

해외 바이오의약품 임상 현황 ('23년 9월 4주)

한국바이오의약품협회, 2023.10.04.

※ ClinicalTrials.gov에 등록된 국가별 바이오의약품 임상시험 목록(병용요법 포함)을 한국바이오의약품협회에서 주간 업데이트하여 제공합니다.

URL을 클릭하시면 세부 정보 페이지로 연결됩니다.

- 출처: ClinicalTrials.gov
- 모니터링 기간: 2023.09.25.~2023.10.01.
- 주간 업데이트 제공국가 : 미국, 유럽(영국, 프랑스, 독일), 중국, 일본

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| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|---|--|---|-----------------|---|
| NCT06027879 | Anti-viral T-cell Therapy by Gamma Capture | Biological: Specific T- Lymphocytes | Paul Szabolcs University of Pittsburgh | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06027879&rank=1 |
| NCT06026657 | Gemcitabine and Ex Vivo Expanded Allogenic Universal Donor, TGFβi Natural Killer (NK) Cells With or Without Naxitamab (Danyelza) for the Treatment of Patients With Metastatic, GD2 Expressing, HER2 Negative Breast Cancer | Procedure: Biospecimen Collection Procedure: Computed Tomography Drug: Gemcitabine Procedure: Magnetic Resonance Imaging Biological: Naxitamab Biological: Universal Donor Expanded TGF-beta-imprinted NK Cells | Margaret Gatti-Mays Ohio State University Comprehensive Cancer Center | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06026657&rank=1 |
| NCT05957367 | A Study of DCC-3116 in Combination With Anticancer Therapies in Participants With Advanced Malignancies | Drug: DCC-3116 Drug: Ripretinib Drug: Cetuximab Drug: Encorafenib | Deciphera Pharmaceuticals LLC Pfizer | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05957367&rank=1 |
| NCT05920798 | A Study of FRaDCs for Ovarian Cancer | Procedure: Biopsy Procedure: Biospecimen Collection Procedure: Computed Tomography Procedure: Magnetic Resonance Imaging Biological: Multi-epitope Folate Receptor Alpha-loaded Dendritic Cell Vaccine Biological: Pembrolizumab Procedure: Pheresis | Mayo Clinic | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05920798&rank=1 |
| NCT05890729 | A Study of XTMAb-16 in Patients With Pulmonary Sarcoidosis | Drug: XTMAb-16 or Placebo | Xentria, Inc. | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05890729&rank=1 |
| NCT05845749 | Safety and Efficacy of Voxzogo for Growth Deficits in MPS IVA and VI | Drug: Vosoritide Injection [Voxzogo] | University of California, San Francisco | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05845749&rank=1 |
| NCT05756166 | Rintatolimod, Celecoxib and Interferon Alpha 2b With Pembrolizumab For the Treatment of Patients With Metastatic or Unresectable Triple Negative Breast Cancer | Procedure: Biopsy Procedure: Biospecimen Collection Drug: Celecoxib Procedure: Computed Tomography Biological: Interferon Alpha-2 Procedure: Magnetic Resonance Imaging Biological: Pembrolizumab Drug: Rintatolimod | Roswell Park Cancer Institute National Cancer Institute (NCI) | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05756166&rank=1 |
| NCT04129515 | NovoTTF-200A + Pembrolizumab In Melanoma Brain Metastasis | Device: NovoTTF-200A Drug: Pembrolizumab | Brown University NovoCure Ltd. | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT04129515&rank=1 |
| NCT03811886 | Natalizumab in Recurrent, Refractory or Progressive Pulmonary Metastatic Osteosarcoma | Drug: Natalizumab | Case Comprehensive Cancer Center | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT03811886&rank=1 |
| NCT05932199 | Neoadjuvant Durvalumab and Tremelimumab With and Without Chemotherapy for Mesothelioma | Drug: Durvalumab / tremelimumab Drug: Platinum cisplatin or carboplatin and pemetrexed chemotherapy plus durvalumab/tremelimumab | Baylor College of Medicine Duke Cancer Institute | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05932199&rank=1 |
| NCT06062966 | The Effects of IL-1 Blockade on Inotrope Sensitivity in Patients With Heart Failure (AID-HEART) | Drug: Anakinra | Virginia Commonwealth University | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT06062966&rank=1 |
| NCT06052176 | Hepatic Encephalopathy and Albumin Lasting Cognitive Improvement | Drug: Albumin | Hunter Holmes Mcguire Veteran Affairs Medical Center Grifols Biologicals, LLC | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06052176&rank=1 |

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|-----------------------------|---|--|--|---------|---|
| NCT06058663 | Radioembolization With Tremelimumab and Durvalumab for Locally Advanced, Unresectable Intrahepatic Cholangiocarcinoma | Procedure: Angiography Procedure: Biopsy Procedure: Biospecimen Collection Procedure: Computed Tomography Biological: Durvalumab Procedure: Magnetic Resonance Imaging Procedure: Positron Emission Tomography Biological: Tremelimumab Procedure: Yttrium-90 Microsphere Radioembolization | Mayo Clinic National Cancer Institute (NCI) | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT06058663&rank=1 |
| NCT06050915 | A Study of DISC-3405 in Healthy Volunteers | Drug: DISC-3405 Drug: Placebo | Disc Medicine, Inc | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT06050915&rank=1 |
| NCT06049576 | Nivolumab and Ipilimumab With and Without Camu Camu for the Treatment of Patients With Metastatic Renal Cell Carcinoma | Procedure: Biospecimen Collection Procedure: Bone Scan Procedure: Computed Tomography Biological: Ipilimumab Procedure: Magnetic Resonance Imaging Drug: Myrciaria dubia Prebiotic Supplement Biological: Nivolumab | City of Hope Medical Center National Cancer Institute (NCI) | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT06049576&rank=1 |
| NCT06048484 | Combination Therapy in Patients With Localized Pancreatic Ductal Adenocarcinoma | Radiation: Stereotactic body radiotherapy (SBRT) Drug: Zimberelimab Drug: Quemiclustat Drug: Etrumadenant Drug: Modified FOLFIRINOX | Gulam Manji Arcus Biosciences, Inc. Columbia University | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06048484&rank=1 |
| NCT06047886 | CD34 Selection Using the Automated CliniMACS Prodigy | Drug: Infusion of CD34 selected hematopoietic stem cells | University of Alabama at Birmingham | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT06047886&rank=1 |
| NCT06042725 | Venetoclax in Combination With Lenalidomide and Dexamethasone (Ven-Rd), Daratumumab and Dexamethasone (Ven-Dd), or Daratumumab-Lenalidomide-Dexamethasone (Ven-DRd) for the Treatment of Multiple Myeloma | Procedure: Biospecimen Collection Procedure: Bone Marrow Aspiration Procedure: Bone Marrow Biopsy Procedure: Chest Radiography Procedure: Computed Tomography Biological: Daratumumab Drug: Dexamethasone Drug: Lenalidomide Procedure: Low Dose Computed Tomography of the Whole Body Procedure: Magnetic Resonance Imaging Procedure: Positron Emission Tomography Drug: Venetoclax Procedure: X-Ray Imaging | Mayo Clinic | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT06042725&rank=1 |
| NCT06038526 | Evaluation of Canakinumab in High-Risk Former-Smokers | Procedure: Biospecimen Collection Procedure: Bronchoscopy Biological: Canakinumab Procedure: Carbon Monoxide Measurement Other: Survey Administration | Peter Shields Ohio State University Comprehensive Cancer Center | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06038526&rank=1 |
| NCT06027268 | Phase II Trial of Trilaciclib, Pembrolizumab, Gemcitabine and Carboplatin in Metastatic Triple-Negative Breast Cancer | Drug: Trilaciclib Drug: Pembrolizumab Drug: Gemcitabine Drug: Carboplatin | Wake Forest University Health Sciences Merck Sharp & Dohme LLC G1 Therapeutics, Inc. | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06027268&rank=1 |
| NCT06027229 | Additional Recombinant COVID-19 Humoral and Cell-Mediated Immunogenicity in Immunosuppressed Populations | Biological: NVX-CoV2372 | University of Wisconsin, Madison Novavax | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06027229&rank=1 |
| NCT06015724 | Anti-CD38 Antibody With KRAS Vaccine and Anti-PD-1 Antibody in Subjects With Pancreatic Ductal Adenocarcinoma and Refractory Non-Small Cell Lung Cancer | Drug: Daratumumab Biological: KRAS vaccine Drug: Nivolumab | Georgetown University Bristol-Myers Squibb Janssen, LP Targovax ASA | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06015724&rank=1 |

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|-----------------------------|---|--|--|---------|---|
| NCT06002503 | Safety, Reactogenicity and Immunogenicity of a Venezuelan Equine Encephalitis DNA Vaccine Candidate Administered by Jet Injection | Drug: Venezuelan Equine Encephalitis DNA Vaccine Device: PharmaJet Stratis Needle-free Injection System Device: PharmaJet Tropis Needle-free Injection System | PharmaJet, Inc. | Phase 1 | https://clinicaltrials.gov/ct2/show/study/NCT06002503 |
| NCT06001853 | Allogeneic BM-MSC's in Patients With Lumbar Facet Arthropathy | Drug: BM-MSC injection Drug: DSMO Injection | Mayo Clinic | Phase 2 | https://clinicaltrials.gov/ct2/show/study/NCT06001853 |
| NCT05981209 | Elotuzumab, CC-92480, and Dexamethasone for the Treatment of Relapsed or Refractory Myeloma After CD38- and BCMA-Targeted Therapies | Procedure: Biospecimen Collection Procedure: Bone Marrow Aspiration Procedure: Bone Marrow Biopsy Procedure: Computed Tomography Drug: Dexamethasone Procedure: Echocardiography Biological: Elotuzumab Procedure: Magnetic Resonance Imaging Biological: Mezigdomide Procedure: X-Ray Imaging | Abdullah Khan Ohio State University Comprehensive Cancer Center | Phase 1 | https://clinicaltrials.gov/ct2/show/study/NCT05981209 |
| NCT05973734 | Islet Transplantation With Recipient T-Reg Cells or Deceased Donor Vertebral Bone Marrow Therapy | Biological: Infusion of recipient T regulatory cell Biological: Infusion of concomitant Donor Derived Vertebral Bone Marrow | Stanford University University of California, San Francisco | Phase 1 | https://clinicaltrials.gov/ct2/show/study/NCT05973734 |
| NCT05956041 | Pembrolizumab and Mogamulizumab in Advanced-stage, Relapsed/Refractory Cutaneous T-cell Lymphomas | Drug: Pembrolizumab Drug: Mogamulizumab | University of Michigan Rogel Cancer Center Merck Sharp & Dohme LLC Hoosier Cancer Research Network | Phase 2 | https://clinicaltrials.gov/ct2/show/study/NCT05956041 |
| NCT05954143 | Trial of BDC-1001 +/- Pertuzumab in Subjects With HER2-Positive Metastatic Breast Cancer | Drug: BDC-1001 Drug: Pertuzumab | Bolt Biotherapeutics, Inc. Hoffmann-La Roche | Phase 2 | https://clinicaltrials.gov/ct2/show/study/NCT05954143 |
| NCT05948826 | First in Human Study of TORL-3-600 in Participants With Advanced Cancer | Drug: TORL-3-600 | TORL Biotherapeutics, LLC Translational Research in Oncology | Phase 1 | https://clinicaltrials.gov/ct2/show/study/NCT05948826 |
| NCT05928806 | Advanced Renal Cell Cancer Combination ImmunoTherapy Clinical Trial | Drug: Botensilimab Drug: Balstilimab Drug: Ipilimumab Drug: Nivolumab | Michael B. Atkins, MD Agenus Inc. Georgetown University Hoosier Cancer Research Network | Phase 2 | https://clinicaltrials.gov/ct2/show/study/NCT05928806 |
| NCT05922904 | PET Adapted Brentuximab Vedotin and Pembrolizumab in Combination With Doxorubicin and Dacarbazine in Classic Hodgkin Lymphoma | Drug: Brentuximab vedotin Drug: Doxorubicin Hydrochloride Drug: Pembrolizumab Drug: Dacarbazine | M.D. Anderson Cancer Center Merck Sharp & Dohme LLC Seagen Inc. | Phase 2 | https://clinicaltrials.gov/ct2/show/study/NCT05922904 |
| NCT05903092 | MONalIZumab in Combination With durvAlumab (MEDI4736) Plus Platinum-based chemotheRapy for First-line Treatment of Extensive Stage Small Cell Lung Cancer | Drug: Durvalumab Drug: Monalizumab Drug: Carboplatin or Cisplatin Drug: Etoposide | Hirva Mamdani AstraZeneca Barbara Ann Karmanos Cancer Institute Hoosier Cancer Research Network | Phase 2 | https://clinicaltrials.gov/ct2/show/study/NCT05903092 |
| NCT05901545 | Evaluating 111In Panitumumab for Nodal Staging in Head and Neck Cancer | Biological: Panitumumab Other: Indium In 111 Panitumumab Procedure: Single Photon Emission Computed Tomography Procedure: Computed Tomography Procedure: Surgical Procedure Other: Imaging agent Procedure: Intraoperative Imaging Procedure: Near Infrared Imaging Procedure: Electrocardiography Procedure: Biospecimen Collection | Vanderbilt-Ingram Cancer Center American Cancer Society, Inc. | Phase 1 | https://clinicaltrials.gov/ct2/show/study/NCT05901545 |

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|-----------------------------|--|--|--|---------|---|
| NCT05887882 | Intra-Tumoral Injections of Natural Killer Cells for Recurrent Malignant Brain Tumors | Biological: Universal Donor (UD) Transforming growth factor beta imprinting (TGFβi) Natural Killer (NK) Cells Procedure: Implantation | Sabine Mueller, MD, PhD Rally Foundation Washington University School of Medicine Nationwide Children's Hospital University of California, San Francisco | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT05887882&rank=1 |
| NCT05871970 | Safety and Efficacy Study of Intracystic TARA-002 for the Treatment of Lymphatic Malformations in Participants 6 Months to Less Than 18 Years of Age | Biological: TARA-002 | Protara Therapeutics | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05871970&rank=1 |
| NCT05870761 | Combination Niraparib and Dostarlimab Therapy for Recurrent or Persistent Uterine Serous Carcinoma | Procedure: Biospecimen Collection Procedure: Computed Tomography Biological: Dostarlimab Procedure: Magnetic Resonance Imaging Drug: Niraparib | Casey Cosgrove Ohio State University Comprehensive Cancer Center | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05870761&rank=1 |
| NCT05854498 | Liposomal Irinotecan With TAS102 and Bevacizumab for Patients With Metastatic Colorectal Cancer | Drug: Liposomal irinotecan Drug: TAS102 Drug: Bevacizumab | University of Wisconsin, Madison Ipsen | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05854498&rank=1 |
| NCT05834244 | A Phase Ib Trial of Azacitidine, Venetoclax and Allogeneic NK Cells for Acute Myeloid Leukemia (ADVENT-AML) | Drug: Azacitidine Drug: Venetoclax Drug: NK Cells | M.D. Anderson Cancer Center | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT05834244&rank=1 |
| NCT05812924 | A Novel Therapy for Breast Cancer Survivors With Genitourinary Syndrome of Menopause | Biological: Platelet-rich plasma (PRP) | University of Miami | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05812924&rank=1 |
| NCT05799612 | Phase I Study of TH1 Dendritic Cell Immunotherapy for the Treatment of Cutaneous Angiosarcoma | Drug: Paclitaxel Biological: mRNA plus Lysate-loaded Dendritic Cell Vaccine Drug: PEGYLATED-INTERFERON ALPHA-2A Drug: Filgrastim | M.D. Anderson Cancer Center Cancer Cures 4 Kids | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT05799612&rank=1 |
| NCT05799144 | pBI-11 & TA-HPV (With Pembrolizumab as Treatment for Patients w/Advanced, PD-L1 CPS≥1, hrHPV+ Oropharyngeal Cancer | Biological: DNA Vaccine Biological: Human Papillomavirus Tumor Antigen Vaccine Biological: Pembrolizumab Procedure: Computed Tomography (CT) Procedure: Magnetic Resonance Imaging (MRI) Procedure: Magnetic Resonance Imaging Procedure: Biopsy | Michael K. Gibson Vanderbilt-Ingram Cancer Center | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05799144&rank=1 |
| NCT05776979 | Post-Transplant Maintenance Therapy With Isatuximab Plus Lenalidomide for High-Risk Multiple Myeloma Patients | Drug: Isatuximab Drug: lenalidomide | M.D. Anderson Cancer Center Sanofi | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05776979&rank=1 |
| NCT05775471 | Pembrolizumab and Enfortumab Vedotin With Pembrolizumab Prior to and After Radical Nephroureterectomy for High-Risk Upper Tract Urothelial Cancer | Procedure: Biopsy Procedure: Biospecimen Collection Drug: Enfortumab Vedotin Procedure: MR Urography Procedure: Nephroureterectomy Biological: Pembrolizumab | Jonsson Comprehensive Cancer Center Merck Sharp & Dohme LLC Seagen Inc. | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05775471&rank=1 |
| NCT05770531 | Circulating Tumor DNA to Guide Changes in Standard of Care Chemotherapy | Procedure: Biospecimen Collection Procedure: Computed Tomography Procedure: Magnetic Resonance Imaging Biological: Sacituzumab Govitecan | Vanderbilt-Ingram Cancer Center National Cancer Institute (NCI) | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05770531&rank=1 |
| NCT05766371 | Pembrolizumab Plus 177Lu-PSMA-617 in Patients With Castration Resistant Prostate Cancer | Drug: Pembrolizumab Drug: 177Lu-PSMA-617 | University of California, San Francisco Merck Sharp & Dohme LLC Prostate Cancer Foundation | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05766371&rank=1 |

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|-----------------------------|--|--|--|---------|-----|
| NCT05757843 | Using Circulating Tumor DNA to Personalize Duration of Consolidation Durvalumab | Diagnostic Test: Signatera ctDNA test Drug: Durvalumab | Indiana University | Phase 2 | |
| NCT05681195 | Zanubrutinib With Pemetrexed to Treat Relapsed/Refractory Primary and Secondary Central Nervous System (CNS) Lymphomas | Drug: Pemetrexed Drug: Zanubrutinib Procedure: Autologous Stem Cell Transplant (ASCT) Radiation: Whole Brain Radiation Therapy (WBRT) | Baptist Health South Florida BeiGene | Phase 2 | |
| NCT05669846 | Responder-derived FMT (R-FMT) and Pembrolizumab in Relapsed/Refractory PD-L1 Positive NSCLC | Drug: Fecal Microbiota Transplant (FMT) Drug: Pembrolizumab | Diwakar Davar Gateway for Cancer Research University of Pittsburgh | Phase 2 | |
| NCT05629546 | Memory-Like Natural Killer Cells With Nivolumab and Relatlimab in Advanced or Metastatic Melanoma After Progression on Checkpoint Inhibitors | Biological: Memory-like natural killer cells Biological: Relatlimab Biological: Nivolumab | Washington University School of Medicine | Phase 1 | |
| NCT05537402 | LOcoregional vs Systemic Therapy in Patients With BCLC Stage B HCC | Drug: Atezolizumab and bevacizumab Radiation: transarterial chemoembolization (TACE) or transarterial radioembolization (TARE) | University of Texas Southwestern Medical Center Genentech, Inc. | Phase 2 | |
| NCT05534646 | Study of Apalutamide With Carotuximab in Metastatic, Castration-Resistant Prostate Cancer | Drug: Apalutamide Drug: Carotuximab | Edwin Posadas, MD Enviro Therapeutics, Inc. Cedars-Sinai Medical Center | Phase 2 | |
| NCT05491226 | Reinvigorating TNBC Response to Immunotherapy With Combination Myeloid Inhibition and Radiation | Drug: Pembrolizumab Radiation: Radiation Therapy Drug: Axatilimab | Stephen Shiao Merck Sharp & Dohme LLC Incyte Corporation Cedars-Sinai Medical Center | Phase 2 | |
| NCT05457959 | Peptide-Pulsed Dendritic Cell Vaccination in Combination With Nivolumab and Ipilimumab for the Treatment of Recurrent and/or Progressive Diffuse Hemispheric Glioma, H3 G34-mutant | Biological: Dendritic Cell Tumor Peptide Vaccine Biological: Ipilimumab Procedure: Leukapheresis Biological: Nivolumab Drug: Placebo Administration Drug: Poly ICLC Procedure: Resection | Jonsson Comprehensive Cancer Center | Phase 1 | |
| NCT04881240 | Study of CD19-directed Allogeneic Memory T-cell Therapy for Relapsed/Refractory CD19+ Leukemia | Biological: CD19-CAR(Mem) T-cells Drug: Cyclophosphamide Drug: Fludarabine Drug: Mesna Device: CliniMACS Procedure: Leukapheresis | St. Jude Children's Research Hospital | Phase 1 | |
| NCT04448106 | Autologous Adipose Tissue-Derived Mesenchymal Stem Cells (AdMSCs) for Osteoarthritis | Biological: Celltex- AdMSCs | Celltex Therapeutics Corporation | Phase 2 | |
| NCT03463239 | Bioengineered Penile Tissue Constructs for Irreversibly Damaged Penile Corpora | Biological: Autologous tissue engineered corpora | Wake Forest University Health Sciences United States Department of Defense | Phase 1 | |
| NCT06043674 | A Phase 2 Study of Glofitamab as Monotherapy or in Combination With Polatuzumab Vedotin or Atezolizumab in Richter's Transformation | Drug: Glofitamab Drug: Obinutuzumab Drug: Polatuzumab Vedotin Drug: Atezolizumab Drug: Tocilizumab | Matthew S. Davids, MD Genentech, Inc. Dana-Farber Cancer Institute | Phase 2 | |
| NCT06006013 | Cabozantinib in Combination With Atezolizumab for the Treatment of Patients With Locally Advanced, Metastatic, or Unresectable Adrenal Cortical Cancer | Biological: Atezolizumab Procedure: Biopsy Procedure: Biospecimen Collection Drug: Cabozantinib S-malate Procedure: Computed Tomography Procedure: Magnetic Resonance Imaging | Emory University National Cancer Institute (NCI) | Phase 2 | |
| NCT05706116 | Controlled Human Infection Study of Orally Administered Trichuris Trichiura Eggs in Naïve Adults | Biological: Trichuris trichiura Egg Inoculum | George Washington University National Institute of Allergy and Infectious Diseases (NIAID) | Phase 1 | |

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|-----------------------------|--|---|---|-----------------|---|
| NCT06052852 | Study of BDC-3042 as Single Agent and in Combination With Pembrolizumab in Patients With Advanced Malignancies | Drug: BDC-3042 Drug: Pembrolizumab | Bolt Biotherapeutics, Inc. | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06052852&rank=1 |
| NCT05814666 | Activity and Safety of Danvatirsén and Pembrolizumab in HNSCC | Drug: Danvatirsén Drug: Pembrolizumab | Flamingo Therapeutics NV | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05814666&rank=1 |
| NCT05715229 | Immune Profile Selection By Fraction of ctDNA in Patients With Advanced NSCLC Treated With Immunotherapy | Drug: Nivolumab Drug: Ipilimumab Drug: Carboplatin Drug: Paclitaxel Drug: Pemetrexed | Hackensack Meridian Health MedSIR | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05715229&rank=1 |
| NCT06014658 | Safety & PK of MBRC-101 in Advanced Refractory Solid Tumors | Drug: Antibody-Drug Conjugate | MBrace Therapeutics | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT06014658&rank=1 |
| NCT05973487 | A Basket Study of Customized Autologous TCR-T Cell Therapies in Patients With Locally Advanced (Unresectable) or Metastatic Solid Tumors | Biological: TSC-204-A0201 Biological: TSC-204-C0702 Biological: TSC-200-A0201 Biological: TSC-204-A0201 + TSC-204-C0702 Biological: TSC-204-A0201 + TSC-200-A0201 | TScan Therapeutics, Inc. | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT05973487&rank=1 |
| NCT05972135 | Outpatient Administration of Teclistamab for Multiple Myeloma | Drug: Teclistamab Drug: Tocilizumab | SCRI Development Innovations, LLC Janssen Research & Development, LLC | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05972135&rank=1 |
| NCT05835206 | Further MT for Antibiotic-Resistant Bacterial Colonization in Inpatients | Drug: Microbiome Therapeutic Drug: Placebo | Emory University Centers for Disease Control and Prevention | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05835206&rank=1 |
| NCT05987332 | IDE196 (Darovasertib) in Combination With Crizotinib as First-line Therapy in Metastatic Uveal Melanoma | Drug: IDE196 Drug: Crizotinib Drug: Pembrolizumab Drug: Ipilimumab Drug: Nivolumab Drug: Dacarbazine | IDEAYA Biosciences | Phase 2 Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05987332&rank=1 |
| NCT05984199 | Donor-Derived Anti-CD33 CAR T Cell Therapy (VCAR33) in Patients With Relapsed or Refractory AML After Allogeneic Hematopoietic Cell Transplant | Biological: VCAR33 | Vor Biopharma | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05984199&rank=1 |
| NCT06060457 | A Study to Evaluate the Safety and Immune Response of mRNA-1345, a Vaccine Targeting Respiratory Syncytial Virus (RSV), When Co-administered With a Fluzone HD, in Adults ≥65 Years of Age | Biological: Placebo Biological: mRNA-1345 Biological: Fluzone HD | ModernaTX, Inc. | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT06060457&rank=1 |
| NCT06045806 | A Study to Compare the Efficacy and Safety of Idecabtagene Vicleucel With Lenalidomide Maintenance Therapy Versus Lenalidomide Maintenance Therapy Alone in Adult Participants With Newly Diagnosed Multiple Myeloma Who Have Suboptimal Response After Autologous Stem Cell Transplantation | Biological: idecabtagene vicleucel Drug: Lenalidomide Drug: Fludarabine Drug: Cyclophosphamide | Bristol-Myers Squibb | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT06045806&rank=1 |
| NCT06045221 | A Study of Orforglipron (LY3502970) Compared With Semaglutide in Participants With Type 2 Diabetes Inadequately Controlled With Metformin | Drug: Orforglipron Drug: Semaglutide | Eli Lilly and Company | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT06045221&rank=1 |
| NCT06033196 | Tocilizumab in Lung Transplantation | Drug: Tocilizumab Drug: Placebo for Tocilizumab | National Institute of Allergy and Infectious Diseases (NIAID) | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06033196&rank=1 |

해외 바이오의약품 임상 현황 ('23년 9월 4주)

한국바이오의약품협회, 2023.10.04.

○ 미국 81건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|---|--|--|---------|---|
| NCT06007690 | A Phase 3 Randomized, Masked, Controlled Trial to Evaluate Efficacy and Safety of Belzupacap Sarotalocan (AU-011) Treatment Compared to Sham Control in Subjects With Primary Indeterminate Lesions or Small Choroidal Melanoma | Drug: Belzupacap Sarotalocan Device: Suprachoroidal Microinjector Device: Infrared Laser Device: Sham Infrared Laser Device: Sham Microinjector Drug: Sham Treatment | Aura Biosciences | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT06007690&rank=1 |
| NCT05949684 | ELEMENT-MDS: A Study to Compare the Efficacy and Safety of Luspatercept in Participants With Myelodysplastic Syndrome (MDS) and Anemia Not Receiving Blood Transfusions | Biological: Luspatercept Biological: Epoetin Alfa | Bristol-Myers Squibb | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05949684&rank=1 |
| NCT05878717 | A Study of the Efficacy and Safety of Belimumab in Adults With Systemic Sclerosis Associated Interstitial Lung Disease | Biological: Belimumab Other: Placebo | GlaxoSmithKline | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05878717&rank=1 |
| NCT05743270 | Study of RP3 in Combination With Nivolumab and Other Therapy in Patients With Locoregionally Advanced or Recurrent SCCHN | Biological: RP3 Other: CCRT(concurrent chemoradiation therapy) Other: carboplatin and paclitaxel Biological: nivolumab | Replimune Inc. Bristol-Myers Squibb | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05743270&rank=1 |
| NCT05873205 | Open-Label, Phase II Trial of Isatuximab for Patients With Refractory Immune Cytopenias After Allogeneic Hematopoietic Cell Transplantation | Biological: Isatuximab | Memorial Sloan Kettering Cancer Center Sanofi | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05873205&rank=1 |
| NCT05748197 | A Study of ADCLEC.syn1 in People With Acute Myeloid Leukemia | Biological: ADCLEC.syn1 CAR T cells Drug: Conditioning chemotherapy | Memorial Sloan Kettering Cancer Center Takeda | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT05748197&rank=1 |
| NCT05695391 | SCOPE HIM SCOPE HIM | Biological: Coagulation Factor VIIa (Recombinant) | Laboratoire français de Fractionnement et de Biotechnologies | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05695391&rank=1 |
| NCT05904886 | A Study Evaluating Atezolizumab and Bevacizumab, With or Without Tiragolumab, in Participants With Untreated Locally Advanced or Metastatic Hepatocellular Carcinoma (IMbrave152) | Drug: Atezolizumab Drug: Bevacizumab Drug: Tiragolumab Other: Placebo | Hoffmann-La Roche Chugai Pharmaceutical | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05904886&rank=1 |
| NCT05199688 | A Study To Evaluate Pharmacokinetics, Efficacy, Safety, Tolerability, And Pharmacodynamics Of Satralizumab In Pediatric Patients With Aquaporin-4 Antibody Positive Neuromyelitis Optica Spectrum Disorder (NMOSD) | Drug: Satralizumab | Hoffmann-La Roche | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05199688&rank=1 |

○ 영국 11건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|---|---|--|---------|---|
| NCT04856215 | 90Y-labelled Anti-CD66 ab in Childhood High Risk Leukaemia | Drug: 90-Yttrium-labelled anti-CD66 monoclonal antibody | Great Ormond Street Hospital for Children NHS Foundation Trust | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT04856215&rank=1 |
| NCT06052306 | A Study to Learn How Safe the Study Treatment Actinium-225-macropapulgifamab (BAY3546828) is, How it Affects the Body, How it Moves Into, Through and Out of the Body, and About Its Anticancer Activity in Men With Advanced Metastatic Castration-resistant Prostate Cancer (mCRPC) | Drug: BAY3546828 Drug: BAY2616505 Drug: BAY2315493 | Bayer | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT06052306&rank=1 |

해외 바이오의약품 임상 현황 ('23년 9월 4주)

한국바이오의약품협회, 2023.10.04.

○ 영국 11건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|--|--|--|---------|---|
| NCT05965479 | Developing ctDNA Guided Adjuvant Therapy for Gastroesophageal Cancer | Drug: Trastuzumab deruxtecan | University of Southampton AstraZeneca Natera, Inc. | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05965479&rank=1 |
| NCT05615818 | Personalized Medicine for Advanced Biliary Cancer Patients | Drug: Futibatinib Drug: Ivosidenib Drug: Zanidatamab Drug: Trastuzumab Drug: Neratinib Drug: Encorafenib Drug: Binimetinib Drug: Niraparib Drug: Cisplatin Drug: Gemcitabine | UNICANCER Cancer Research UK & UCL Cancer Trials Centre Belgian Group of Digestive Oncology National Cancer Institute, France Cancer Research UK 등 | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05615818&rank=1 |
| NCT06045806 | A Study to Compare the Efficacy and Safety of Idecabtagene Vicleucel With Lenalidomide Maintenance Therapy Versus Lenalidomide Maintenance Therapy Alone in Adult Participants With Newly Diagnosed Multiple Myeloma Who Have Suboptimal Response After Autologous Stem Cell Transplantation | Biological: idecabtagene vicleucel Drug: Lenalidomide Drug: Fludarabine Drug: Cyclophosphamide | Bristol-Myers Squibb | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT06045806&rank=1 |
| NCT05936359 | A Study to Evaluate INCA033989 Administered as a Monotherapy or in Combination With Ruxolitinib in Participants With Myeloproliferative Neoplasms | Drug: INCA033989 Drug: Ruxolitinib | Incyte Corporation | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT05936359&rank=1 |
| NCT05878717 | A Study of the Efficacy and Safety of Belimumab in Adults With Systemic Sclerosis Associated Interstitial Lung Disease | Biological: Belimumab Other: Placebo | GlaxoSmithKline | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05878717&rank=1 |
| NCT05257083 | A Study of Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucel Versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Autologous Stem Cell Transplant (ASCT) in Participants With Newly Diagnosed Multiple Myeloma | Drug: Daratumumab Drug: Bortezomib Drug: Lenalidomide Drug: Dexamethasone Drug: Cilta-cell Drug: Cyclophosphamide Drug: Fludarabine | European Myeloma Network Janssen Research & Development, LLC | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05257083&rank=1 |
| NCT05718297 | Brigatinib Post Definitive Chemoradiotherapy in Patients With ALK-fusion Non-small Cell Lung Cancer | Drug: Brigatinib Drug: Durvalumab | ETOP IBCSG Partners Foundation Takeda | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05718297&rank=1 |
| NCT05743270 | Study of RP3 in Combination With Nivolumab and Other Therapy in Patients With Locoregionally Advanced or Recurrent SCCHN | Biological: RP3 Other: CCRT(concurrent chemoradiation therapy) Other: carboplatin and paclitaxel Biological: nivolumab | Replimune Inc. Bristol-Myers Squibb | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05743270&rank=1 |
| NCT05199688 | A Study To Evaluate Pharmacokinetics, Efficacy, Safety, Tolerability, And Pharmacodynamics Of Satralizumab In Pediatric Patients With Aquaporin-4 Antibody Positive Neuromyelitis Optica Spectrum Disorder (NMOSD) | Drug: Satralizumab | Hoffmann-La Roche | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05199688&rank=1 |

○ 프랑스 13건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|--|--------------------------------|--|-----------------|---|
| NCT05654753 | The Efficacy of Fecal Microbiota Transplantation on Axial Spondyloarthritis Patients Resistant to Conventional Treatment | Drug: active FMT Drug: Placebo | Assistance Publique - Hôpitaux de Paris Fondation Arthritis & Clarins Worldwide 2016 | Phase 2 Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05654753&rank=1 |

해외 바이오의약품 임상 현황 ('23년 9월 4주)

한국바이오의약품협회, 2023.10.04.

○ 프랑스 13건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|--|--|--|---------|---|
| NCT06038331 | Use of a Treated, Devitalized and Sterile Umbilical Cord Amniotic Membrane in the Treatment of STT Osteoarthritis | Biological: SclerFIX-IP | TBF Genie Tissulaire | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06038331&rank=1 |
| NCT06034262 | Use of a Treated, Devitalized and Sterile Umbilical Cord Amniotic Membrane in the Treatment of PIP Joint Osteoarthritis | Biological: SclerFIX-IP | TBF Genie Tissulaire | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06034262&rank=1 |
| NCT05622071 | Testing Immunotherapy for Patients With Liver Cancer and Moderately Altered Liver Functions | Drug: Tislelizumab | UNICANCER | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05622071&rank=1 |
| NCT05615818 | Personalized Medicine for Advanced Biliary Cancer Patients | Drug: Futibatinib Drug: Ivosidenib Drug: Zanidatamab Drug: Trastuzumab Drug: Neratinib Drug: Encorafenib Drug: Binimetinib Drug: Niraparib Drug: Cisplatin Drug: Gemcitabine | UNICANCER Cancer Research UK & UCL Cancer Trials Centre Belgian Group of Digestive Oncology National Cancer Institute, France Cancer Research UK 등 | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05615818&rank=1 |
| NCT06045806 | A Study to Compare the Efficacy and Safety of Idecabtagene Vicleucel With Lenalidomide Maintenance Therapy Versus Lenalidomide Maintenance Therapy Alone in Adult Participants With Newly Diagnosed Multiple Myeloma Who Have Suboptimal Response After Autologous Stem Cell Transplantation | Biological: idecabtagene vicleucel Drug: Lenalidomide Drug: Fludarabine Drug: Cyclophosphamide | Bristol-Myers Squibb | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT06045806&rank=1 |
| NCT05949684 | ELEMENT-MDS: A Study to Compare the Efficacy and Safety of Luspatercept in Participants With Myelodysplastic Syndrome (MDS) and Anemia Not Receiving Blood Transfusions | Biological: Luspatercept Biological: Epoetin Alfa | Bristol-Myers Squibb | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05949684&rank=1 |
| NCT05257083 | A Study of Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucel Versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Autologous Stem Cell Transplant (ASCT) in Participants With Newly Diagnosed Multiple Myeloma | Drug: Daratumumab Drug: Bortezomib Drug: Lenalidomide Drug: Dexamethasone Drug: Cilta-cel Drug: Cyclophosphamide Drug: Fludarabine | European Myeloma Network Janssen Research & Development, LLC | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05257083&rank=1 |
| NCT05878717 | A Study of the Efficacy and Safety of Belimumab in Adults With Systemic Sclerosis Associated Interstitial Lung Disease | Biological: Belimumab Other: Placebo | GlaxoSmithKline | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05878717&rank=1 |
| NCT05743270 | Study of RP3 in Combination With Nivolumab and Other Therapy in Patients With Locoregionally Advanced or Recurrent SCCHN | Biological: RP3 Other: CCRT(concurrent chemoradiation therapy) Other: carboplatin and paclitaxel Biological: nivolumab | Replimune Inc. Bristol-Myers Squibb | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05743270&rank=1 |
| NCT05718297 | Brigatinib Post Definitive Chemo-radiotherapy in Patients With ALK-fusion Non-small Cell Lung Cancer | Drug: Brigatinib Drug: Durvalumab | ETOP IBCSG Partners Foundation Takeda | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05718297&rank=1 |
| NCT05936359 | A Study to Evaluate INCA033989 Administered as a Monotherapy or in Combination With Ruxolitinib in Participants With Myeloproliferative Neoplasms | Drug: INCA033989 Drug: Ruxolitinib | Incyte Corporation | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT05936359&rank=1 |

해외 바이오의약품 임상 현황 ('23년 9월 4주)

한국바이오의약품협회, 2023.10.04.

○ 프랑스 13건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|--|--------------------|-----------------------|---------|---|
| NCT05199688 | A Study To Evaluate Pharmacokinetics, Efficacy, Safety, Tolerability, And Pharmacodynamics Of Satralizumab In Pediatric Patients With Aquaporin-4 Antibody Positive Neuromyelitis Optica Spectrum Disorder (NMOSD) | Drug: Satralizumab | Hoffmann-La Roche | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05199688&rank=1 |

○ 독일 7건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|--|---|--|---------|---|
| NCT05937295 | FusionVAC22_01: Fusion Transcript-based Peptide Vaccine Combined With Immune Checkpoint Inhibition | Drug: Fusion-VAC-XS15 | University Hospital Tuebingen | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT05937295&rank=1 |
| NCT06045806 | A Study to Compare the Efficacy and Safety of Idecabtagene Vicleucel With Lenalidomide Maintenance Therapy Versus Lenalidomide Maintenance Therapy Alone in Adult Participants With Newly Diagnosed Multiple Myeloma Who Have Suboptimal Response After Autologous Stem Cell Transplantation | Biological: iclecabtagene vicleucel Drug: Lenalidomide Drug: Fludarabine Drug: Cyclophosphamide | Bristol-Myers Squibb | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT06045806&rank=1 |
| NCT05949684 | ELEMENT-MDS: A Study to Compare the Efficacy and Safety of Luspatercept in Participants With Myelodysplastic Syndrome (MDS) and Anemia Not Receiving Blood Transfusions | Biological: Luspatercept Biological: Epoetin Alfa | Bristol-Myers Squibb | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05949684&rank=1 |
| NCT05257083 | A Study of Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucel Versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Autologous Stem Cell Transplant (ASCT) in Participants With Newly Diagnosed Multiple Myeloma | Drug: Daratumumab Drug: Bortezomib Drug: Lenalidomide Drug: Dexamethasone Drug: Cilta-cell Drug: Cyclophosphamide Drug: Fludarabine | European Myeloma Network Janssen Research & Development, LLC | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05257083&rank=1 |
| NCT05878717 | A Study of the Efficacy and Safety of Belimumab in Adults With Systemic Sclerosis Associated Interstitial Lung Disease | Biological: Belimumab Other: Placebo | GlaxoSmithKline | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05878717&rank=1 |
| NCT05743270 | Study of RP3 in Combination With Nivolumab and Other Therapy in Patients With Locoregionally Advanced or Recurrent SCCHN | Biological: RP3 Other: CCRT(concurrent chemoradiation therapy) Other: carboplatin and paclitaxel Biological: nivolumab | Replimune Inc. Bristol-Myers Squibb | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05743270&rank=1 |
| NCT05936359 | A Study to Evaluate INCA033989 Administered as a Monotherapy or in Combination With Ruxolitinib in Participants With Myeloproliferative Neoplasms | Drug: INCA033989 Drug: Ruxolitinib | Incyte Corporation | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT05936359&rank=1 |

○ 중국 23건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|---|--|-------------------------------|-----------------|---|
| NCT06041035 | A Study of QLS31905 Combination Chemotherapy as First-Line Treatment in Patients With Advanced Solid Tumors | Drug: QLS31905 Drug: Nab paclitaxel Drug: Gemcitabine Drug: Oxaliplatin Drug: Capecitabine Drug: Cisplatin | Qilu Pharmaceutical Co., Ltd. | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06041035&rank=1 |

해외 바이오의약품 임상 현황 ('23년 9월 4주)

한국바이오의약품협회, 2023.10.04.

○ 중국 23건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|---|--|---|-----------------|---|
| NCT05985863 | Human Umbilical Cord Mesenchymal Stem Cell Transplantation for The Treatment of Acute-on-Chronic Liver Failure | Drug: standard medical treatment Drug: Placebo Drug: hUC- MSC Drug: hUC- MSC_Prolonged | Beijing 302 Hospital Shulan (Hang Zhou) Hospital Beijing Youan Hospital Shenzhen Third People's Hospital Shen Zhen Wingor Biotechnology CO. LTD | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05985863&rank=1 |
| NCT06062641 | Selinexor Combined With R-GDP Regimen for TP53-altered R/R DLBCL | Drug: SR-GDP | Ruijin Hospital | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06062641&rank=1 |
| NCT06056752 | QH103 Cell Injection for the Treatment of Relapsed/Refractory B-cell Acute Lymphoblastic Leukemia | Biological: QH103 Cell Injection Drug: Fludarabine Drug: Cyclophosphamide | Anhui Provincial Hospital | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT06056752&rank=1 |
| NCT06055816 | Gemcitabine Combined With Endostar and Envafoimab in Elderly Patients With Locally Advanced Nasopharyngeal Carcinoma | Drug: Endostar and Envafoimab | Zhejiang Cancer Hospital | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06055816&rank=1 |
| NCT06054906 | Neoadjuvant of Sintilimab Combined Weekly Metronomic Chemotherapy (PLOF) for Resectable Locally Advanced Gastric Cancer | Drug: sintilimab+metronomic PLOF | Huashan Hospital | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06054906&rank=1 |
| NCT06047080 | An Open-Label Study Comparing Glofitamab and Polatuzumab Vedotin + Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone Versus Pola-R-CHP in Previously Untreated Patients With Large B-Cell Lymphoma | Drug: Glofitamab Drug: Polatuzumab vedotin Drug: Rituximab Drug: Cyclophosphamide Drug: Doxorubicin Drug: Prednisone | Hoffmann-La Roche | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT06047080&rank=1 |
| NCT06038058 | A Phase I Study of BRY812 for Injection Alone in Subjects With Advanced Malignancies | Drug: BRY812 for injection | BioRay Pharmaceutical Co., Ltd. | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT06038058&rank=1 |
| NCT06028633 | Efficacy and Safety of Nab-paclitaxel-Lenvatinib-Pembrolizumab as Second-line Treatment in Advanced NSCLC Patients | Drug: pembrolizumab Drug: lenvatinib Drug: albumin-bound paclitaxel | Peking University First Hospital Merck Sharp & Dohme LLC | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06028633&rank=1 |
| NCT06010875 | A Clinical Research About CD70-targeted CAR-T in the Treatment of CD70-positive Advanced/Metastatic Solid Tumors | Biological: CD70 CAR-T cells | Chongqing Precision Biotech Co., Ltd The First Affiliated Hospital of Nanchang University | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT06010875&rank=1 |
| NCT06010862 | Clinical Study of CEA-targeted CAR-T Therapy for CEA-positive Advanced/Metastatic Malignant Solid Tumors | Biological: CEA CAR-T cells | Chongqing Precision Biotech Co., Ltd The First Affiliated Hospital of Nanchang University | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT06010862&rank=1 |
| NCT05979155 | A Study of NWY001 in Subjects With Advanced Solid Tumors | Biological: NWY001 | Chipscreen Biosciences, Ltd. | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT05979155&rank=1 |
| NCT05975151 | Efficacy and Safety of Pseudomonas Aeruginosa for Intermediate and High-risk Non-muscle Invasive Bladder Cancer | Drug: Pseudomonas aeruginosa | Qilu Hospital of Shandong University | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05975151&rank=1 |
| NCT05952947 | HRYZ-T101 Injection for HPV18 Positive Solid Tumor | Biological: HRYZ-T101 Injection Drug: Fludarabine + Cyclophosphamide | SYZ Cell Therapy Co.. | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT05952947&rank=1 |
| NCT05881668 | MSC-EV in Acute-on-Chronic Liver Failure After Liver Transplantation | Biological: MSC-EV | Third Affiliated Hospital, Sun Yat-Sen University | Phase 1 | https://clinicaltrials.gov/ct2/show/study?term=NCT05881668&rank=1 |

해외 바이오의약품 임상 현황 ('23년 9월 4주)

한국바이오의약품협회, 2023.10.04.

○ 중국 23건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|---|--|---|---------|---|
| NCT05894889 | Pembrolizumab and Chemotherapy Neoadjuvant/Adjuvant of NSCLC | Biological: Pembrolizumab 200 mg IV infusion | Peking University Merck Sharp & Dohme LLC Shanghai Pulmonary Hospital, Shanghai, China Guangdong Provincial People's Hospital Cancer Institute and Hospital, Chinese Academy of Medical Sciences | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05894889&rank=1 |
| NCT05624099 | Camrelizumab Combined With Chemoradiotherapy in Advanced Esophageal Cancer. | Drug: camrelizumab Drug: Paclitaxel drugs Drug: Platinum drug Radiation: Radiation | Fujian Cancer Hospital | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05624099&rank=1 |
| NCT05996224 | Allogenic Adipose-Derived Mesenchymal Progenitor Cells for the Treatment of Knee Osteoarthritis | Biological: Mesenchymal progenitor cells Drug: Sodium Hyaluronate Injection | Cellular Biomedicine Group Ltd. | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05996224&rank=1 |
| NCT06036927 | A Clinical Study of TQC2731 Injection in the Treatment of Chronic Rhinosinusitis With Nasal Polyps | Drug: TQC2731 injection Drug: TQC2731 matching placebo | Chia Tai Tianqing Pharmaceutical Group Co., Ltd. | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT06036927&rank=1 |
| NCT05998759 | Telitacicept for the Treatment of Connective Tissue Disease-associated Thrombocytopenia | Biological: Telitacicept Drug: Placebo | Beijing Hospital The First Affiliated Hospital of China University of Science and Technology (Anhui Provincial) Peking University People's Hospital Peking University Third Hospital First Affiliated Hospital, Sun Yat-Sen University Guangdong Provincial People's Hospital | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05998759&rank=1 |
| NCT06045221 | A Study of Orforglipron (LY3502970) Compared With Semaglutide in Participants With Type 2 Diabetes Inadequately Controlled With Metformin | Drug: Orforglipron Drug: Semaglutide | Eli Lilly and Company | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT06045221&rank=1 |
| NCT05949684 | ELEMENT-MDS: A Study to Compare the Efficacy and Safety of Luspatercept in Participants With Myelodysplastic Syndrome (MDS) and Anemia Not Receiving Blood Transfusions | Biological: Luspatercept Biological: Epoetin Alfa | Bristol-Myers Squibb | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05949684&rank=1 |
| NCT05878717 | A Study of the Efficacy and Safety of Belimumab in Adults With Systemic Sclerosis Associated Interstitial Lung Disease | Biological: Belimumab Other: Placebo | GlaxoSmithKline | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT05878717&rank=1 |

○ 일본 7건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|---|--|---|---------|---|
| NCT05879653 | Pembrolizumab and EV With Radiation Therapy for MIBC Patients (PEVRAD) | Drug: MK-3475 Drug: ASG-22CE Procedure: maximal TURBT Radiation: Radiation therapy | Kyoto University Hospital University of Tsukuba Osaka Metropolitan University Kobe City Medical Center General Hospital Merck Sharp & Dohme LLC Astellas Pharma Inc | Phase 2 | https://clinicaltrials.gov/ct2/show/study?term=NCT05879653&rank=1 |
| NCT06002490 | A Study to Evaluate P1101 in Japanese PV Patients | Drug: P1101 Drug: Low-dose aspirin Procedure: Phlebotomy | PharmaEssentia Japan K.K. | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT06002490&rank=1 |
| NCT06045221 | A Study of Orforglipron (LY3502970) Compared With Semaglutide in Participants With Type 2 Diabetes Inadequately Controlled With Metformin | Drug: Orforglipron Drug: Semaglutide | Eli Lilly and Company | Phase 3 | https://clinicaltrials.gov/ct2/show/study?term=NCT06045221&rank=1 |

해외 바이오의약품 임상 현황 ('23년 9월 4주)

한국바이오의약품협회, 2023.10.04.

○ 일본 7건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|--|---|--|---------|---|
| NCT06045806 | A Study to Compare the Efficacy and Safety of Idecabtagene Vicleucel With Lenalidomide Maintenance Therapy Versus Lenalidomide Maintenance Therapy Alone in Adult Participants With Newly Diagnosed Multiple Myeloma Who Have Suboptimal Response After Autologous Stem Cell Transplantation | Biological: iclecabtagene vicleucel Drug: Lenalidomide Drug: Fludarabine Drug: Cyclophosphamide | Bristol-Myers Squibb | Phase 3 | https://clinicaltrials.gov/ct2/show/study/NCT06045806 |
| NCT05257083 | A Study of Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucel Versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Autologous Stem Cell Transplant (ASCT) in Participants With Newly Diagnosed Multiple Myeloma | Drug: Daratumumab Drug: Bortezomib Drug: Lenalidomide Drug: Dexamethasone Drug: Cilta-cell Drug: Cyclophosphamide Drug: Fludarabine | European Myeloma Network Janssen Research & Development, LLC | Phase 3 | https://clinicaltrials.gov/ct2/show/study/NCT05257083 |
| NCT05878717 | A Study of the Efficacy and Safety of Belimumab in Adults With Systemic Sclerosis Associated Interstitial Lung Disease | Biological: Belimumab Other: Placebo | GlaxoSmithKline | Phase 3 | https://clinicaltrials.gov/ct2/show/study/NCT05878717 |
| NCT05936359 | A Study to Evaluate INCA033989 Administered as a Monotherapy or in Combination With Ruxolitinib in Participants With Myeloproliferative Neoplasms | Drug: INCA033989 Drug: Ruxolitinib | Incyte Corporation | Phase 1 | https://clinicaltrials.gov/ct2/show/study/NCT05936359 |