

해외 바이오의약품 임상 현황 ('24년 1월 4주)

한국바이오의약품협회, 2024.02.06.

※ 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: 2024.01.29.~2024.02.04.
- 주간 업데이트 제공국가 : 미국, 유럽(영국, 프랑스, 독일), 중국, 일본

○ 미국 57건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06238921	SG and Zimberelimab w/SRS in the Management of Metastatic Triple Negative BCBM	Radiation: Stereotactic Radiation Drug: Zimberelimab Drug: Sacituzumab govitecan	H. Lee Moffitt Cancer Center and Research Institute Gilead Sciences	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06238921
NCT06110572	Phase I/II Trial in ES-SCLC to Enhance Response to Atezolizumab Plus Chemotherapy With Total Body Irradiation	Drug: Carboplatin Biological: Atezolizumab Drug: Etoposide Radiation: Total Body Irradiation Radiation: Hypofractionated Radiation Therapy Procedure: Magnetic Resonance Imaging	Vanderbilt-Ingram Cancer Center Genentech, Inc.	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06110572
NCT06027086	DRP-104 (Glutamine Antagonist) in Combination With Durvalumab in Patients With Advanced Stage Fibrolamellar Carcinoma (FLC)	Drug: Durvalumab Drug: DRP-104	Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Dracen Pharmaceuticals, Inc. Fibrolamellar Cancer Foundation	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06027086
NCT05746039	Feasibility of Semaglutide in Advanced Lung Disease	Drug: Semaglutide Pen Injector	University of Pennsylvania	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05746039
NCT05669352	A Study of Oral IRAK-4 Inhibitor CA-4948 in Combination With Pembrolizumab Following Stereotactic Radiosurgery in Patients With Melanoma Brain Metastases	Drug: CA-4948 Drug: Pembrolizumab	University of Florida Merck Sharp & Dohme LLC	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05669352
NCT06199531	Safety and Efficacy of GS-100 Gene Therapy in Patients With NGLY1 Deficiency	Genetic: GS-100	Grace Science, LLC	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06199531
NCT06238648	Epcoritamab Compared to Observation for Treating B-cell Lymphoma Patients Not in Complete Remission After CD19-directed CAR-T Therapy	Procedure: Biopsy Procedure: Biospecimen Collection Procedure: Computed Tomography Biological: Epcoritamab Procedure: Magnetic Resonance Imaging Other: Patient Observation Procedure: Positron Emission Tomography	Academic and Community Cancer Research United	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06238648
NCT06236425	TBio-4101 and Pembro wi/ or w/o Chemo in Recurrent/Metastatic HNSCC	Biological: TBio-4101 Drug: Pembrolizumab Drug: Platinum based chemotherapy Drug: Cyclophosphamide Drug: Fludarabine Drug: Aldesleukin	H. Lee Moffitt Cancer Center and Research Institute Turnstone Biologics, Corp.	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06236425
NCT06223009	Phase 1 Healthy Volunteer Burn Therapy Study	Drug: cNP8 Other: Placebo	Neomatrix Therapeutics, Inc. United States Department of Defense	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06223009
NCT06218303	Prototype DAA/TAA Vaccine Targeting MUC1 for Immune Interception and Prevention in Ductal Carcinoma In Situ	Biological: MUC1 Peptide Vaccine Drug: Hiltonol® Drug: Aromatase Inhibitor	Finn, Olivera, PhD A Glimmer of Hope Foundation Breast Cancer Research Foundation University of Pittsburgh	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06218303
NCT06179511	Study of AZD9829 in CD123+ Hematological Malignancies	Drug: AZD9829	AstraZeneca	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06179511

해외 바이오의약품 임상 현황 ('24년 1월 4주)

한국바이오의약품협회, 2024.02.06.

○ 미국 57건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06209619	CC-99282 + Rituximab Early Post CART for Non-Hodgkin's Lymphoma	Procedure: Biopsy Procedure: Biospecimen Collection Procedure: Computed Tomography Drug: Golcadomide Procedure: Positron Emission Tomography Biological: Rituximab	Nathan Denlinger Bristol-Myers Squibb Ohio State University Comprehensive Cancer Center	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06209619
NCT06205849	Intra-tumoral Mitazalimab (CD40 Antibody) With Irreversible Electroporation (IRE) in Locally Advanced Pancreas Cancer	Drug: IRE + intratumoral mitazalimab (CD40 antibody) injection Device: NanoKnife	University of California, San Diego University of California, Los Angeles National Cancer Institute (NCI)	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06205849
NCT06191887	B-Cell Activating Factor Receptor (BAFFR)-Based Chimeric Antigen Receptor T-Cells With Fludarabine and Cyclophosphamide Lymphodepletion for the Treatment of Relapsed or Refractory B-cell Hematologic Malignancies	Biological: Autologous BAFFR-targeting CAR T Cells Drug: Bendamustine Procedure: Biopsy Procedure: Biospecimen Collection Procedure: Bone Marrow Aspiration and Biopsy Procedure: Computed Tomography Drug: Cyclophosphamide Procedure: Echocardiography Drug: Fludarabine Procedure: Leukapheresis Procedure: Magnetic Resonance Imaging Procedure: Positron Emission Tomography	Mayo Clinic	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06191887
NCT06186219	Recapturing Immune Tolerance to Pegloticase for the Management of Tophaceous Gout	Drug: Rituximab	University of California, Los Angeles	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06186219
NCT06148181	A Study to Evaluate Adverse Events and How Single Ascending Doses of ABBV-141 Move Through the Body of Healthy Adult Western and Asian Participants	Drug: ABBV-141 Drug: Placebo for ABBV-141	AbbVie	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06148181
NCT06138132	A Study of Anti-CD19 Chimeric Antigen Receptor T-Cell (CAR-T) Therapy in Subjects With Non-relapsing and Progressive Forms of Multiple Sclerosis	Biological: KYV-101 anti-CD19 CAR-T cell therapy Drug: Standard lymphodepletion regimen	Stanford University Kyverna Therapeutics	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06138132
NCT06137157	Evaluation of Topical ATR12-351 in Adults With Netherton Syndrome	Drug: ATR12-351	Azitra Inc.	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06137157
NCT06237881	A Phase 1/2 Study of KSQ-001EX, Autologous Tumor Infiltrating Lymphocytes Engineered to Inactivate the SOCS1 Gene, in Patients With Select Advanced Solid Tumors	Drug: KSQ-001EX Drug: Interleukin-2 Drug: Cyclophosphamide Drug: Fludarabine	M.D. Anderson Cancer Center KSQ Therapeutics, Inc.	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06237881
NCT06083883	Phase I/Ib Study of NK Expressing an Affinity-enhanced T-cell Receptor (TCR) Against the NY-ESO-1	Drug: Fludarabine phosphate Drug: NY-ESO-1 TCR/IL-15 NK Drug: Cyclophosphamide	M.D. Anderson Cancer Center	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06083883
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/NCT06042725

해외 바이오의약품 임상 현황 ('24년 1월 4주)

한국바이오의약품협회, 2024.02.06.

○ 미국 57건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06030037	Pembrolizumab/Lenvatinib With and Without Responder-derived FMT in Relapsed/Refractory Melanoma	Biological: Responder-Derived Fecal microbiota transplantation (R-FMT) Drug: Pembrolizumab Drug: Lenvatinib	Diwakar Davar Merck Sharp & Dohme LLC Gateway for Cancer Research University of Pittsburgh	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06030037
NCT05961709	The Phoenix Trial: Phase II Trial of Cemiplimab for the Non-operative Management of Localized dMMR Colon Cancer	Drug: Cemiplimab	M.D. Anderson Cancer Center Regeneron Pharmaceuticals	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05961709
NCT05913388	GB1211 and Pembrolizumab Versus Pembrolizumab and Placebo in Patients With Metastatic Melanoma and Head and Neck Squamous Cell Carcinoma	Drug: GB1211 Drug: Pembrolizumab Drug: Placebo	Providence Health & Services Providence Cancer Center Providence Cancer Center, Earle A. Chiles Research Institute Galeto Biotech AB	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05913388
NCT05887167	Feasibility and Safety of Collecting and Combining Autologous Hematopoietic Stem Cells With Chimeric Antigen Receptor (CAR) T-Cell Therapy in Subjects With Relapsed/Refractory Hematological Malignancies	Biological: autologous hematopoietic stem cells added to planned CAR T	Joshua Sasine, MD, PhD Cedars-Sinai Medical Center	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05887167
NCT05854966	CPI-613 Given With Metformin in Patients With Relapsed or Refractory Acute Myeloid Leukemia (AML)	Drug: CPI 613 Drug: Metformin Biological: Blood draws Procedure: Bone marrow biopsy	Wake Forest University Health Sciences National Cancer Institute (NCI) Cornerstone Pharmaceuticals	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05854966
NCT05707702	Lactobacillus Lozenges as Preventative Care in Low-grade Dysplasia	Biological: Probiotic oral lozenges Other: Standard of care for oral dysplasia	Boston Medical Center University of Alabama at Birmingham	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05707702
NCT05664113	Feasibility, Safety, and Potential Efficacy of Fecal Microbiota Transplantation (FMT) for Gastrointestinal Dysfunction in Children Following Hematopoietic Cell Transplant (HCT).	Drug: Fecal microbiota transplant (FMT)	St. Jude Children's Research Hospital	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05664113
NCT05609994	ViCToRy: Vorasidenib in Combination With Tumor Specific Peptide Vaccine for Recurrent IDH1 Mutant Lower Grade Gliomas	Drug: PEPIDH1M vaccine + vorasidenib	Katy Peters, MD, PhD Servier Duke University	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05609994
NCT05546723	LMY-920 for Treatment of Relapsed or Refractory Myeloma	Biological: Autologous CAR-T cell therapy expressing the BAFF-ligand.	Luminary Therapeutics The Cleveland Clinic Case Western Reserve University	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05546723
NCT05375825	Phase I Evaluation of Immunotoxin LMB-100 Administered by Normothermic, Intrapleural Perfusion Following Cytoreductive Surgery in Participants With Pleural Mesotheliomas, or Pleural Effusions From Cancers Expressing Mesothelin	Procedure: Cytoreductive surgery Drug: LMB-100 Diagnostic Test: Immunohistochemical Assay for Mesothelin	National Cancer Institute (NCI) National Institutes of Health Clinical Center (CC)	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05375825
NCT05264974	Novel RNA-nanoparticle Vaccine for the Treatment of Early Melanoma Recurrence Following Adjuvant Anti-PD-1 Antibody Therapy	Biological: Autologous total tumor mRNA loaded DOTAP liposome vaccine	University of Florida	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05264974
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	https://clinicaltrials.gov/ct2/show/study/NCT04881240

해외 바이오의약품 임상 현황 ('24년 1월 4주)

한국바이오의약품협회, 2024.02.06.

○ 미국 57건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT04579523	²¹¹ At-OKT10-B10 and Fludarabine Alone or in Combination With Cyclophosphamide and Low-Dose TBI Before Donor Stem Cell Transplant for the Treatment of Newly Diagnosed, Recurrent, or Refractory High-Risk Multiple Myeloma	Procedure: Allogeneic Hematopoietic Stem Cell Transplantation Biological: Astatine At 211 Anti-CD38 Monoclonal Antibody OKT10-B10 Drug: Cyclophosphamide Drug: Fludarabine Phosphate Radiation: Total-Body Irradiation	Fred Hutchinson Cancer Center National Cancer Institute (NCI)	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT04579523
NCT03988283	Neopeptide-based Personalized DNA Vaccine Approach in Pediatric Patients With Recurrent Brain Tumors	Biological: Personalized neoantigen DNA vaccine Device: Ichor TDS-IM v2.0 Procedure: Peripheral blood draw	Washington University School of Medicine Children's Discovery Institute	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT03988283
NCT06228326	A Study Assessing KB707 for the Treatment of Advanced Solid Tumor Malignancies Affecting the Lungs	Biological: KB707	Krystal Biotech, Inc.	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06228326
NCT06120504	A Safety Study of SGN-35T in Adults With Advanced Cancers	Drug: SGN-35T	Seagen Inc.	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06120504
NCT06047977	Tumor Infiltrating Lymphocyte Therapy for Pediatric High Risk Solid Tumors	Biological: Tumor Infiltrating Lymphocytes, Fludarabine, Cyclophosphamide, Interleukin-2	Johns Hopkins All Children's Hospital Swim Across America Foundation Benjamin Gilkey Fund Cannonball Kids' Cancer Foundation	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06047977
NCT06046287	Daratumumab for Polyneuropathy Associated With MGUS	Drug: Daratumumab and hyaluronidase-fihj	Georgetown University Janssen, LP	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06046287
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	https://clinicaltrials.gov/ct2/show/study/NCT05706116
NCT04563520	SAFE Study: Safety of aPCC Following Emicizumab Prophylaxis	Drug: aPCC-emicizumab Drug: FEIBA Drug: rFVIIa	Emory University Takeda Pharmaceuticals North America, Inc.	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT04563520
NCT06221813	Study to Evaluate Safety and Immunogenicity of a Prime-Boost Regimen of rVSV-Nipah Virus Vaccine Candidate PHV02 in Healthy Adult Subjects	Biological: PHV02 Biological: Lactated Ringer's	Public Health Vaccines LLC Coalition for Epidemic Preparedness Innovations	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06221813
NCT05730712	Pertuzumab, Trastuzumab, Hyaluronidase-zzxf and Enzalutamide for the Treatment of Metastatic Castration-Resistant Prostate Cancer, TraPPer Study	Procedure: Biopsy Procedure: Biospecimen Collection Procedure: Computed Tomography Procedure: Echocardiography Drug: Enzalutamide Drug: Hyaluronidase-zzxf Pertuzumab Trastuzumab Procedure: Magnetic Resonance Imaging Other: Questionnaire Administration	Mayo Clinic	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05730712
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/NCT06015724

해외 바이오의약품 임상 현황 ('24년 1월 4주)

한국바이오의약품협회, 2024.02.06.

○ 미국 57건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05588388	Study of Bevacizumab in Combination With Chemoimmunotherapy and Atezolizumab in Patients With Extensive Stage Small Cell Lung Cancer and Liver Metastases	Drug: Bevacizumab	Kamya Sankar Genentech, Inc. University of Michigan VA Ann Arbor Healthcare System Cedars-Sinai Medical Center	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05588388
NCT06105021	Phase I Study of Autologous CD8+ and CD4+ Engineered T Cell Receptor T Cells in Subjects With Advanced or Metastatic Solid Tumor	Drug: AFNT-211	Affini-T Therapeutics, Inc.	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06105021
NCT06223958	Study to Evaluate the Efficacy and Safety of Intravitreal OTX-TKI (Ocular Therapeutix) (Axitinib Implant) in Subjects With Neovascular Age-Related Macular Degeneration	Drug: OTX-TKI (axitinib implant) Drug: Aflibercept	Ocular Therapeutix, Inc. Fortrea Duke University	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06223958
NCT06237049	A Study to Learn About a Combined COVID-19 and Influenza Shot in Healthy Adults	Biological: BNT162b2 (Omi XBB.1.5)/RIV Biological: BNT162b2 (Omi XBB.1.5) Biological: RIV Other: Normal saline placebo	Pfizer	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06237049
NCT06123338	A Study of Pembrolizumab With Trastuzumab and Chemotherapy in People With Esophagogastric Cancer	Drug: Pembrolizumab Drug: Trastuzumab	Memorial Sloan Kettering Cancer Center Genentech, Inc. Merck Sharp & Dohme LLC	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06123338
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/NCT06033196
NCT06008093	A Study to Investigate the Efficacy of Durvalumab Plus Tremelimumab in Combination With Chemotherapy Compared With Pembrolizumab in Combination With Chemotherapy in Metastatic Non-Small Cell Lung Cancer (NSCLC) Patients	Drug: Durvalumab Drug: Tremelimumab Drug: Pemetrexed Drug: Pembrolizumab Drug: Carboplatin Drug: Cisplatin	AstraZeneca	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06008093
NCT06196879	A Study to Investigate the Efficacy and Safety of Verekitug (UPB-101) in Adult Participants With Severe Asthma (VALIANT)	Drug: Verekitug (UPB-101) Drug: Placebo	Upstream Bio Inc.	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06196879
NCT05743270	Study of RP3 in Combination With Nivolumab and Other Therapy in Patients With Locoregionally Advanced or Recurrent SCCN	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/NCT05743270
NCT05719441	A Clinical Trial of Combination HIV-Specific Broadly Neutralizing Monoclonal Antibodies Combined With ART Initiation During Acute HIV Infection to Induce HIV Remission	Biological: VRC07-523LS Biological: PGT121.414.LS Other: Placebo Drug: ART	National Institute of Allergy and Infectious Diseases (NIAID)	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05719441
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/NCT05748197
NCT05703971	Quaratusugene Ozeplasmid (Reqorsa) and Atezolizumab Maintenance Therapy in ES-SCLC Patients	Biological: quaratusugene ozeplasmid Biological: atezolizumab	Genprex, Inc.	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05703971
NCT06240728	A Study of NPX887 for Participants With Solid Tumors Known to Express HHLA-2/B7-H7	Drug: NPX887	NextPoint Therapeutics, Inc.	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06240728

해외 바이오의약품 임상 현황 ('24년 1월 4주)

한국바이오의약품협회, 2024.02.06.

○ 영국 4건					
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
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
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
NCT06230354	Explore the Efficacy and Mechanism of Action of Tezepelumab in Eosinophilic Granulomatosis With Polyangiitis	Drug: Tezepelumab Drug: Placebo	Imperial College London AstraZeneca	Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT06230354&rank=1

○ 프랑스 4건					
NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06150703	Luteal Phase Support With GnRH Agonist After GnRH Agonist Triggering in IVF/ICSI Cycles	Drug: Ovulation induction with hCG + Luteal phase support with vaginal progesterone Drug: Ovulation triggering by Triptorelin + Luteal phase support by Nafarelin	Assistance Publique - Hôpital Pitié-Salpêtrière de Paris	Phase 3	https://clinicaltrials.gov/ct2/show/study?term=NCT06150703&rank=1
NCT06186648	Evaluation of Treatment by Glofitamab in Combination With Rituximab or Obinutuzumab Plus CHOP in Patients With Richter Syndrome	Drug: Glofitamab + Obinutuzumab	French Innovative Leukemia Organisation Hoffmann-La Roche	Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT06186648&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

○ 독일 5건					
NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05836896	A Phase I Trial to Establish the Safety and Maximum Tolerated Dose of High-affinity Autologous BCMA-targeting Chimeric Antigen Receptor (CAR) T-cells in Patients With Relapsed and Refractory B-cell Malignancies	Genetic: MDC-CAR-BCMA001 (BCMA directed CAR T-cells)	Technische Universität Dresden German Cancer Research Center	Phase 1	https://clinicaltrials.gov/ct2/show/study?term=NCT05836896&rank=1
NCT05959421	Immunity Induced by VSV-EBOV and Assessment of a Booster Dose in Individuals at Potential Occupational Risk for Exposure	Biological: ERVEBO® (rVSVΔG-ZEBOV-GP)	Universitätsklinikum Hamburg-Eppendorf Bernhard Nocht Institute for Tropical Medicine Goethe University German Federal Ministry of Education and Research Monipol Deutschland GmbH	Phase 3	https://clinicaltrials.gov/ct2/show/study?term=NCT05959421&rank=1
NCT06216158	Iberdomide vs. Iberdomide Plus Isatuximab Maintenance Therapy Post ASCT in Newly Diagnosed Multiple Myeloma	Drug: Iberdomide Drug: Isatuximab Drug: Dexamethasone	University of Heidelberg Medical Center KKS Netzwerk Wuerzburg University Hospital Sanofi Bristol-Myers Squibb	Phase 3	https://clinicaltrials.gov/ct2/show/study?term=NCT06216158&rank=1

해외 바이오의약품 임상 현황 ('24년 1월 4주)

한국바이오의약품협회, 2024.02.06.

○ 독일 5건					
NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05743270	Study of RP3 in Combination With Nivolumab and Other Therapy in Patients With Locoregionally Advanced or Recurrent SCCN	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/NCT05743270
NCT06179511	Study of AZD9829 in CD123+ Hematological Malignancies	Drug: AZD9829	AstraZeneca	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06179511

○ 중국 30건					
NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06238024	Effect of Interleukin-6 Receptor Inhibition in Patients With Ischemic Stroke Undergoing Endovascular Treatment	Drug: Tocilizumab Drug: NaCl 0.9% 100ml	Suzhou Municipal Hospital of Anhui Province Xuanwu Hospital, Beijing	Phase 2 Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06238024
NCT06232083	Application of PLDR External Irradiation Combined With Immune Checkpoint Inhibitors in Recurrent Cervical Cancer	Radiation: PLDR+Cardunizumab	Anhui Provincial Hospital	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06232083
NCT06221774	Safety and Efficacy of TT-00420 Tablets Combined With Toripalimab Injection in Advanced Urological Tumors	Drug: TT-00420 + Toripalimab	The Affiliated Nanjing Drum Tower Hospital of Nanjing University Medical School	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06221774
NCT06217757	Safety and Tolerability of LDRT+Sugemalimab+Chemotherapy+Olaparib for First-Line Treatment of SLFN-11 Positive ES-SCLC	Radiation: Low-dose radiotherapy Drug: Etoposide Drug: Cisplatin Drug: Sugemalimab Drug: Olaparib	Sichuan University	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06217757
NCT06132217	A Study of Simmitinib Plus SG001 in Advanced Solid Tumors	Drug: Simmitinib Drug: SG001	Shanghai Runshi Pharmaceutical Technology Co., Ltd	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06132217
NCT06131450	A Study of BL-M07D1 in Patients With HER2-expressing Recurrent or Metastatic Gynecologic Malignancies	Drug: BL-M07D1	Sichuan Baili Pharmaceutical Co., Ltd. Baili-Bio (Chengdu) Pharmaceutical Co., Ltd.	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06131450
NCT06234904	Study of IBR733 Cell Injection in Acute Myeloid Leukemia	Biological: IBR733 Cell Injection	Imbioray (Hangzhou) Biomedicine Co., Ltd. The First Affiliated Hospital of Soochow University	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06234904
NCT06227325	Disitamab Vedotin Combined With Sintilimab and XELOX Perioperative Treatment for Resectable Gastric Cancer With HER2 Overexpression	Drug: RC48 combined with Sintilimab and XELOX	Henan Cancer Hospital	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06227325
NCT06220487	A Single-arm, Open-label Study of Olverembatinib, CD3/CD19 Bispecific T-cell Engager, and Chidamide in Patients With Newly Diagnosed Ph+ALL	Drug: Prednisone, Olverembatinib, Blinatumomab, Chidamide	Nanfeng Hospital, Southern Medical University	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06220487
NCT06220097	Mitoxantrone Hydrochloride Liposome Injection-containing Bridging Regimen and CD19-targeting CAR-T Therapies	Drug: Mitoxantrone hydrochloride liposome Injection-based bridging therapy+ Fludarabine-based chemotherapy +CD19 CAR-T Cells	Wuhan Union Hospital, China CSPC Pharmaceutical Group Limited	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06220097
NCT06211114	Study to Evaluate the Efficacy and Safety of Immunotherapy With Axitinib in Advanced Collecting Duct Carcinoma	Drug: PD-(L)1 inhibitor Drug: Axitinib	Peking University Cancer Hospital & Institute	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06211114

해외 바이오의약품 임상 현황 ('24년 1월 4주)

한국바이오의약품협회, 2024.02.06.

○ 중국 30건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06210438	SHR-A1921 Combined With Bevacizumab in Triple-negative Breast Cancer With Brain Metastases	Drug: SHR-A1921 + Bevacizumab	Fudan University	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06210438
NCT06202014	Phase II Study of Concurrent Radiotherapy With Envafolelimab and Capecitabine in LAPC	Radiation: concurrent radiotherapy with envafolelimab and capecitabine	Cancer Institute and Hospital, Chinese Academy of Medical Sciences	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06202014
NCT06196775	A Study of Cadonilimab Combined With AK112 as Second-line Therapy in Patients With Advanced Hepatocellular Carcinoma	Biological: AK104+AK112	Harbin Medical University	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06196775
NCT06196320	Tenecteplase Reperfusion Therapy in Acute Ischaemic Cerebrovascular Events-5	Drug: Tenecteplase Drug: Best Practice (which may include intravenous Alteplase)	Beijing Tiantan Hospital	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06196320
NCT06192797	Combined HAIC, Lenvatinib and Pucotenlimab as Conversion Therapy for Unresectable Intrahepatic Cholangiocarcinoma	Procedure: HAIC Drug: Lenvatinib plus pucotenlimab	Ze-yang Ding, MD Geneplus-Beijing Co. Ltd. Chinese Cooperative Group of Liver Cancer (CCGLC) Tongji Hospital	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06192797
NCT06184568	A Study Comparing IBI362 vs Semaglutide in Chinese Adults With Early Type 2 Diabetes and Obesity	Drug: IBI362 Drug: Semaglutide	Innovent Biologics (Suzhou) Co. Ltd.	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06184568
NCT04968509	Effect of PCSK9 Inhibitors on Calcific Aortic Valve Stenosis: A Randomized Trial	Drug: PCSK9 inhibitors and statins with or without ezetimibe Drug: Statins with or without ezetimibe	Beijing Anzhen Hospital Beijing Municipal Health Commission	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT04968509
NCT06231680	Thalidomide Prevention or Treatment of Camrelizumab-induced Reactive Cutaneous Capillary Endothelial Proliferation (RCCEP)	Drug: Camrelizumab Drug: Thalidomide 50mg Drug: Thalidomide 100mg Drug: Thalidomide 200mg Drug: Chemotherapy	Henan Cancer Hospital First Affiliated Hospital Xi'an Jiaotong University	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06231680
NCT06227156	DV With HER2 Expression, Gene Amplification or Mutation Metastatic Castration-resistant Prostate Cancer	Drug: Disitamab Vedotin Injection	RemeGen Co., Ltd.	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06227156
NCT06139536	Assessment of Safety, Tolerability and Pharmacokinetics With BAT4706 and BAT1308 in Advanced Solid Tumors Patients	Drug: BAT4706 Injection Drug: BAT1308 Injection	Bio-Thera Solutions	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06139536
NCT06198751	A Study of Neoadjuvant Treatment With TQB2102 for Injection for Human Epidermal Growth Factor Receptor 2 (HER2) Positive Breast Cancer	Drug: 6.0 mg/kg of TQB2102 for injection Drug: 7.5 mg/kg of TQB2102 for injection	Chia Tai Tianqing Pharmaceutical Group Co., Ltd.	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06198751
NCT05956587	A Study of SI-B003 and BL-B01D1+SI-B003 in Patients With Locally Advanced or Metastatic Non-small Cell Lung Cancer, Nasopharyngeal Carcinoma and Other Solid Tumors	Drug: BL-B01D1 Drug: SI-B003	Sichuan Baili Pharmaceutical Co., Ltd. Baili-Bio (Chengdu) Pharmaceutical Co., Ltd.	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05956587
NCT06241846	A Phase II Study to Evaluate the Safety, Efficacy, and Pharmacokinetics of YL201 in Patients With Metastatic Castration-Resistant Prostate Cancer	Drug: YL201 for Injection	MediLink Therapeutics (Suzhou) Co., Ltd.	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06241846

해외 바이오의약품 임상 현황 ('24년 1월 4주)

한국바이오의약품협회, 2024.02.06.

○ 중국 30건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06235203	Neoadjuvant vs Adjuvant in Locally Advanced Recurrent NPC	Procedure: endoscopic surgery Drug: Neoadjuvant therapy,Toripalimab Injection and Gemcitabine based therapy Drug: Adjuvant therapy in experimental group,Toripalimab Injection and Gemcitabine based therapy Drug: Adjuvant therapy in control group,Toripalimab Injection and Gemcitabine based therapy	Eye & ENT Hospital of Fudan University Shanghai Zhongshan Hospital Shanghai 6th People's Hospital Changhai Hospital Fujian Medical University Union Hospital People's Hospital of Guangxi Shenzhen Second People's Hospital	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06235203
NCT06228079	Adjuvant vs Surgery Only in Early-stage Recurrent NPC	Drug: Immunotherapy,Toripalimab Injection Drug: Chemotherapy,Gemcitabine based regimen	Eye & ENT Hospital of Fudan University Shanghai Zhongshan Hospital Shanghai 6th People's Hospital Changhai Hospital Fujian Medical University Union Hospital People's Hospital of Guangxi Shenzhen Second People's Hospital	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06228079
NCT06241599	A Multi-center, Randomized, Double-blind, Phase II/III Clinical Trial of AK104 or Placebo in Combination With Chemotherapy as Second-line or More Lines for Recurrent or Metastatic Nasopharyngeal Carcinoma (NPC)	Drug: GP/PFLL+AK104 Drug: GP/PFLL+placebo	Sun Yat-sen University	Phase 2 Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06241599
NCT06241469	Efficacy and Safety of Sintilimab Combined With Nab-paclitaxel and Tegio (aTS) as First-line Treatment of Unresectable Locally Advanced, Recurrent or Metastatic Adenocarcinoma of Gastric and Gastroesophageal Junction, a Phase II Clinical Study	Drug: Sintilimab,nab-paclitaxel and tegio	Wu Jun The First People's Hospital of Changzhou	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06241469
NCT06241781	Autologous Tumor Infiltrating Lymphocytes (GT101 Injection) in Patients With Recurrent or Metastatic Cervical Cancer	Biological: GT101 injection Drug: Gemcitabine injection	Grit Biotechnology	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06241781
NCT06179511	Study of AZD9829 in CD123+ Hematological Malignancies	Drug: AZD9829	AstraZeneca	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06179511

○ 일본 1건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06179511	Study of AZD9829 in CD123+ Hematological Malignancies	Drug: AZD9829	AstraZeneca	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06179511