non-small Cell Lung Cancer Hepatocellular Carcinoma	Drug: Nivolumab Drug: BMS-813160 Drug: BMS-986253	Icahn School of Medicine at Mount Sinai Bristol-Myers Squibb	Phase 2
NCT04119830	Rintatolimod and Pembrolizumab for the Treatment of Refractory Metastatic or Unresectable Colorectal Cancer	Metastatic Colorectal Adenocarcinoma Microsatellite Stable Mismatch Repair Proficient Refractory Colorectal Adenocarcinoma Stage III Colorectal Cancer AJCC v8 Stage IIIA Colorectal Cancer AJCC v8 Stage IIIB Colorectal Cancer AJCC v8 Stage IIIC Colorectal Cancer AJCC v8 Stage IVD Colorectal Cancer AJCC v8 Stage IVA Colorectal Cancer AJCC v8 Stage IVB Colorectal Cancer AJCC v8 Stage IVC Colorectal Cancer AJCC v8 Unresectable Colorectal Carcinoma	Biological: Pembrolizumab Other: Questionnaire Administration Drug: Rintatolimod	Roswell Park Cancer Institute National Cancer Institute (NCI)	Phase 2
NCT04114136	Anti-PD-1 mAb Plus Metabolic Modulator in Solid Tumor Malignancies	Melanoma Renal Cell Carcinoma NSCLC Hepatocellular Carcinoma Urothelial Cancer Gastric Adenocarcinoma HNSCC Esophageal Adenocarcinoma Microsatellite Instability-High Solid Malignant Tumor	Drug: Nivolumab or Pembrolizumab (dependent upon approved indication) Drug: Metformin Drug: Rosiglitazone	Dan Zandberg University of Pittsburgh	Phase 2
NCT04099836	Atezolizumab and Bevacizumab in Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer in Patients With Progressive Disease After Receiving Osimertinib	Non Small Cell Lung Cancer	Drug: Atezolizumab Drug: Bevacizumab	Duke University	Phase 2
NCT04089904	Phase II Trial of Neoadjuvant Pembrolizumab for Patients With Early Stage Gastroesophageal Adenocarcinoma	Gastroesophageal Junction Adenocarcinoma Gastric Adenocarcinoma Esophageal Adenocarcinoma	Drug: Pembrolizumab Injection	University of Chicago	Phase 2
NCT04089579	hCT-MSC in Children With Autism Spectrum Disorder	Autism Autism Spectrum Disorder	Biological: Cord Tissue Mesenchymal Stromal Cells Other: Placebo Infusion	Joanne Kurtzberg, MD The Marcus Foundation Duke University	Phase 2
NCT04087941	Efficacy and Safety of VM202 in Painful Diabetic Peripheral Neuropathy -The HOPES Trial	Painful Diabetic Neuropathy	Biological: VM-202	Brigham and Women's Hospital	Phase 2
NCT04073472	Mesenchymal Stem Cells for the Treatment of Pouch Fistulas in Crohn's	Crohn's Disease Fistula Anal Fistula Pouch, Ileal Pouches, Ileoanal	Drug: mesenchymal-stem cells (MSCs)	The Cleveland Clinic	Phase 1
NCT04061746	Cellular Therapy for Type 1 Diabetes Using Mesenchymal Stem Cells	Diabetes Mellitus, Type 1	Biological: Mesenchymal Stem Cells (MSCs) Other: Placebo Infusion (Plasmalyte A with 0.5% human serum albumin)	Medical University of South Carolina National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	Phase 1
NCT04058964	Pembrolizumab and PEGPH20 in Treating Patients With Metastatic Pancreatic Cancer	Metastatic Pancreatic Adenocarcinoma Stage IV Pancreatic Cancer AJCC v8	Biological: Pegylated Recombinant Human Hyaluronidase PH20 Biological: Pembrolizumab	M.D. Anderson Cancer Center National Cancer Institute (NCI)	Phase 2
NCT04032418	Pembrolizumab Every 12 Weeks Versus Every 3 Weeks in Treating Patients With Non-small Cell Lung Cancer	Lung Non-Small Cell Carcinoma	Biological: Pembrolizumab	Roswell Park Cancer Institute National Cancer Institute (NCI)	Phase 2
NCT04003246	Phase II Concurrent Durvalumab and Radiotherapy for for Stage III Non-Small Cell Lung Cancer	Non Small Cell Lung Cancer Lung Cancer Stage III	Radiation: Thoracic RT and Durvalumab Drug: Consolidative Durvalumab	University of Texas Southwestern Medical Center AstraZeneca	Phase 2
NCT03998423	Oral Fecal Microbiota Transplant Feasibility Study in Alzheimer's Disease	Alzheimer Disease	Biological: Fecal Microbiota Transplant	University of Wisconsin, Madison Wisconsin Partnership Program	Phase 1
NCT03989466	Itacitinib and Alemtuzumab in Treating Patients With T-Cell Prolymphocytic Leukemia	Recurrent T-Cell Prolymphocytic Leukemia T-Cell Prolymphocytic Leukemia	Biological: Alemtuzumab Drug: Itacitinib	M.D. Anderson Cancer Center National Cancer Institute (NCI)	Phase 1
NCT03961971	Trial of Anti-Tim-3 in Combination With Anti-PD-1 and SRS in Recurrent GBM	Glioblastoma Multiforme	Drug: MBG453	Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Novartis Pharmaceuticals	Phase 1
NCT03961815	Open-label Extension Study of Brazikumab in Crohn's Disease	Crohn's Disease	Drug: Brazikumab	Allergan	Phase 3
NCT03941769	Recombinant Human Interleukin-7 to Promote T-Cell Recovery After Cord Blood Transplant	Acute Myeloid Leukemia Chronic Myelogenous Leukemia, BCR-ABL1 Positive Cord Blood Transplant Recipient Myelodysplastic Syndrome Myeloproliferative Neoplasm	Biological: Recombinant Interleukin-7	M.D. Anderson Cancer Center National Cancer Institute (NCI)	Phase 1
NCT03938792	Study of the Efficacy and Safety PF-06741086 in Adult and Teenage Patients With Severe Hemophilia A or B	Hemophilia A Hemophilia B	Drug: PF-06741086	Pfizer	Phase 3
NCT03929120	Allogeneic Bone Marrow Mesenchymal Stem Cells for Patients With Interstitial Lung Disease (ILD) & Connective Tissue Disorders (CTD)	Interstitial Lung Disease Connective Tissue Diseases	Biological: Allogeneic Bone Marrow Derived Mesenchymal Stem Cells (BMD-MSCs)	Mayo Clinic	Phase 1
NCT03929029	Neoantigen Vaccine Plus Locally Administered Ipilimumab and Systemic Nivolumab in Advanced Melanoma	Melanoma	Drug: Nivolumab Biological: NeoVax plus Montanide Drug: Ipilimumab	Dana-Farber Cancer Institute National Cancer Institute (NCI)	Phase 1
NCT03920631	Microtransplantation and Checkpoint Blockade Immunotherapy for Relapsed or Refractory B Cell Lymphomas	B Cell Lymphomas	Drug: Nivolumab Biological: Microtransplantation	Ahmed Galal, MD Duke University	Phase 1
NCT03899987	Aspirin and Rintatolimod With or Without Interferon-alpha 2b in Treating Patients With Prostate Cancer Before Surgery	Prostate Adenocarcinoma Stage I Prostate Cancer AJCC v8 Stage II Prostate Cancer AJCC v8 Stage IIA Prostate Cancer AJCC v8 Stage IIB Prostate Cancer AJCC v8 Stage IIC Prostate Cancer AJCC v8 Stage III Prostate Cancer AJCC v8 Stage IIIA Prostate Cancer AJCC v8 Stage IIIB Prostate Cancer AJCC v8 Stage IIIC Prostate Cancer AJCC v8	Drug: Aspirin Procedure: Radical Prostatectomy Biological: Recombinant Interferon Alfa-2b Drug: Rintatolimod	Roswell Park Cancer Institute National Cancer Institute (NCI) Hemispherx Biopharma	Phase 2

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NCT03887741	Plasmapheresis Versus Plasma Infusion From Young APOE3 Homozygotes Into MCI APOE4 Homozygotes to Slow Disease Progression	Mild Cognitive Impairment	Biological: Plasmapheresis Biological: Plasma infusion	Mayo Clinic	Phase 1
NCT03865082	Study of Tilsotolimod in Combination With Nivolumab and Ipilimumab for the Treatment of Solid Tumors (ILLUMINATE-206)	Solid Tumor	Drug: Tilsotolimod Drug: Nivolumab Drug: Ipilimumab	Idera Pharmaceuticals, Inc. Bristol-Myers Squibb	Phase 2
NCT03810911	Mechanisms of EPO-induced Hypertension	Chronic Kidney Disease Blood Pressure Anemia	Drug: Darbepoetin	VA Office of Research and Development	Phase 2
NCT03807063	Rivogenlecleucel Donor Lymphocyte Immunotherapy in Treating Patients With Recurrent Blood Cancers After Stem Cell Transplant	Acute Bilineal Leukemia Myelodysplastic/Myeloproliferative Neoplasm Myelodysplastic/Myeloproliferative Neoplasm, Unclassifiable Myeloproliferative Neoplasm Recurrent Acute Biphentotypic Leukemia Recurrent Acute Lymphoblastic Leukemia Recurrent Acute Myeloid Leukemia Recurrent Blastic Plasmacytoid Dendritic Cell Neoplasm Recurrent Chronic Lymphocytic Leukemia Recurrent Chronic Myelogenous Leukemia, BCR-ABL1 Positive Recurrent Chronic Myelomonocytic Leukemia Recurrent Myelodysplastic Syndrome	Biological: Rivogenlecleucel Drug: Rimiducid	Fred Hutchinson Cancer Research Center National Cancer Institute (NCI) Bellicum Pharmaceuticals	Phase 1
NCT03798301	Treatment of Cytomegalovirus (CMV) Infections With Viral-Specific T Cells	CMV Infection Cytomegalovirus Infections CMV Viremia Opportunistic Infections	Biological: CMV-specific T-cells	University of Wisconsin, Madison University of Wisconsin Program for Advanced Cell Therapy (PACT) University of Wisconsin Carbone Cancer Center (UWCCC) University of Wisconsin School of Medicine and Public Health (UWSMPH) UW Health	Phase 1
NCT03735277	Evaluation of the Safety and Efficacy of Hemacord HPC, Cord Blood in Subjects With Acute Ischemic Stroke	Acute Ischemic Stroke	Biological: HPC, Cord Blood	BHI Therapeutic Sciences	Phase 1
NCT03680092	Comparing Cyclophosphamide and Abatacept With Standard of Care Treatment Following Stem Cell Transplantation in Patients With Hematologic Malignancy	GVHD Hematologic Neoplasms	Drug: Cyclophosphamide Drug: abatacept Drug: Methotrexate Drug: Tacrolimus	Dimitrios Tzachanis, MD PhD Bristol-Myers Squibb University of California, San Diego	Phase 2
NCT03602898	Comparing ATG or Post-Transplant Cyclophosphamide to Calcineurin Inhibitor-Methotrexate as GVHD Prophylaxis After Myeloablative Unrelated Donor Peripheral Blood Stem Cell Transplantation	Acute Lymphoblastic Leukemia in Remission Acute Myeloid Leukemia Arising From Previous Myelodysplastic Syndrome Acute Myeloid Leukemia in Remission Blasts 5 Percent or Less of Bone Marrow Nucleated Cells Chronic Myelomonocytic Leukemia Chronic Phase Chronic Myelogenous Leukemia, BCR-ABL1 Positive Donor Minimal Residual Disease Myelodysplastic Syndrome Myelofibrosis Myeloproliferative Neoplasm Recurrent Acute Myeloid Leukemia Recurrent Hodgkin Lymphoma Recurrent Non-Hodgkin Lymphoma Refractory Acute Myeloid Leukemia Therapy-Related Acute Myeloid Leukemia	Biological: Anti-Thymocyte Globulin Drug: Busulfan Drug: Cyclophosphamide Drug: Cyclosporine Drug: Fludarabine Phosphate Drug: Methotrexate Procedure: Peripheral Blood Stem Cell Transplantation Other: Quality-of-Life Assessment Other: Questionnaire Administration Drug: Tacrolimus Radiation: Total-Body Irradiation	Fred Hutchinson Cancer Research Center National Cancer Institute (NCI)	Phase 2
NCT03598816	PolyImmune (Durvalumab (MEDI4736) and Tremelimumab) & Vaccine Orchestrated Treatment for Patients With Advanced/Metastatic Renal Cell Carcinoma	Renal Cell Carcinoma	Drug: Durvalumab Drug: Tremelimumab Device: TDS-IM System Biological: Neoantigen DNA Vaccine Procedure: Research blood draw	Washington University School of Medicine MedImmune LLC	Phase 2
NCT03463239	Bioengineered Penile Tissue Constructs for Irreversibly Damaged Penile Corpora	Urologic Diseases Male Urogenital Diseases Penile Diseases Corpus Callosum Malformation Corpora Cavernosa; Inflammation Trauma Injury	Biological: Autologous tissue engineered corpora	Wake Forest University Health Sciences United States Department of Defense	Phase 1
NCT04126070	Nivolumab + Docetaxel + ADT in Metastatic Hormone Sensitive Prostate Cancer	Hormone Sensitive Prostate Cancer Prostate Adenocarcinoma Metastasis Prostate Adenocarcinoma	Drug: Androgen Deprivation Therapy Drug: Nivolumab Drug: Docetaxel	Xiao X. Wei Bristol-Myers Squibb Dana-Farber Cancer Institute	Phase 2
NCT04119024	Gene Modified Immune Cells (IL13Ralpha2 CAR T Cells) After Conditioning Regimen for the Treatment of Stage IIIC or IV Melanoma	Clinical Stage IV Cutaneous Melanoma AJCC v8 IL13RA2 Positive Metastatic Melanoma Cutaneous Melanoma, Stage III Cutaneous Melanoma, Stage IV	Drug: Cyclophosphamide Drug: Fludarabine Phosphate Biological: IL13Ralpha2-specific Hinge-optimized 4-1BB-co-stimulatory CAR Truncated CD19-expressing Autologous TN/MEM Cells Drug: Recombinant Interleukin-2	Jonsson Comprehensive Cancer Center National Cancer Institute (NCI)	Phase 1
NCT04118036	Abemaciclib + Pembrolizumab In Glioblastoma	Glioblastoma	Drug: Pembrolizumab Drug: Abemaciclib	Dana-Farber Cancer Institute	Phase 2
NCT04144335	N-803 Combined With the Broadly Neutralizing Antibodies Plus or Minus haNK Cells for HIV	Hiv HIV/AIDS HIV Infections AIDS AIDS and Infections Aids/Hiv Problem	Biological: N-803 and bNAbs Biological: haNK??Cells	University of Minnesota	Phase 1 Phase 2
NCT04129151	Palbociclib + Ganitumab In Ewing Sarcoma	Ewing Sarcoma Ewing's Sarcoma Recurrent	Drug: Palbociclib Drug: Ganitumab	Dana-Farber Cancer Institute 1 Million 4 Anna Foundation Carson Sarcoma Foundation Teaming up to Fight Childhood Cancer ChemoWarrior: the eli sidler foundation i-ROK Foundation Rutledge Cancer Foundation	Phase 2
NCT03961698	Evaluation of IPI-549 Combined With Front-line Treatments in Pts. With Triple-Negative Breast Cancer or Renal Cell Carcinoma (MARIO-3)	Breast Cancer Renal Cell Carcinoma	Drug: IPI-549 Drug: Atezolizumab Drug: nab-paclitaxel Drug: Bevacizumab	Infinity Pharmaceuticals, Inc. Roche Pharma AG	Phase 2
NCT03406884	Autologous Cardiac Stem Cell Injection in Patients With Hypoplastic Left Heart Syndrome: An Open Label Pilot Study.	Hypoplastic Left Heart Syndrome	Drug: c-kit+ cells Drug: Placebo	Joshua M Hare University of Maryland, College Park University of Miami	Phase 1
NCT04134143	Multiple Applications of ExpressGraft-C9T1 Skin Tissue as a Treatment for Diabetic Foot Ulcers	Diabetes Diabetic Foot Ulcer Non-healing Wound	Biological: ExpressGraft-C9T1 Skin Tissue	Stratatech, a Mallinckrodt Company Mallinckrodt	Phase 1

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NCT04066114	Treg Modulation With CD28 and IL-6 Receptor Antagonists	Living-Donor Kidney Transplant Kidney Transplant Recipients	Biological: lulizumab pegol Biological: antithymocyte globulin (rabbit) Drug: methylprednisolone Biological: tocilizumab Drug: Prednisone Drug: everolimus Biological: belatacept Drug: mycophenolate mofetil Drug: mycophenolic acid	National Institute of Allergy and Infectious Diseases (NIAID) Bristol-Myers Squibb Clinical Trials in Organ Transplantation	Phase 1 Phase 2
NCT03834688	Phase II Study of Bendamustine and Rituximab Plus Venetoclax in Untreated Mantle Cell Lymphoma Over 60 Years of Age	Mantle Cell Lymphoma	Drug: Venetoclax Drug: Bendamustine Drug: Rituximab	PreCOG, LLC. Genentech, Inc.	Phase 2
NCT04104893	A Study of CHeckpoint Inhibitors in Men With prOgressive Metastatic Castrate Resistant Prostate Cancer Characterized by a Mismatch Repair Deficiency or Biallelic CDK12 Inactivation	Metastatic Castration Resistant Prostate Cancer	Drug: Pembrolizumab	VA Office of Research and Development Merck Sharp & Dohme Corp.	Phase 2
NCT04027387	Dose Escalation Safety Study of TMB-365 in HIV-1 Infected Participants	HIV-1-infection	Biological: TMB-365	TaiMed Biologics Inc. Westat	Phase 1
NCT03995017	Rucaparib Plus Ramucirumab With or Without Nivolumab in Advanced Gastric and Esophageal Adenocarcinoma	Esophagus Cancer, Adenocarcinoma Stomach Cancer, Adenocarcinoma	Drug: Rucaparib Drug: Ramucirumab Drug: Nivolumab	Anwaar Saeed Bristol-Myers Squibb Clovis Oncology, Inc. University of Kansas Medical Center	Phase 1 Phase 2
NCT04129931	PreciSE (Precision Interventions for Severe and/or Exacerbation-Prone Asthma) Network Study	Asthma	Drug: MCT Drug: Clazakizumab Drug: Broncho-Vaxom Drug: Imatinib Mesylate Drug: Cavosonstat Drug: Itacitinib Other: Placebo	University of North Carolina, Chapel Hill National Heart, Lung, and Blood Institute (NHLBI)	Phase 2
NCT04047628	Best Available Therapy Versus Autologous Hematopoietic Stem Cell Transplant for Multiple Sclerosis (BEAT-MS)	Relapsing Multiple Sclerosis Relapsing Remitting Multiple Sclerosis Secondary Progressive Multiple Sclerosis	Procedure: Autologous Hematopoietic Stem Cell Transplantation Biological: Best Available Therapy (BAT)	National Institute of Allergy and Infectious Diseases (NIAID) Immune Tolerance Network (ITN)	Phase 3
NCT03949855	Belimumab With Rituximab for Primary Membranous Nephropathy	Membranous Nephropathy MN	Drug: Belimumab Drug: Placebo for Belimumab Drug: Rituximab	National Institute of Allergy and Infectious Diseases (NIAID) Immune Tolerance Network (ITN) GlaxoSmithKline	Phase 2
NCT04127695	A Study to Evaluate the Safety and Tolerability of ABBV-0805 in Patients With Parkinson's Disease	Parkinson's Disease	Drug: ABBV-0805 Drug: Placebo ABBV-0805	AbbVie	Phase 1
NCT03739996	Long-Acting Cabotegravir Plus VRC01LS for Viral Suppression in Adults Living With HIV-1	HIV Infections	Drug: Oral Cabotegravir (CAB) Drug: Nucleoside Reverse Transcriptase Inhibitors (NRTIs) Drug: Long-Acting Injectable Cabotegravir (CAB LA) Biological: VRC01LS Drug: Standard of Care (SOC) Oral ART	National Institute of Allergy and Infectious Diseases (NIAID) Viv	Phase 2
NCT04134936	Phase Ib Study to Assess Safety and Preliminary Efficacy of Tafasitamab or Tafasitamab Plus Lenalidomide in Addition to R-CHOP in Patients With Newly Diagnosed DLBCL	Diffuse Large B-cell Lymphoma	Drug: Tafasitamab Drug: Tafasitamab plus Lenalidomide	MorphoSys AG	Phase 1
NCT03958877	A Study to Evaluate the Safety, Tolerability, and Efficacy of BIIB017 (Peginterferon Beta-1a) in Pediatric Participants for the Treatment of Relapsing-Remitting Multiple Sclerosis	Multiple Sclerosis, Relapsing-Remitting	Drug: BIIB017 (peginterferon beta-1a) Drug: Interferon beta type 1a	Biogen	Phase 3
NCT04143724	Study of Safety & PK of Luspatercept (ACE-536) in Pediatric Subjects Who Require Regular RBC Transfusions Due to Beta (β)-Thalassemia.	Beta-Thalassemia	Drug: ACE-536	Celgene Acceleron Pharma, Inc.	Phase 2

### ○ 영국 3건

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NCT03944876	Botulinum Toxin Type A Blockade of the Sphenopalatine Ganglion in Treatment-refractory Chronic Cluster Headache	Cluster Headache	Drug: Botulinum toxin type A Drug: placebo	Norwegian University of Science and Technology St. Olavs Hospital University College, London Fondazione I.R.C.C.S. Istituto Neurologico Carlo Besta Catholic University of Valencia University Hospital, Essen	Phase 3
NCT04088409	A Study of Baricitinib (LY3009104) in Participants From 2 Years to Less Than 18 Years Old With Active JIA-Associated Uveitis or Chronic Anterior Antinuclear Antibody-Positive Uveitis	Uveitis	Drug: Baricitinib Drug: Adalimumab	Eli Lilly and Company	Phase 3
NCT04047628	Best Available Therapy Versus Autologous Hematopoietic Stem Cell Transplant for Multiple Sclerosis (BEAT-MS)	Relapsing Multiple Sclerosis Relapsing Remitting Multiple Sclerosis Secondary Progressive Multiple Sclerosis	Procedure: Autologous Hematopoietic Stem Cell Transplantation Biological: Best Available Therapy (BAT)	National Institute of Allergy and Infectious Diseases (NIAID) Immune Tolerance Network (ITN)	Phase 3

### ○ 프랑스 6건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04133233	Low Dose IL-2 Therapy in Patients With a Depressive Episode in the Course of a Bipolar Disorder	Bipolar Depression	Drug: ILT101 Drug: Placebos	Assistance Publique - Hôpital de Paris Ilttoo Pharma	Phase 2
NCT04117932	Efficacy and Safety of Ustekinumab in Bullous Pemphigoid	Bullous Pemphigoid	Drug: Ustekinumab	CHU de Reims	Phase 2
NCT04095208	Combination of Nivolumab Plus Relatlimab in Patients With Advanced or Metastatic Soft-tissue Sarcoma: a Proof-of-concept Randomized Phase II Study	Soft Tissue Sarcoma Adult Advanced Cancer	Drug: Association of Nivolumab + Relatlimab Drug: Nivolumab	Institut Bergonié Bristol-Myers Squibb	Phase 2
NCT03940690	Interest of Intravitreal Injections of Anti-VEGF as Initial and Adjuvant Treatment in Coats Disease	Retinal Telangiectasis Coats Disease	Drug: Anti-VEGF injections of bevacizumab Device: Laser	Fondation Ophtalmologique Adolphe de Rothschild	Phase 3
NCT04088409	A Study of Baricitinib (LY3009104) in Participants From 2 Years to Less Than 18 Years Old With Active JIA-Associated Uveitis or Chronic Anterior Antinuclear Antibody-Positive Uveitis	Uveitis	Drug: Baricitinib Drug: Adalimumab	Eli Lilly and Company	Phase 3
NCT03958877	A Study to Evaluate the Safety, Tolerability, and Efficacy of BIIB017 (Peginterferon Beta-1a) in Pediatric Participants for the Treatment of Relapsing-Remitting Multiple Sclerosis	Multiple Sclerosis, Relapsing-Remitting	Drug: BIIB017 (peginterferon beta-1a) Drug: Interferon beta type 1a	Biogen	Phase 3

## 해외 바이오의약품 임상 현황 (2019.10.29~2019.11.04)

한국바이오의약품협회, 2019.11.5.  
출처: ClinicalTrials.gov

### ○ 독일 8건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04136067	A Study to Look at How Safe NNC0268-0965 is in People With Type 2 Diabetes	Diabetes Mellitus, Type 2	Drug: NNC0268-0965 Drug: insulin glargine	Novo Nordisk A/S	Phase 1
NCT04073147	Venetoclax and Obinutuzumab for Relapsed Primary CNS Lymphoma	Primary CNS Lymphoma	Drug: Venetoclax Drug: Obinutuzumab	Klinikum Stuttgart University Hospital Freiburg	Phase 1
NCT04057261	Effect of Liraglutide on the Metabolic Profile in Patients With Type 2 Diabetes and Cardiovascular Disease	Type 2 Diabetes Cardiovascular Diseases	Drug: Liraglutide Pen Injector [Victoza] Drug: Placebo	RWTH Aachen University Novo Nordisk A/S	Phase 3
NCT03944876	Botulinum Toxin Type A Blockade of the Sphenopalatine Ganglion in Treatment-refractory Chronic Cluster Headache	Cluster Headache	Drug: Botulinum toxin type A Drug: placebo	Norwegian University of Science and Technology St. Olavs Hospital University College, London Fondazione I.R.C.C.S. Istituto Neurologico Carlo Besta Catholic University of Valencia University Hospital, Essen	Phase 3
NCT03996473	Study to Test the Safety and How Radium-223 Dichloride an Alpha Particle-emitting Radioactive Agent Works in Combination With Pembrolizumab an Immune Checkpoint Inhibitor in Patients With Stage IV Non-small Cell Lung Cancer With Bone Metastases	Carcinoma, Non-Small-Cell Lung	Drug: Radium-223 dichloride (Xofigo, BAY 88-8223) Drug: Pembrolizumab	Bayer	Phase 1 Phase 2
NCT04134936	Phase Ib Study to Assess Safety and Preliminary Efficacy of Tafasitamab or Tafasitamab Plus Lenalidomide in Addition to R-CHOP in Patients With Newly Diagnosed DLBCL	Diffuse Large B-cell Lymphoma	Drug: Tafasitamab Drug: Tafasitamab plus Lenalidomide	MorphoSys AG	Phase 1
NCT04088409	A Study of Baricitinib (LY3009104) in Participants From 2 Years to Less Than 18 Years Old With Active JIA-Associated Uveitis or Chronic Anterior Antinuclear Antibody-Positive Uveitis	Uveitis	Drug: Baricitinib Drug: Adalimumab	Eli Lilly and Company	Phase 3
NCT04143724	Study of Safety & PK of Luspatercept (ACE-536) in Pediatric Subjects Who Require Regular RBC Transfusions Due to Beta (β)-Thalassemia.	Beta-Thalassemia	Drug: ACE-536	Celgene Accelleron Pharma, Inc.	Phase 2

### ○ 중국 13건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04152057	Pyrotinib Maleate Tablets Combined With Albumin Paclitaxel and Trastuzumab for Her2-positive Breast Cancer	Breast Cancer HER2 Positive Combination Chemotherapy	Drug: Pyrotinib Maleate Tablets Drug: Albumin Paclitaxel Drug: Trastuzumab	West China Hospital Jiangsu HengRui Medicine Co., Ltd.	Phase 1 Phase 2
NCT04133337	Apatinib Combined With SHR-1210 Injection in the Treatment of Patients With Removable IB-IIIa NSCLC	Lung Diseases Neoplasms Respiratory Tract Diseases Thoracic Neoplasms Non-small-cell Lung Cancer	Drug: Apatinib Drug: SHR-1210	Sichuan Cancer Hospital and Research Institute Jiangsu HengRui Medicine Co., Ltd.	Phase 1 Phase 2
NCT04146610	Study of DP303c Administered Intravenously to Subjects With HER2-Positive in Advanced Solid Tumors	Neoplasms	Drug: an antibody drug conjugate	CSPC ZhongQi Pharmaceutical Technology Co., Ltd.	Phase 1
NCT04136145	Single Dose Study to Investigate the Pharmacokinetics (PK) and Safety of Belimumab 200 Milligrams (mg) Intravenous and 200 mg Subcutaneous Via Auto-injector in Chinese Healthy Subjects	Systemic Lupus Erythematosus	Drug: Belimumab for IV Drug: Belimumab for SC	GlaxoSmithKline	Phase 1
NCT04088110	Pyrotinib Combined With Trastuzumab Plus Aromatase Inhibitor in Treatment of Breast Cancer	Breast Cancer Female HER2-positive Breast Cancer Hormone Receptor Positive Malignant Neoplasm of Breast Metastatic Breast Cancer Breast Diseases Hormone Receptor Positive Tumor	Drug: Pyrotinib Drug: Trastuzumab Drug: Aromatase Inhibitors	Fuzhou General Hospital	Phase 2
NCT04049123	A Study of LY900014 in Healthy Chinese Participants	Healthy	Drug: LY900014 Drug: Insulin Lispro (Humalog)	Eli Lilly and Company	Phase 1
NCT04030533	Study of Guselkumab and Ustekinumab Following a Single Intravenous or Subcutaneous Administration in Healthy Chinese Participants	Healthy	Drug: Guselkumab (SC): Dose 1 Drug: Guselkumab (SC): Dose 2 Drug: Guselkumab (IV): Dose 1 Drug: Guselkumab (IV): Dose 2 Drug: Ustekinumab 6 mg/mL	Janssen Research & Development, LLC	Phase 1
NCT03952923	CD19-CAR-T in B-cell Malignancies Patients	B-cell Malignancy	Biological: CD19-CAR-T cells	Hebei Yanda Ludaopei Hospital China Immunotech Co., Ltd. Avalon GloboCare Corp.	Phase 1
NCT03930498	Programmed Death-1 (PD-1) Antibody Combined With Chemoradiotherapy in High-risk Recurrent Nasopharyngeal Carcinoma	Recurrent Nasopharyngeal Carcinoma	Drug: PD-1 blocking antibody Drug: Chemotherapy Radiation: IMRT	Sun Yat-sen University	Phase 2
NCT03907826	Programmed Death-1 (PD-1) Antibody Combined With IMRT in Recurrent Nasopharyngeal Carcinoma Patients	Recurrent Nasopharyngeal Carcinoma	Drug: PD-1 blocking antibody Radiation: IMRT	Sun Yat-sen University	Phase 3
NCT03898895	Combination of Radiotherapy With Anti-PD-1 Antibody for unREsectable Intrahepatic Cholangiocarcinoma	Intrahepatic Cholangiocarcinoma Radiotherapy Immunotherapy	Combination Product: Radiotherapy+anti-PD-1 Drug: Gemcitabine+cisplatin	Sun Yat-sen University	Phase 2
NCT04044651	Lenvatinib Plus Nivolumab Versus Lenvatinib for Advanced Hepatocellular Carcinoma With Hepatitis B Virus Infection	Hepatocellular Carcinoma	Drug: Lenvatinib Drug: Nivolumab	Shi Ming First Affiliated Hospital, Sun Yat-Sen University Guangzhou No.12 People's Hospital Guangdong Provincial People's Hospital Third Affiliated Hospital, Sun Yat-Sen University Sun Yat-sen University	Phase 2 Phase 3
NCT04102982	Microwave Ablation in Combination With Camrelizumab Versus Camrelizumab in Metastatic Non-small-cell Lung Cancer	NSCLC Stage IV	Drug: Camrelizumab Other: Camrelizumab plus microwave ablation	Shandong Provincial Hospital	Phase 2