

해외 바이오의약품 임상 현황 (2020.11.30~2020.12.6)

한국바이오의약품협회, 2020.12.8.
출처: ClinicalTrials.gov

○ 미국 94건

| NCT Number | Title | Conditions | Interventions | Sponsor/Collaborators | Phases |
|-------------|---|---|---|---|---------------------|
| NCT04620603 | Low-Dose-Rate Brachytherapy Combined With Immune Checkpoint Inhibition in Cancer | Cutaneous Malignant Melanoma | Radiation: Low Dose Rate Brachytherapy (LDR) Drug: Nivolumab | Case Comprehensive Cancer Center | Phase 1 Phase 2 |
| NCT04616183 | LY3214996 and Cetuximab Alone or in Combination With Abemaciclib for the Treatment of Unresectable or Metastatic Colorectal Cancer | Metastatic Colon Adenocarcinoma Metastatic Colorectal Carcinoma Metastatic Rectal Adenocarcinoma Recurrent Colorectal Carcinoma Stage III Colon Cancer AJCC v8 Stage III Colorectal Cancer AJCC v8 Stage III Rectal Cancer AJCC v8 Stage IIIA Colon Cancer AJCC v8 Stage IIIA Colorectal Cancer AJCC v8 Stage IIIA Rectal Cancer AJCC v8 Stage IIIB Colon Cancer AJCC v8 Stage IIIB Colorectal Cancer AJCC v8 Stage IIIB Rectal Cancer AJCC v8 Stage IIIC Colon Cancer AJCC v8 Stage IIIC Colorectal Cancer AJCC v8 Stage IIIC Rectal Cancer AJCC v8 Stage IVC Colon Cancer AJCC v8 Stage IVC Colorectal Cancer AJCC v8 Stage IVC Rectal Cancer AJCC v8 Stage IV Colon Cancer AJCC v8 Stage IV Colorectal Cancer AJCC v8 Stage IV Rectal Cancer AJCC v8 Stage IVA Colon Cancer AJCC v8 Stage IVA Colorectal Cancer AJCC v8 Stage IVA Rectal Cancer AJCC v8 Stage IVB Colon Cancer AJCC v8 Stage IVB Colorectal Cancer AJCC v8 Stage IVB Rectal Cancer AJCC v8 Stage IVC Colon Cancer AJCC v8 Stage IVC Colorectal Cancer AJCC v8 Stage IVC Rectal Cancer AJCC v8 Unresectable Colon Adenocarcinoma Unresectable Colorectal Carcinoma Unresectable Rectal Adenocarcinoma | Drug: Abemaciclib Biological: Cetuximab Drug: ERK1/2 Inhibitor LY3214996 | M.D. Anderson Cancer Center National Cancer Institute (NCI) | Phase 1 Phase 2 |
| NCT04517435 | ME-401 and R-CHOP in Newly Diagnosed Diffuse Large B-Cell Lymphoma | Diffuse Large B-Cell Lymphoma | Drug: ME-401 Drug: Rituximab Drug: Cyclophosphamide Drug: Doxorubicin Drug: Vincristine Drug: Prednisone | Deepa Jagadeesh Case Comprehensive Cancer Center | Phase 1 Phase 2 |
| NCT04499924 | Tucatinib, Trastuzumab, Ramucirumab, and Paclitaxel Versus Paclitaxel and Ramucirumab in Previously Treated HER2+ Gastroesophageal Cancer | Gastric Adenocarcinoma Gastroesophageal Junction Adenocarcinoma Esophageal Adenocarcinoma | Drug: tucatinib Drug: trastuzumab Drug: ramucirumab Drug: paclitaxel Other: tucatinib placebo Other: trastuzumab placebo | Seagen Inc. | Phase 2 Phase 3 |
| NCT04454528 | BreastVax: Radiation Boost to Enhance Effectiveness of Immune Checkpoint Blockade Therapy in Operable Breast Cancer | Breast Cancer | Radiation: Hypofractionated radiotherapy Drug: Pembrolizumab infusion Procedure: Blood and tissue sampling | University of Pennsylvania | Phase 1 Phase 2 |
| NCT04364230 | Melanoma Vaccine Against Neoantigen and Shared Antigens by CD40 Activation and TLR Agonists In Patients With Melanoma | Melanoma | Drug: 6MHP Drug: NeoAg-mBRAF Drug: Poly[CLC] Drug: CDX-1140 | Craig L Slingluff, Jr Celldex Therapeutics University of Virginia | Phase 1 Phase 2 |
| NCT04287478 | Bacteriophage Therapy in Patients With Urinary Tract Infections | Urinary Tract Infection Bacterial | Biological: Bacteriophage Therapy | Adaptive Phage Therapeutics, Inc. United States Department of Defense | Phase 1 Phase 2 |
| NCT04285671 | Necitumumab and Trastuzumab in Combination With Osimertinib for the Treatment of Refractory Epidermal Growth Factor Receptor (EGFR)-Mutated Stage IV Non-small Cell Lung Cancer | Metastatic Lung Non-Small Cell Carcinoma Refractory Lung Non-Small Cell Carcinoma Stage IV Lung Cancer American Joint Committee on Cancer (AJCC) v8 Stage IVA Lung Cancer AJCC v8 Stage IVB Lung Cancer AJCC v8 | Biological: Necitumumab Drug: Osimertinib Other: Quality-of-Life Assessment Other: Questionnaire Administration Biological: Trastuzumab | Jonsson Comprehensive Cancer Center Eli Lilly and Company Genentech, Inc. | Phase 1 Phase 2 |
| NCT04201821 | Fecal Microbial Transplantation for the Treatment of Fecal Incontinence in Women | Fecal Incontinence | Biological: fecal microbial transplantation (FMT) | University of Pennsylvania | Phase 1 Phase 2 |
| NCT04029038 | Modified Immune Cells (CD19-CD22 CAR T Cells) in Treating Patients With Recurrent or Refractory CD19 Positive, CD22 Positive Leukemia or Lymphoma | CD19 Positive CD22 Positive Minimal Residual Disease Progressive Disease Recurrent B Acute Lymphoblastic Leukemia Recurrent Chronic Lymphocytic Leukemia Recurrent Non-Hodgkin Lymphoma Refractory B Acute Lymphoblastic Leukemia Refractory Chronic Lymphocytic Leukemia Refractory Non-Hodgkin Lymphoma | Biological: Autologous CD19/CD22 Chimeric Antigen Receptor T-cells Drug: Cyclophosphamide Drug: Fludarabine | M.D. Anderson Cancer Center National Cancer Institute (NCI) | 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 Pfizer | Phase 1 Phase 2 |
| NCT03674320 | Cycled Testosterone Administration During Pulmonary Rehabilitation in Early Stage COPD | COPD | Drug: Testosterone Enanthate Drug: Placebo | The University of Texas Medical Branch, Galveston | Phase 2 Phase 3 |
| NCT03597594 | Haplocompatible Transplant Using TCRα/β Depletion Followed by CD45RA-Depleted Donor Lymphocyte Infusions for Severe Combined Immunodeficiency (SCID) | Severe Combined Immunodeficiency | Drug: Anti-thymocyte globulin (rabbit) Drug: Busulfan Drug: Fludarabine Drug: Thiotepa Device: CliniMACS Other: Donor Lymphocyte Infusion | St. Jude Children's Research Hospital | Phase 1 Phase 2 |
| NCT03520751 | Phase I/IIa Trial of scAAV1.tMCK.NTF3 for Treatment of CMT1A | Charcot-Marie-Tooth Neuropathy Type 1A | Drug: scAAV1.tMCK.NTF3 | Nationwide Children's Hospital | Phase 1 Phase 2 |
| NCT03487731 | Allogeneic Human Mesenchymal Stem Cell Injection in PatieNts With FaceTogenic Back Pain | Facetogenic Back Pain Back Pain | Biological: Allogeneic Human Mesenchymal Stem Cells (hMSCs) Drug: Placebo | Joshua M Hare University of Miami | Phase 1 Phase 2 |
| NCT00424866 | FGF-1 for Intramuscular Injection for the Treatment of Peripheral Arterial Disease | Peripheral Arterial Disease Stenosis Intermittent Claudication | Drug: FGF-1 Drug: Placebo | CardioVascular BioTherapeutics, Inc. | Phase 1 Phase 2 |
| NCT04305795 | An Open-label Study Using ASP-1929 Photoimmunotherapy in Combination With Anti-PD1 Therapy in EGFR Expressing Advanced Solid Tumors | Recurrent Head and Neck Squamous Cell Carcinoma Metastatic Head-and-neck Squamous-cell Carcinoma Locally Advanced Cutaneous Squamous Cell Carcinoma Metastatic Cutaneous Squamous Cell Carcinoma | Biological: 200 mg Pembrolizumab Biological: Cemiplimab 350mg Combination Product: ASP-1929 | Rakuten Medical, Inc. | Phase 1 Phase 2 |
| NCT04263831 | LOW DOSE IL-2 FOR THE TREATMENT OF CROHN'S DISEASE | Crohn Disease | Drug: Interleukin-2 (aldesleukin). | Boston Children's Hospital | Phase 1 Phase 2 |
| NCT04640987 | Stem Cell Transplant From Donors After Alpha Beta Cell Depletion in Children and Adults With T-allo10 Cells Addback | Hematologic Diseases | Biological: Allogeneic Stem Cell Transplant Device: CliniMACS Prodigy System Drug: T-allo10 cells addback | Stanford University | Phase 1 |

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| NCT04635995 | Phase 1 Trial of LVGN7409 (CD40 Agonist Antibody) as Single Agent and Combination Therapies in Advanced or Metastatic Malignancy | Cancer | Biological: LVGN7409 | Lyvgen Biopharma Holdings Limited | Phase 1 |
| NCT04632966 | Safety Study of PTP-001 for Treating Knee Osteoarthritis | Knee Osteoarthritis | Biological: Biological: PTP-001 | Bioventus LLC | Phase 1 |
| NCT04627675 | CORVax12: SARS-CoV-2 Spike (S) Protein Plasmid DNA Vaccine Trial for COVID-19 (SARS-CoV-2) | SARS-CoV-2 | Drug: CORVax[Drug: IL-12 plasmid][Device: Cliniporator | Providence Health & Services OncoSec Medical Incorporated | Phase 1 |
| NCT04617782 | Crossover Pharmacokinetic (PK) Study of 5 and 10 mg Corlex™/Donepezil TDS Compared to 10 mg Aricept® in Healthy Volunteers | Healthy Subjects | Combination Product: Donepezil TDS[Drug: Aricept | Corium, Inc. | Phase 1 |
| NCT04616248 | Radio-immunotherapy (CDX-301, Radiotherapy, CDX-1140 and Poly-ICLC) for the Treatment of Unresectable or Metastatic Breast Cancer Patients | Anatomic Stage IV Breast Cancer AJCC v8 Metastatic Breast Carcinoma Prognostic Stage IV Breast Cancer AJCC v8 Unresectable Breast Carcinoma | Biological: Anti-CD40 Agonist Monoclonal Antibody CDX-1140[Drug: Poly ICLC][Radiation: Radiation Therapy Biological: Recombinant Flt3 Ligand | Roswell Park Cancer Institute | Phase 1 |
| NCT04613492 | A Study of MEDI9253 in Combination With Durvalumab in Select Solid Tumors | Solid Tumors | Biological: MEDI9253 Biological: Durvalumab | AstraZeneca | Phase 1 |
| NCT04611880 | Crizanlizumab for Treatment of Retinal Vasculopathy With Cerebral Leukoencephalopathy (RVCL) | RVCL - Retinal Vasculopathy Cerebral Leukoencephalopathy | Drug: Crizanlizumab | Washington University School of Medicine | Phase 2 |
| NCT04611139 | Pilot Trial of SP-2577 Plus Pembrolizumab in Select Gynecologic Cancers | SCCOHT Ovarian Clear Cell Tumor Ovarian Endometrioid Adenocarcinoma Endometrial Cancer | Drug: SP-2577[Drug: Pembrolizumab | HonorHealth Research Institute Merck Sharp & Dohme Corp Salaris Pharmaceuticals, LLC | Phase 1 |
| NCT04607954 | Durvalumab and Topotecan for the Treatment of Relapsed or Refractory Small Cell Lung Cancer | Platinum-Sensitive Lung Small Cell Carcinoma Recurrent Extensive Stage Lung Small Cell Carcinoma Refractory Extensive Stage Lung Small Cell Carcinoma | Biological: Durvalumab[Drug: Topotecan Hydrochloride | Mayo Clinic National Cancer Institute (NCI) | Phase 2 |
| NCT04606316 | Surgical Nivolumab And Ipilimumab For Recurrent GBM | Glioblastoma GBM Glioblastoma Multiforme Grade IV Astrocytoma | Drug: Nivolumab-Placebo[Drug: Nivolumab][Drug: Ipilimumab-Placebo][Drug: Ipilimumab]Procedure: Surgery | Patrick Y. Wen, MD Bristol-Myers Squibb Dana-Farber Cancer Institute | Phase 1 |
| NCT04602117 | Evaluating the Safety of Weekly Paclitaxel With Trastuzumab Duocarmazine (SYD985) in Patients With Metastatic Cancer | HER2-positive Breast Cancer | Drug: Vic-trastuzumab duocarmazine (SYD985) | QuantumLeap Healthcare Collaborative | Phase 1 |
| NCT04594031 | US Phase I Study of ECT-001-CB in Patients With Sickle-Cell Disease | Sickle Cell Disease Umbilical Cord Blood Hematopoietic Cell Proliferation | Biological: ECT-001-CB (UM171-Expanded Cord Blood Transplant) | ExCellThera inc. California Institute for Regenerative Medicine (CIRM) | Phase 1 |
| NCT04592237 | Cabazitaxel, Carboplatin, and Cetrelimab Followed by Niraparib With or Without Cetrelimab for the Treatment of Aggressive Variant Metastatic Prostate Cancer | Aggressive Variant Prostate Carcinoma Castration-Resistant Prostate Carcinoma Metastatic Prostate Carcinoma Metastatic Prostate Neuroendocrine Carcinoma Metastatic Prostate Small Cell Carcinoma Stage IV Prostate Cancer AJCC v8 | Drug: Cabazitaxel[Drug: Carboplatin Biological: Cetrelimab][Drug: Niraparib | M.D. Anderson Cancer Center | Phase 2 |
| NCT04588948 | A Pharmacokinetic study of intravitreal Afibercept Injection in Vitrectomized and Non-vitrectomized Eyes With Diabetic Macular Edema | Diabetic Macular Edema | Drug: Intravitreal Afibercept | Stanford University Regeneron Pharmaceuticals | Phase 2 |
| NCT04576988 | A Study of Sotatercept for the Treatment of Pulmonary Arterial Hypertension (STELLAR) | Pulmonary Arterial Hypertension | Drug: Sotatercept[Drug: Placebo | Acceleron Pharma, Inc. | Phase 3 |
| NCT04564339 | Study of Ravulizumab in Proliferative Lupus Nephritis (LN) or Immunoglobulin A Nephropathy (IgAN) | Lupus Nephritis Immunoglobulin A Nephropathy | Drug: Ravulizumab[Drug: Placebo Other: Background Therapy | Alexion Pharmaceuticals | Phase 2 |
| NCT04547777 | Phase 1 Trial of D2C7-IT in Combination With 2141-V11 for Recurrent Malignant Glioma | Glioma, Malignant | Drug: D2C7-IT[Drug: 2141-V11 | Darell Bigner Rockefeller University Duke University | Phase 1 |
| NCT04536077 | Immunologic Effects of CDX-301 and CDX-1140 in Resectable Pancreatic Cancer Patients | Pancreatic Cancer Cancer of the Pancreas Pancreas Cancer | Drug: CDX-301[Drug: CDX-1140]Procedure: Research blood draw | Washington University School of Medicine Celldex Therapeutics | Phase 2 |
| NCT04535102 | POLA+BR for Relapsed or Refractory DLBCL | Diffuse Large B Cell Lymphoma | Drug: Polatuzumab Vedotin | University of Colorado, Denver National Cancer Institute (NCI) | Phase 2 |
| NCT04511078 | Phase II Pantumumab-IRDye800 in Head & Neck Cancer | Head and Neck Cancer | Drug: Panitumumab-IRDye800 | University of Alabama at Birmingham | Phase 2 |
| NCT04508647 | Ublituximab Followed by Response-driven Addition of Umalisib for Treatment-naïve Follicular or Marginal Zone Lymphoma | Marginal Zone Lymphoma Follicular Lymphoma | Drug: Ublituximab[Drug: Umalisib | University of Colorado, Denver | Phase 2 |
| NCT04493203 | Nivolumab Plus Axitinib in Patients With Anti-PD1 Refractory Advanced Melanoma | Advanced Melanoma Unresectable Melanoma | Drug: Nivolumab[Drug: Axitinib | Yana Najjar Pfizer Bristol-Myers Squibb University of Pittsburgh | Phase 2 |
| NCT04477759 | Dose-Escalated Hypofractionated Adaptive Radiotherapy for Head and Neck Cancer | Head and Neck Neoplasm | Radiation: 50 Gy Radiation Therapy[Radiation: 55 Gy Radiation Therapy Radiation: 60 Gy Radiation Therapy Drug: Atezolizumab | Medical College of Wisconsin | Phase 1 |
| NCT04466618 | Endogenous GLP-1 Secretion on Islet Function in People With and Without Type 2 Diabetes | Healthy Type 2 Diabetes | Biological: Saline Biological: Exendin-9,39 Biological: Saline + Intralipid/Heparin Biological: Exendin-9,39 + Intralipid/Heparin | Adrian Vella National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Mayo Clinic | Phase 3 |
| NCT04465643 | Neoadjuvant Nivolumab Plus Ipilimumab for Newly Diagnosed Malignant Peripheral Nerve Sheath Tumor | Nerve Sheath Tumors | Drug: Nivolumab[Drug: Ipilimumab | Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Bristol-Myers Squibb | Phase 1 |
| NCT04462328 | Acalabrutinib and Durvalumab in Primary and Secondary Central Nervous System Lymphoma | Primary Central Nervous System Lymphoma Secondary Central Nervous System Lymphoma | Drug: Durvalumab[Drug: Acalabrutinib | Washington University School of Medicine AstraZeneca | Phase 1 |
| NCT04454489 | Quad Shot Radiotherapy in Combination With Immune Checkpoint Inhibition | Advanced Head and Neck Squamous Cell Carcinoma Recurrent Head and Neck Squamous Cell Carcinoma Metastatic Head-and-neck Squamous-cell Carcinoma | Drug: Pembrolizumab (immunotherapy) Radiation: Quad-shot palliative radiotherapy | Wake Forest University Health Sciences National Cancer Institute (NCI) | Phase 2 |
| NCT04450173 | Obinutuzumab, Ibrutinib, and Venetoclax for the Treatment of Previously Untreated Stage II-IV Follicular Lymphoma | Ann Arbor Stage II Follicular Lymphoma Ann Arbor Stage III Follicular Lymphoma Ann Arbor Stage IV Follicular Lymphoma Grade 1 Follicular Lymphoma Grade 2 Follicular Lymphoma Grade 3a Follicular Lymphoma | Drug: Ibrutinib Biological: Obinutuzumab[Drug: Venetoclax | Joseph Tuscano National Cancer Institute (NCI) Pharmacyclics LLC. Genentech, Inc. University of California, Davis | Phase 2 |

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| NCT04441138 | Chemoradiation Followed by Durvalumab in Poor Risk and/or Elderly Patients With Stage III NSCLC | Stage III Non-small-cell Lung Cancer | Drug: Durvalumab | Rush University Medical Center AstraZeneca | Phase 2 |
| NCT04375527 | Binimetinib and Nivolumab for the Treatment of Locally Advanced Unresectable or Metastatic BRAF V600 Wildtype Melanoma | Clinical Stage III Cutaneous Melanoma AJCC v8 Clinical Stage IV Cutaneous Melanoma AJCC v8 Locally Advanced Cutaneous Melanoma Metastatic Cutaneous Melanoma Pathologic Stage III Cutaneous Melanoma AJCC v8 Pathologic Stage IIIA Cutaneous Melanoma AJCC v8 Pathologic Stage IIIB Cutaneous Melanoma AJCC v8 Pathologic Stage IIIC Cutaneous Melanoma AJCC v8 Pathologic Stage IIID Cutaneous Melanoma AJCC v8 Pathologic Stage IV Cutaneous Melanoma AJCC v8 Unresectable Cutaneous Melanoma | Drug: Binimetinib Biological: Nivolumab Other: Questionnaire Administration | Jonsson Comprehensive Cancer Center | Phase 2 |
| NCT04350125 | PRP for the Treatment of Erectile Dysfunction (ED) | Erectile Dysfunction | Biological: Autologous Platelet Rich Plasma | Mayo Clinic | Phase 1 |
| NCT04303572 | The Hemophilia Inhibitor Eradication Trial | Hemophilia A With Inhibitor | Drug: Eloctate ITI Drug: Emicizumab | Margaret Ragni Health Resources and Services Administration (HRSA) University of Pittsburgh | Phase 3 |
| NCT04303559 | The Hemophilia Inhibitor Prevention Trial | Hemophilia A Without Inhibitor | Drug: Eloctate Injectable Product Drug: Emicizumab Injection [Hemlibra] | Margaret Ragni Health Resources and Services Administration (HRSA) University of Pittsburgh | Phase 3 |
| NCT04301778 | Durvalumab in Combination With a CSF-1R Inhibitor (SNDX-6532) Following Chemo or Radio-Embolization for Patients With Intrahepatic Cholangiocarcinoma | Unresectable Intrahepatic Cholangiocarcinoma | Drug: Durvalumab Drug: SNDX-6352 | Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Syndax Pharmaceuticals AstraZeneca | Phase 2 |
| NCT04295863 | Comparing Dosing Intervals of Nivolumab or Pembrolizumab in Locally Advanced or Metastatic Cancers | Metastatic Cancer | Drug: Nivolumab Standard Drug: Pembrolizumab Standard Drug: Nivolumab Extended Drug: Pembrolizumab Extended | University of Chicago | Phase 1 |
| NCT04149275 | Cabozantinib Plus Nivolumab and Ipilimumab in Women With Recurrent Gynecologic Carcinosarcoma | Carcinosarcoma of Ovary Carcinosarcoma of Uterus Carcinosarcoma of Vagina | Drug: Cabozantinib Drug: Ipilimumab Drug: Nivolumab | University of Alabama at Birmingham | Phase 2 |
| NCT04095689 | TAC Chemotherapy and Pembrolizumab Plus Interleukin-12 Gene Therapy and L-NMMA in Triple Negative Breast Cancer | Triple Negative Breast Cancer | Drug: Docetaxel Drug: Doxorubicin Drug: Cyclophosphamide Drug: Pembrolizumab Drug: IL-12 gene therapy Drug: L-NMMA | The Methodist Hospital System Merck Sharp & Dohme Corp. | 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 |
| NCT03939585 | Preemptive Infusion of Donor Lymphocytes Depleted of TCR + T Cells + CD19+ B Cells Following ASCT | Allogeneic Stem Cell Transplant Candidate Acute Myeloid/Lymphoblastic Leukemia Myelodysplastic Syndrome Myeloproliferative Neoplasm Lymphoproliferative Disorders | Biological: Cellular therapy product | Case Comprehensive Cancer Center | Phase 1 |
| 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 |
| NCT03872505 | Pre-operative Non-Anthracycline Chemotherapy, Durvalumab +/- Radiation Therapy in Triple Negative Breast Cancer | Breast Cancer Triple Negative Breast Cancer | Drug: Durvalumab Radiation: Radiation Therapy Drug: Carboplatin Drug: Paclitaxel | Cedars-Sinai Medical Center AstraZeneca | Phase 2 |
| NCT03747718 | Randomized Trial Comparing Single vs. Maintenance Fecal Microbiota Transplant for Refractory Crohn's Disease in Children | Crohn Disease | Biological: Fecal Microbiota Transplantation Other: Placebo | Stanford University | Phase 1 |
| NCT03068832 | Neopeptide-based Personalized Vaccine Approach in Pediatric Patients With Recurrent Brain Tumors | Pediatric Brain Tumor | Biological: Personalized peptide vaccine Drug: Poly ICLC Procedure: Peripheral blood draw | Washington University School of Medicine | Phase 1 |
| NCT02035085 | 19F Hot Spot MRI of Human Adipose-derived Stem Cells for Breast Reconstruction | Breast Cancer | Drug: CS-1000 labeled SVF cells | Johns Hopkins University Cosmeticsurg.net | Phase 1 |
| NCT04614558 | Isatuximab in Patients With Monoclonal Gammopathy of Renal Significance | Monoclonal Gammopathy | Drug: Isatuximab | Columbia University Genzyme, a Sanofi Company | Phase 2 |
| NCT04609566 | Brentuximab Vedotin With Pembrolizumab in Metastatic Solid Tumors | Melanoma Non-small Cell Lung Cancer | Drug: brentuximab vedotin Drug: pembrolizumab | Seagen Inc. Merck Sharp & Dohme Corp. | Phase 2 |
| NCT04607200 | AGEN2034 & AGEN1884 in Patients With Recurrent, Inoperable Angiosarcoma | Angiosarcoma | Drug: AGEN2034 Drug: AGEN1884 | Agenus Inc. | Phase 2 |
| NCT04522180 | A Study to Assess the Safety, Tolerability, and Efficacy of IONIS-GHR-LRx Administered in Patients With Acromegaly | Acromegaly | Drug: IONIS-GHR-LRx | Ionis Pharmaceuticals, Inc. | Phase 2 |
| NCT04398680 | A Study of Belantamab Mafodotin (GSK2857916) in Multiple Myeloma Participants With Normal and Impaired Hepatic Function | Multiple Myeloma | Drug: Belantamab mafodotin | GlaxoSmithKline | Phase 1 |
| NCT04118036 | Abemaciclib + Pembrolizumab In Glioblastoma | Glioblastoma | Drug: Pembrolizumab Drug: Abemaciclib | Dana-Farber Cancer Institute | Phase 2 |
| NCT04596319 | Ph 1/2 Study Evaluating Safety and Tolerability of Inhaled AP-PA02 in Subjects With Chronic Pseudomonas Aeruginosa Lung Infections and Cystic Fibrosis | Cystic Fibrosis Pseudomonas Aeruginosa Pseudomonas Lung Infection Lung Infection Pseudomonal | Biological: AP-PA02 Other: Placebo | Armata Pharmaceuticals, Inc. Cystic Fibrosis Foundation | Phase 1 Phase 2 |
| NCT04375228 | Study of Rituximab or Tocilizumab for Patients With Steroid-Dependent Immune-Related Adverse Events (irAEs) | Immune-related Adverse Events Advanced Solid Tumor | Drug: Rituximab Drug: Tocilizumab | Columbia University Genentech, Inc. | Phase 2 |
| NCT04098250 | Multidisciplinary Translational Approach to Investigate Mechanisms Predictors & Prevention of Persistent PTH | Post-Traumatic Headache | Drug: Erenumab Other: Placebo | Mayo Clinic University of Arizona Translational Genomics Research Institute Arizona State University Phoenix VA Health Care System United States Department of Defense Amgen | Phase 2 |
| NCT04617691 | A Study of Intravenous Formulation of Guselkumab Using Prefilled Syringes and Final Vial Product in Healthy Participants | Healthy | Drug: Guselkumab | Janssen Research & Development, LLC | Phase 1 |
| NCT04480502 | ENVASARC: Envafolelimab And Envafolelimab With Ipilimumab In Patients With Undifferentiated Pleomorphic Sarcoma Or Myxofibrosarcoma | Undifferentiated Pleomorphic Sarcoma Myxofibrosarcoma | Biological: Envafolelimab Drug: Ipilimumab | Tracon Pharmaceuticals Inc. | Phase 2 |

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| NCT04568434 | A Study of AKCEA-APOCIII-LRx Administered to Patients With Familial Chylomicronemia Syndrome (FCS) | Familial Chylomicronemia Syndrome | Drug: AKCEA-APOCIII-LRx Drug: Placebo | Ionis Pharmaceuticals, Inc. Akcea Therapeutics | Phase 3 |
| NCT04644809 | A Study of LY3561774 in Participants With Dyslipidemia | Dyslipidemias | Drug: LY3561774 Drug: Placebo | Eli Lilly and Company | Phase 1 |
| NCT04083170 | Cord Blood Transplant With OTS for the Treatment of HIV Positive Hematologic Cancers | Acute Erythroid Leukemia Acute Lymphoblastic Leukemia Acute Megakaryoblastic Leukemia Acute Myeloid Leukemia Chronic Myelogenous Leukemia, BCR-ABL1 Positive Hematopoietic and Lymphoid Cell Neoplasm HIV Infection Myelodysplastic Syndrome Myelodysplastic Syndrome With Excess Blasts Non-Hodgkin Lymphoma Refractory Anemia | Drug: Fludarabine Drug: Cyclophosphamide Drug: Thiotepea Radiation: Total-Body Irradiation Procedure: Umbilical Cord Blood Transplantation Other: Cellular Therapy | Fred Hutchinson Cancer Research Center National Cancer Institute (NCI) National Heart, Lung, and Blood Institute (NHLBI) | Phase 2 |
| NCT04639219 | A Study of T-DXd for the Treatment of Solid Tumors Harboring HER2 Activating Mutations | Advanced Solid Tumors With HER2 Mutation | Drug: Trastuzumab deruxtecan | AstraZeneca Daiichi Sankyo Co., Ltd. | Phase 2 |
| NCT04642638 | Safety, Immunogenicity, and Efficacy of INO-4800 for COVID-19 in Healthy Seronegative Adults at High Risk of SARS-CoV-2 Exposure | Coronavirus Infection Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) COVID-19 Disease | Drug: INO-4800 Device: CELLECTRA 2000 Drug: Placebo | Inovio Pharmaceuticals | Phase 2 Phase 3 |
| NCT04607772 | Study of Selinexor in Combination With Backbone Treatments or Novel Therapies In Participants With Relapsed or Refractory (RR) Diffuse Large B-Cell Lymphoma (DLBCL) | Relapsed or Refractory Diffuse Large B-Cell Lymphoma | Drug: Selinexor Drug: Rituximab Drug: Bendamustine Drug: Polatuzumab Vedotin Drug: Ibrutinib Drug: Lenalidomide Drug: Tafasitamab Drug: Venetoclax Drug: Gemcitabine Drug: Oxaliplatin | Karyopharm Therapeutics Inc | Phase 1 Phase 2 |
| NCT04649151 | A Study to Evaluate the Safety, Reactogenicity, and Effectiveness of mRNA-1273 Vaccine in Adolescents 12 to <18 Years Old to Prevent COVID-19 | SARS-CoV-2 | Biological: mRNA-1273 Biological: Placebo | ModernaTX, Inc. Biomedical Advanced Research and Development Authority | Phase 2 Phase 3 |
| NCT04622319 | A Study of Trastuzumab Deruxtecan (T-DXd) Versus Trastuzumab Emtansine (T-DM1) in High-risk HER2-positive Participants With Residual Invasive Breast Cancer Following Neoadjuvant Therapy (DESTINY-Breast05) | HER2-Positive Primary Breast Cancer Residual Invasive Breast Cancer | Drug: DS-8201a Drug: T-DM1 | Daiichi Sankyo, Inc. AstraZeneca NSABP Foundation Inc German Breast Group Spanish Breast Cancer Research Group (SOLTI) | Phase 3 |
| NCT04620811 | An Extension Study of Lirentelimab in Eosinophilic Gastritis and/or Eosinophilic Duodenitis (Formerly Referred to as Eosinophilic Gastroenteritis) | Eosinophilic Gastritis Eosinophilic Duodenitis | Drug: lirentelimab | Allakos, Inc. | Phase 3 |
| NCT04616326 | A Study of Galcanezumab (LY2951742) in Participants 12 to 17 Years of Age With Chronic Migraine | Chronic Migraine | Drug: Galcanezumab Drug: Placebo | Eli Lilly and Company | Phase 3 |
| NCT04589845 | Tumor-Agnostic Precision Immuno-Oncology and Somatic Targeting Rational for You (TAPISTRY) Platform Study | Solid Tumors | Drug: Entrectinib Drug: Alectinib Drug: Atezolizumab Drug: Ipatasertib Drug: Trastuzumab emtansine Drug: Idasanutlin Drug: GDC-0077 | Hoffmann-La Roche | Phase 2 |
| NCT04592874 | A Phase 2 Study to Evaluate Efficacy and Safety of AL002 in Participants With Early Alzheimer's Disease | Alzheimer Disease | Drug: AL002 Drug: Placebo | Alector Inc. AbbVie | Phase 2 |
| NCT04539938 | A Study of Tucatinib Plus Trastuzumab Deruxtecan in HER2+ Breast Cancer | Breast Cancer | Drug: tucatinib Drug: trastuzumab deruxtecan | Seagen Inc. | Phase 2 |
| NCT04515394 | Study of Tepotinib Combined With Cetuximab in Participants Left-Sided Metastatic Colorectal Cancer (mCRC) Acquired Resistance Due to Mesenchymal Epithelial Transition (MET) Amplification | Colorectal Neoplasms | Drug: Tepotinib Biological: Cetuximab | EMD Serono Research & Development Institute, Inc. Merck KGaA, Darmstadt, Germany EMD Serono | Phase 2 |
| NCT04484142 | Study of DS-1062a in Advanced or Metastatic Non-small Cell Lung Cancer With Actionable Genomic Alterations (TROPION-Lung05) | Non-small Cell Lung Cancer | Drug: DS-1062a | Daiichi Sankyo, Inc. AstraZeneca | Phase 2 |
| NCT04447768 | The Combination of Venetoclax and Obinutuzumab in People With Chronic Lymphocytic Leukemia (CLL) | Chronic Lymphocytic Leukemia (CLL) | Drug: Obinutuzumab Drug: Venetoclax | Memorial Sloan Kettering Cancer Center Genentech, Inc. | Phase 2 |
| NCT04193189 | B-Enhancement of HBV Vaccination in Persons Living With HIV (BEE-HIVe): Evaluation of HEPLISAV-B | HIV Infection Hepatitis B | Biological: HEPLISAV-B Biological: ENGERIX-B | National Institute of Allergy and Infectious Diseases (NIAID) Dynavax Technologies Corporation | Phase 3 |
| NCT04633447 | A Study to Evaluate Guselkumab for the Treatment of Participants With New-onset or Relapsing Giant Cell Arteritis | Giant Cell Arteritis | Drug: Guselkumab Drug: Placebo | Janssen Research & Development, LLC | Phase 2 |
| NCT04623775 | A Study of Relatlimab Plus Nivolumab in Combination With Chemotherapy vs. Nivolumab in Combination With Chemotherapy as First Line Treatment for Participants With Stage IV or Recurrent Non-small Cell Lung Cancer (NSCLC) | Non-small Cell Lung Cancer Recurrent Non-small Cell Lung Cancer Metastatic Non-small Cell Lung Cancer | Biological: Nivolumab Biological: Relatlimab Drug: Carboplatin Drug: Cisplatin Drug: Paclitaxel Drug: Nab-Paclitaxel Drug: Pemetrexed | Bristol-Myers Squibb | Phase 2 |
| NCT04249362 | Study of Durvalumab Following Radiation Therapy in Patients With Stage 3 Unresectable NSCLC Ineligible for Chemotherapy | Non-small Cell Lung Cancer | Drug: Durvalumab | AstraZeneca | Phase 2 |

해외 바이오의약품 임상 현황 (2020.11.30~2020.12.6)

한국바이오의약품협회, 2020.12.8.
출처: ClinicalTrials.gov

○ 영국 7건

| NCT Number | Title | Conditions | Interventions | Sponsor/Collaborators | Phases |
|-------------|---|---|---|--|---------|
| NCT04619628 | Safety and Immunogenicity of COVI-VAC, a Live Attenuated Vaccine Against COVID-19 | COVID-19 | Biological: COVI-VAC Other: Placebo | Codagenix, Inc | Phase 1 |
| NCT04285827 | Safety of Single Ascending Doses of CSL889 in Adult Patients With Stable Sickle Cell Disease | Sickle Cell Disease | Biological: CSL889 | CSL Behring | Phase 1 |
| NCT04624399 | Phase 2 Study of Neoadjuvant Immune Checkpoint Inhibitors in Urothelial Cancer | Urogenital Cancer | Drug: Atezolizumab | Queen Mary University of London Hoffmann-La Roche | Phase 2 |
| NCT04622319 | A Study of Trastuzumab Deruxtecan (T-DXd) Versus Trastuzumab Emtansine (T-DM1) in High-risk HER2-positive Participants With Residual Invasive Breast Cancer Following Neoadjuvant Therapy (DESTINY-Breast05) | HER2-Positive Primary Breast Cancer Residual Invasive Breast Cancer | Drug: DS-8201a Drug: T-DM1 | Daiichi Sankyo, Inc. AstraZeneca NSABP Foundation Inc German Breast Group Spanish Breast Cancer Research Group (SOLTI) | Phase 3 |
| NCT04515394 | Study of Tepotinib Combined With Cetuximab in Participants Left-Sided Metastatic Colorectal Cancer (mCRC) Acquired Resistance Due to Mesenchymal Epithelial Transition (MET) Amplification | Colorectal Neoplasms | Drug: Tepotinib Biological: Cetuximab | EMD Serono Research & Development Institute, Inc Merck KGaA, Darmstadt, Germany EMD Serono | Phase 2 |
| NCT04623775 | A Study of Relatlimab Plus Nivolumab in Combination With Chemotherapy vs. Nivolumab in Combination With Chemotherapy as First Line Treatment for Participants With Stage IV or Recurrent Non-small Cell Lung Cancer (NSCLC) | Non-small Cell Lung Cancer Recurrent Non-small Cell Lung Cancer Metastatic Non-small Cell Lung Cancer | Biological: Nivolumab Biological: Relatlimab Drug: Carboplatin Drug: Cisplatin Drug: Paclitaxel Drug: Nab-Paclitaxel Drug: Pemetrexed | Bristol-Myers Squibb | Phase 2 |
| NCT04615871 | Semaglutide to Reduce Myocardial Injury in PATients With COVID-19 | Covid19 Myocardial Injury | Drug: semaglutide | Vladimír Džavík St. Michael's Hospital, Toronto Canadian Institutes of Health Research (CIHR) University of Toronto University Health Network, Toronto | Phase 2 |

○ 프랑스 11건

| NCT Number | Title | Conditions | Interventions | Sponsor/Collaborators | Phases |
|-------------|---|---|---|---|---------|
| NCT04597424 | Combined Prevention of Sexually Transmitted Infections (STIs) in Men Who Have Sex With Men and Using Oral Tenofovir Disoproxil Fumarate/ Emtricitabine (TDF/FTC) for HIV Pre-Exposure Prophylaxis (PrEP) | Unsafe Sex Risk-Taking | Drug: Experimental: doxycycline Biological: Bexsero vaccine | French National Institute for Health and Medical Research-French National Agency for Research on AIDS and Viral Hepatitis (Inserm-ANRS) | Phase 3 |
| NCT04531046 | Axi-Cel as a 2nd Line Therapy in Patients With Relapsed/Refractory Aggressive B Lymphoma Ineligible to Autologous Stem Cell Transplantation | B-Cell Lymphoma Refractory B-cell Lymphoma Recurrent | Drug: axicabtagene ciloleucel | The Lymphoma Academic Research Organisation | Phase 2 |
| NCT04196868 | Methotrexate and Metformin in Rheumatoid Arthritis Patients | Arthritis, Rheumatoid | Drug: Metformin treatment Other: Placebo Drug: Methotrexate treatment | University Hospital, Bordeaux Ministry for Health and Solidarity, France | Phase 2 |
| NCT04622319 | A Study of Trastuzumab Deruxtecan (T-DXd) Versus Trastuzumab Emtansine (T-DM1) in High-risk HER2-positive Participants With Residual Invasive Breast Cancer Following Neoadjuvant Therapy (DESTINY-Breast05) | HER2-Positive Primary Breast Cancer Residual Invasive Breast Cancer | Drug: DS-8201a Drug: T-DM1 | Daiichi Sankyo, Inc. AstraZeneca NSABP Foundation Inc German Breast Group Spanish Breast Cancer Research Group (SOLTI) | Phase 3 |
| NCT04589845 | Tumor-Agnostic Precision Immuno-Oncology and Somatic Targeting Rational for You (TAPISTRY) Platform Study | Solid Tumors | Drug: Entrectinib Drug: Alectinib Drug: Atezolizumab Drug: Ipatasertib Drug: Trastuzumab emtansine Drug: Idasanutlin Drug: GDC-0077 | Hoffmann-La Roche | Phase 2 |
| NCT04515394 | Study of Tepotinib Combined With Cetuximab in Participants Left-Sided Metastatic Colorectal Cancer (mCRC) Acquired Resistance Due to Mesenchymal Epithelial Transition (MET) Amplification | Colorectal Neoplasms | Drug: Tepotinib Biological: Cetuximab | EMD Serono Research & Development Institute, Inc Merck KGaA, Darmstadt, Germany EMD Serono | Phase 2 |
| NCT04484142 | Study of DS-1062a in Advanced or Metastatic Non-small Cell Lung Cancer With Actionable Genomic Alterations (TROPION-Lung05) | Non-small Cell Lung Cancer | Drug: DS-1062a | Daiichi Sankyo, Inc. AstraZeneca | Phase 2 |
| NCT04616326 | A Study of Galcanezumab (LY2951742) in Participants 12 to 17 Years of Age With Chronic Migraine | Chronic Migraine | Drug: Galcanezumab Drug: Placebo | Eli Lilly and Company | Phase 3 |
| NCT04633447 | A Study to Evaluate Guselkumab for the Treatment of Participants With New-onset or Relapsing Giant Cell Arteritis | Giant Cell Arteritis | Drug: Guselkumab Drug: Placebo | Janssen Research & Development, LLC | Phase 2 |
| NCT04623775 | A Study of Relatlimab Plus Nivolumab in Combination With Chemotherapy vs. Nivolumab in Combination With Chemotherapy as First Line Treatment for Participants With Stage IV or Recurrent Non-small Cell Lung Cancer (NSCLC) | Non-small Cell Lung Cancer Recurrent Non-small Cell Lung Cancer Metastatic Non-small Cell Lung Cancer | Biological: Nivolumab Biological: Relatlimab Drug: Carboplatin Drug: Cisplatin Drug: Paclitaxel Drug: Nab-Paclitaxel Drug: Pemetrexed | Bristol-Myers Squibb | Phase 2 |
| NCT04249362 | Study of Durvalumab Following Radiation Therapy in Patients With Stage 3 Unresectable NSCLC Ineligible for Chemotherapy | Non-small Cell Lung Cancer | Drug: Durvalumab | AstraZeneca | Phase 2 |

해외 바이오의약품 임상 현황 (2020.11.30~2020.12.6)

한국바이오의약품협회, 2020.12.8.
출처: ClinicalTrials.gov

○ 독일 9건

| NCT Number | Title | Conditions | Interventions | Sponsor/Collaborators | Phases |
|-------------|---|---|---|--|---------------------|
| NCT04652102 | A Study to Determine the Safety and Efficacy of SARS-CoV-2 mRNA Vaccine CVnCoV in Adults | Covid19 SARS-CoV-2 | Biological: CVnCoV Biological: Placebo | CureVac AG | Phase 2 Phase 3 |
| NCT04119440 | Safety and Immunogenicity of the Candidate Vaccine MVA-MERS-S_DF-1 Against MERS | MERS (Middle East Respiratory Syndrome) | Biological: MVA-MERS-S_DF1 - Low Dose Biological: MVA-MERS-S_DF1 - High Dose Other: Placebo | Universitätsklinikum Hamburg-Eppendorf Coalition for Epidemic Preparedness Innovations DT Biologika Dessau.Rossau German Center for Infection Research CR2O Clinical Trial Center North (CTC North GmbH & Co. KG) Erasmus Medical Center | Phase 1 |
| NCT04617691 | A Study of Intravenous Formulation of Guselkumab Using Prefilled Syringes and Final Vial Product in Healthy Participants | Healthy | Drug: Guselkumab | Janssen Research & Development, LLC | Phase 1 |
| NCT04622319 | A Study of Trastuzumab Deruxtecan (T-DXd) Versus Trastuzumab Emtansine (T-DM1) in High-risk HER2-positive Participants With Residual Invasive Breast Cancer Following Neoadjuvant Therapy (DESTINY-Breast05) | HER2-Positive Primary Breast Cancer Residual Invasive Breast Cancer | Drug: DS-8201a Drug: T-DM1 | Daichi Sankyo, Inc. AstraZeneca NSABP Foundation Inc German Breast Group Spanish Breast Cancer Research Group (SOLTI) | Phase 3 |
| NCT04589845 | Tumor-Agnostic Precision Immuno-Oncology and Somatic Targeting Rational for You (TAPISTRY) Platform Study | Solid Tumors | Drug: Entrectinib Drug: Alectinib Drug: Atezolizumab Drug: Ipatasertib Drug: Trastuzumab emtansine Drug: Idasanutlin Drug: GDC-0077 | Hoffmann-La Roche | Phase 2 |
| NCT04484142 | Study of DS-1062a in Advanced or Metastatic Non-small Cell Lung Cancer With Actionable Genomic Alterations (TROPION-Lung05) | Non-small Cell Lung Cancer | Drug: DS-1062a | Daichi Sankyo, Inc. AstraZeneca | Phase 2 |
| NCT04633447 | A Study to Evaluate Guselkumab for the Treatment of Participants With New-onset or Relapsing Giant Cell Arteritis | Giant Cell Arteritis | Drug: Guselkumab Drug: Placebo | Janssen Research & Development, LLC | Phase 2 |
| NCT04623775 | A Study of Relatlimab Plus Nivolumab in Combination With Chemotherapy vs. Nivolumab in Combination With Chemotherapy as First Line Treatment for Participants With Stage IV or Recurrent Non-small Cell Lung Cancer (NSCLC) | Non-small Cell Lung Cancer Recurrent Non-small Cell Lung Cancer Metastatic Non-small Cell Lung Cancer | Biological: Nivolumab Biological: Relatlimab Drug: Carboplatin Drug: Cisplatin Drug: Paclitaxel Drug: Nab-Paclitaxel Drug: Pemetrexed | Bristol-Myers Squibb | Phase 2 |
| NCT04616326 | A Study of Galcanezumab (LY2951742) in Participants 12 to 17 Years of Age With Chronic Migraine | Chronic Migraine | Drug: Galcanezumab Drug: Placebo | Eli Lilly and Company | Phase 3 |

○ 중국 33건

| NCT Number | Title | Conditions | Interventions | Sponsor/Collaborators | Phases |
|-------------|--|--|--|---|---------------------|
| NCT04637698 | OH2 Oncolytic Viral Therapy in Pancreatic Cancer | Pancreatic Cancer | Biological: OH2 injection | Wuhan Binhui Biotechnology Co., Ltd. | Phase 1 Phase 2 |
| NCT04616443 | OH2 Injection in Combination With HX008 for Melanoma. | Melanoma | Biological: OH2 injection Biological: HX008 injection | Wuhan Binhui Biotechnology Co., Ltd. | Phase 1 Phase 2 |
| NCT04612712 | A Phase 1/2 Study of Donafenib in Combination With KN046 in Advanced Gastrointestinal Tumors | Advanced Gastrointestinal Tumors | Drug: Donafenib Tosilate Tablets Biological: KN046 Injection | Suzhou Zelgen Biopharmaceuticals Co.,Ltd Jiangsu Alphamab Biopharmaceuticals Co., Ltd | Phase 1 Phase 2 |
| NCT04606303 | A Single-center, Prospective, Single-arm Phase II Trial of Neoadjuvant Toripalimab Plus Platinum-doublet Chemotherapy (Chemo) in Locally Advanced NSCLC. | Locally Advanced NSCLC | Drug: Toripalimab combination with platinum-containing dual-drug chemotherapy. | Beijing Cancer Hospital | Phase 1 Phase 2 |
| NCT04599452 | NK Cell Therapy Recurrent/Refractory Elderly AML | AML Recurrent Refractory Elderly | Biological: Allogeneic NK cell regimen group | The Second Hospital of Shandong University | Phase 1 Phase 2 |
| NCT04599426 | Allogeneic NK Cell Transfusion Azacitidine MDS-EB | MDS-EB | Biological: Allogeneic NK cell regimen group | The Second Hospital of Shandong University | Phase 1 Phase 2 |
| NCT04590118 | The Safety, Tolerability, and Preliminary Efficacy of It-hMSC in Ischemic Stroke Patients | Ischemic Stroke | Drug: it-hMSC Drug: Placebo | Jiuzhitang Maker (Beijing) Cell Technology Co.,Ltd Beijing Tiantan Hospital | Phase 1 Phase 2 |
| NCT04205435 | β-globin Restored Autologous HSC in β-thalassemia Major Patients | β-thalassemia Major | Biological: β-globin restored autologous HSC | Shanghai Bioray Laboratory Inc PLA 923 Hospital | Phase 1 Phase 2 |
| NCT04653389 | Perioperative Therapy for Hepatocellular Carcinoma | Hepatocellular Carcinoma | Drug: Sintilimab Injection Drug: TACE Radiation: Radiotherapy | Zhejiang University | Phase 2 |
| NCT04649476 | Neoadjuvant PD-1 Blockade in Resectable Oral Squamous Cell Carcinoma | Oral Squamous Cell Carcinoma | Drug: Camrelizumab Drug: Camrelizumab plus TPF | Hospital of Stomatology, Wuhan University Jiangsu HengRui Medicine Co., Ltd. | Phase 2 |
| NCT04649021 | Safety and Immunogenicity of SARS-CoV-2 mRNA Vaccine (BNT162b2) in Chinese Healthy Population | SARS-CoV-2 | Biological: BNT162b2 Other: Placebo | BioNTech SE Shanghai Fosun Pharmaceutical Development Co, Ltd. | Phase 2 |
| NCT04646590 | A Phase III Clinical Trial to Determine the Safety and Efficacy of ZF2001 for Prevention of COVID-19 | Prevention of COVID-19 Safety and Efficacy of COVID-19 | Biological: Recombinant new coronavirus vaccine (CHO cell) group Biological: Recombinant new coronavirus vaccine (CHO cells) placebo group | Anhui Zhifei Longcom Biologic Pharmacy Co., Ltd. | Phase 3 |
| NCT04625894 | The Combination of Immunotherapy and Stereotactic Ablative Radiotherapy in Oligometastatic Gastrointestinal Cancer | Oligometastatic Gastrointestinal Cancer | Radiation: Stereotactic Ablative Radiotherapy (SABR) Drug: Camrelizumab for injection (200 mg, iv), D1, Q2W, 14-day cycle | Fudan University | Phase 1 |
| NCT04625543 | Neoadjuvant Immunotherapy to ESCC | Esophagus SCC | Drug: Sintilimab Injection plus Paclitaxel and Cisplatin Drug: Paclitaxel and Cisplatin | Qilu Hospital of Shandong University | Phase 2 |
| NCT04623892 | A Study to Evaluate the Tolerance and Pharmacokinetics of TQB2618 Injection in Subjects With Advanced Solid Tumors | Advanced Solid Tumors | Drug: TQB2618 injection | Chia Tai Tianqing Pharmaceutical Group Co., Ltd. | Phase 1 |
| NCT04623333 | A Study of TQB2450 Injection in Subjects With PD-L1 Positive Recurrent or Metastatic Cervical Cancer | Recurrent or Metastatic Cervical Cancer | Drug: TQB2450 | Chia Tai Tianqing Pharmaceutical Group Co., Ltd. | Phase 2 |

해외 바이오의약품 임상 현황 (2020.11.30~2020.12.6)

한국바이오의약품협회, 2020.12.8.
출처: ClinicalTrials.gov

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|-------------|--|--|---|--|---------------------|
| NCT04613804 | Toripalimab as Maintenance Therapy in Patients With Driver-gene Negative Advanced NSCLC After First-line Chemotherapy | NSCLC Stage IV | Drug: Toripalimab Injection | Fujian Cancer Hospital | Phase 2 |
| NCT04612894 | Camrelizumab and Apatinib for Neoadjuvant Therapy in Thyroid Cancer | Thyroid Cancer | Drug: Camrelizumab and Apatinib Procedure: surgery Procedure: core needle biopsy | Fudan University | Phase 2 |
| NCT04570410 | Primary Excision Combined With Preoperative Neoadjuvant and Adjuvant Therapy for Oligometastasis of Urothelial Carcinoma | Bladder Urothelial Carcinoma | Procedure: primary focal resection plus lymph node dissection Drug: Tislelizumab Drug: Gemcitabine plus cisplatin | The First Affiliated Hospital with Nanjing Medical University | Phase 2 |
| NCT04535024 | The Combination of Immunotherapy and Stereotactic Ablative Radiotherapy in MSS Oligometastatic Colorectal Cancer | Colorectal Cancer | Radiation: Stereotactic Ablative Radiotherapy (SABR) Drug: Sintilimab | Fudan University | Phase 2 |
| NCT04517539 | Abscopal Effect of SBRT in Combination With rhGM-CSF and INF-α 2b for Metastatic Thymic Epithelial Tumors | Thymic Epithelial Tumor | Drug: rhGM-CSF , Peginterferon alfa-b2 , radiation | Shanghai Cancer Hospital, China | Phase 2 |
| NCT04469725 | KN046 (a Humanized PD-L1/CTLA4 Bispecific Single Domain Fc Fusion Protein Antibody) in Subjects With Thymic Carcinoma | Thymic Carcinoma | Drug: KN046 | Jiangsu Alphamab Biopharmaceuticals Co., Ltd | Phase 2 |
| NCT04449861 | Durvalumab Plus Chemotherapy in ES-SCLC (Oriental) | Small Cell Lung Carcinoma Extensive Disease | Drug: Durvalumab plus chemotherapy | AstraZeneca | Phase 3 |
| NCT04417166 | Pembrolizumab and Radiotherapy for Patients With NK/T Cell Lymphoma | Lymphoma, Extranodal NK-T-Cell | Drug: Pembrolizumab Radiation: Involved Field Radiation Therapy | International Extranodal Lymphoma Study Group (IELSG) | Phase 2 |
| NCT04211012 | A Study on Toripalimab Plus Nab-Paclitaxel With or Without Cisplatin as First-line Treatment of Urothelial Carcinoma | Urothelial Carcinoma | Drug: Toripalimab plus Nab-Paclitaxel +/- cisplatin | Jun Guo Beijing Cancer Hospital | Phase 2 |
| NCT03902067 | UC-MSC Transplantation for Left Ventricular Dysfunction After AMI | Left Ventricular Dysfunction Acute Myocardial Infarction | Biological: UC-MSC Biological: Control Group | Shanghai Life Science & Technology Shanghai Jiao Tong University Affiliated Sixth People's Hospital | Phase 1 |
| NCT04388033 | Clinical Study of an Dendritic and Glioma Cells Fusion Vaccine With IL-12 for Treatment-naïve GBM Patients. | Glioblastoma Glioma Neoplasms, Neuroepithelial Neuroectodermal Tumors Neoplasms Neoplasms, Nerve Tissue Vaccines Immunologic Factors | Biological: Dendritic Cell/Tumor Fusion Vaccine Drug: Interleukin-12 Drug: Temozolomide | Second Affiliated Hospital, School of Medicine, Zhejiang University Hangzhou Medical Biotechnology Co., Ltd CyTix.Inc | Phase 1 Phase 2 |
| NCT04624958 | Zanubrutinib and Rituximab Followed by R-DHAOx Then Maintenance With Zanubrutinib for Newly-Diagnosed MCL | Mantle Cell Lymphoma Newly-diagnosed Mantle Cell Lymphoma | Drug: Zanubrutinib and Rituximab Drug: R-DHAOx Drug: Zanubrutinib Maintenance | Sun Yat-sen University | Phase 2 |
| NCT04568304 | A Study Evaluating Toripalimab Injection Combined With Standard Chemotherapy as a First-line Treatment for Locally Advanced or Metastatic Urothelial Carcinoma | Locally Advanced or Metastatic Urothelial Carcinoma | Biological: Toripalimab Injection Drug: Gemcitabine Hydrochloride for Injection Drug: Cisplatin for Injection / Carboplatin Injection Drug: Placebo | Shanghai Junshi Bioscience Co., Ltd. | Phase 3 |
| NCT04518280 | The Combination of Immunotherapy and Neoadjuvant Short-course Radiotherapy in Locally Advanced Rectal Cancer | Locally Advanced Rectal Cancer | Drug: PD-1 antibody Drug: Capecitabine Drug: Oxaliplatin Radiation: Short-course radiotherapy | Fudan University | Phase 2 |
| NCT04591626 | A Study of Dulaglutide (LY2189265) in Chinese Participants With Type 2 Diabetes | Type 2 Diabetes Mellitus | Drug: Dulaglutide Drug: Placebo Drug: Insulin Glargine | Eli Lilly and Company | Phase 3 |
| NCT04622319 | A Study of Trastuzumab Deruxtecan (T-DXd) Versus Trastuzumab Emtansine (T-DM1) in High-risk HER2-positive Participants With Residual Invasive Breast Cancer Following Neoadjuvant Therapy (DESTINY-Breast05) | HER2-Positive Primary Breast Cancer Residual Invasive Breast Cancer | Drug: DS-8201a Drug: T-DM1 | Daiichi Sankyo, Inc. AstraZeneca NSABP Foundation Inc German Breast Group Spanish Breast Cancer Research Group (SOLTI) | Phase 3 |
| NCT04589845 | Tumor-Agnostic Precision Immuno-Oncology and Somatic Targeting Rational for You (TAPISTRY) Platform Study | Solid Tumors | Drug: Entrectinib Drug: Alectinib Drug: Atezolizumab Drug: Ipatasertib Drug: Trastuzumab emtansine Drug: Idasanutlin Drug: GDC-0077 | Hoffmann-La Roche | Phase 2 |

○ 일본 5건

| NCT Number | Title | Conditions | Interventions | Sponsor/Collaborators | Phases |
|-------------|--|---|----------------------------------|--|---------------------|
| NCT04649073 | Safety and Efficacy Study of OPC-415 in Patients With Relapsed and/or Refractory Multiple Myeloma | Multiple Myeloma (MM) | Biological: OPC-415 | Otsuka Pharmaceutical Co., Ltd. | Phase 1 Phase 2 |
| NCT04635423 | Efficacy, Immunogenicity, and Safety Study of the 9vHPV Vaccine in Japanese Males (V503-064) | Warts, Genital Neoplasms, Anal | Biological: V503 Other: Placebo | Merck Sharp & Dohme Corp. | Phase 3 |
| NCT04622319 | A Study of Trastuzumab Deruxtecan (T-DXd) Versus Trastuzumab Emtansine (T-DM1) in High-risk HER2-positive Participants With Residual Invasive Breast Cancer Following Neoadjuvant Therapy (DESTINY-Breast05) | HER2-Positive Primary Breast Cancer Residual Invasive Breast Cancer | Drug: DS-8201a Drug: T-DM1 | Daiichi Sankyo, Inc. AstraZeneca NSABP Foundation Inc German Breast Group Spanish Breast Cancer Research Group (SOLTI) | Phase 3 |
| NCT04616326 | A Study of Galcanezumab (LY2951742) in Participants 12 to 17 Years of Age With Chronic Migraine | Chronic Migraine | Drug: Galcanezumab Drug: Placebo | Eli Lilly and Company | Phase 3 |
| NCT04484142 | Study of DS-1062a in Advanced or Metastatic Non-small Cell Lung Cancer With Actionable Genomic Alterations (TROPION-Lung05) | Non-small Cell Lung Cancer | Drug: DS-1062a | Daiichi Sankyo, Inc. AstraZeneca | Phase 2 |