

해외 바이오의약품 임상 현황 ('23년 10월 4주)

한국바이오의약품협회, 2023.10.31.

※ 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: 2023.10.23.~2023.10.29.
- 주간 업데이트 제공국가 : 미국, 유럽(영국, 프랑스, 독일), 중국, 일본

○ 미국 14건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05715619	Safety and Efficacy of Oral Administration of the Phage Cocktail, VRElysins™ In Healthy and VRE-Colonized Subjects	Biological: VRElysins™ Other: Placebo	Intralix, Inc.	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT05715619&rank=1
NCT06060613	Safety and Efficacy of OBX-115 in Advanced/Metastatic Melanoma Resistant to Immune Checkpoint Inhibitors	Biological: OBX-115	Obsidian Therapeutics, Inc.	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT06060613&rank=1
NCT06066424	Phase 1 Dose Escalation and Expansion Study of TROP2 CAR Engineered IL15-transduced Cord Blood-derived NK Cells in Patients With Advanced Solid Tumors (TROPIKANA)	Drug: Rimiducid Drug: TROP2-CAR-NK Cells Drug: Fludarabine phosphate Drug: Cyclophosphamide	M.D. Anderson Cancer Center Bellicum Pharmaceuticals	Phase 1	https://clinicaltrials.gov/ct2/show/study?term=NCT06066424&rank=1
NCT05995353	A Study to Assess Adverse Events, Change in Disease Activity, and How Intravenous and Subcutaneous Risankizumab Moves Through the Body of Pediatric Participants With Moderately to Severely Active Crohn's Disease	Drug: Risankizumab	AbbVie	Phase 3	https://clinicaltrials.gov/ct2/show/study?term=NCT05995353&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
NCT05436444	Low Pathogenicity Avian H10N7 Influenza Virus in a Healthy Human Challenge Model	Biological: A/Mallard/Ohio-99/MM4/1989 H10N7	National Institute of Allergy and Infectious Diseases (NIAID) National Institutes of Health Clinical Center (CC)	Phase 1	https://clinicaltrials.gov/ct2/show/study?term=NCT05436444&rank=1
NCT06059391	CMV-MVA Triplex Vaccination in HLA-Matched Related Stem Cell Donors for the Prevention of CMV Infection in Patients Undergoing Hematopoietic Stem Cell Transplant	Procedure: Allogeneic Hematopoietic Stem Cell Transplantation Procedure: Biospecimen Collection Drug: Granulocyte Colony-Stimulating Factor Drug: Hematopoietic Cell Transplantation Conditioning Regimen Biological: Multi-peptide CMV-Modified Vaccinia Ankara Vaccine Procedure: Pheresis Drug: Placebo Administration Drug: Stem Cell Mobilization Therapy	City of Hope Medical Center National Cancer Institute (NCI)	Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT06059391&rank=1
NCT05545072	Add-on Dupilumab for AFRS as Postoperative Therapy (ADAPT)	Drug: Dupilumab 300 MG/2 ML Subcutaneous Solution Drug: Placebo	Emory University Sanofi	Phase 3	https://clinicaltrials.gov/ct2/show/study?term=NCT05545072&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

해외 바이오의약품 임상 현황 ('23년 10월 4주)

한국바이오의약품협회, 2023.10.31.

○ 미국 14건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06097299	A Study of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus, in Children 2 to <18 Years of Age at High Risk of Respiratory Syncytial Virus	Biological: mRNA-1345 Biological: Placebo	ModernaTX, Inc.	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06097299
NCT06046729	A Study of Eltrekibart (LY3041658) in Adult Participants With Moderate to Severe Hidradenitis Suppurativa	Drug: Eltrekibart Drug: Placebo	Eli Lilly and Company	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06046729
NCT05784246	A Study of Mirikizumab (LY3074828) in Pediatric Participants With Moderately to Severely or Active Ulcerative Colitis	Drug: Mirikizumab IV Drug: Mirikizumab SC	Eli Lilly and Company	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05784246
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
NCT05509777	A Study of Mirikizumab (LY3074828) in Pediatric Participants With Crohn's Disease	Drug: Mirikizumab	Eli Lilly and Company	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05509777

○ 영국 2건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05509777	A Study of Mirikizumab (LY3074828) in Pediatric Participants With Crohn's Disease	Drug: Mirikizumab	Eli Lilly and Company	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05509777
NCT05784246	A Study of Mirikizumab (LY3074828) in Pediatric Participants With Moderately to Severely or Active Ulcerative Colitis	Drug: Mirikizumab IV Drug: Mirikizumab SC	Eli Lilly and Company	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05784246

○ 프랑스 2건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05509777	A Study of Mirikizumab (LY3074828) in Pediatric Participants With Crohn's Disease	Drug: Mirikizumab	Eli Lilly and Company	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05509777
NCT05784246	A Study of Mirikizumab (LY3074828) in Pediatric Participants With Moderately to Severely or Active Ulcerative Colitis	Drug: Mirikizumab IV Drug: Mirikizumab SC	Eli Lilly and Company	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05784246

○ 독일 1건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05784246	A Study of Mirikizumab (LY3074828) in Pediatric Participants With Moderately to Severely or Active Ulcerative Colitis	Drug: Mirikizumab IV Drug: Mirikizumab SC	Eli Lilly and Company	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05784246

○ 중국 10건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06101082	An Exploratory Clinical Study Evaluating the Safety and Efficacy of Anti-HER2-CAR-T Cells Injection in Patients With HER2+ Locally Advanced and/ or Metastatic Solid Tumors	Biological: Intravenous infusion anti-HER2-CAR-T cell	China Medical University, China Shanghai First Song Therapeutics Co., Ltd	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06101082

해외 바이오의약품 임상 현황 ('23년 10월 4주)

한국바이오의약품협회, 2023.10.31.

○ 중국 10건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06099821	KN046 Plus Regorafenib or Apatinib in MSI-H Digestive System Cancers Resistant to PD-1/PD-L1 Blockade	Drug: KN046 Drug: Regorafenib Drug: Apatinib	Peking University Cancer Hospital & Institute	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06099821
NCT06095583	A Study to Assess Toripalimab Alone or in Combination With Tifcemalimab as Consolidation Therapy in Patients With Limited-stage Small Cell Lung Cancer (LS-SCLC)	Drug: Tifcemalimab injection Drug: toripalimab injection Drug: Placebo for Tifcemalimab Drug: Placebo for toripalimab	Shanghai Junshi Bioscience Co., Ltd.	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06095583
NCT06090656	Bevacizumab in Combination With Sintilimab Versus Transcatheter Arterial Chemoembolization for the Treatment of Intermediate Stage Hepatocellular Carcinoma (Beyond Up-To-Seven Criteria)	Drug: Bevacizumab combined with Sintilimab Procedure: Transcatheter arterial chemoembolization	Sun Yat-sen University	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06090656
NCT05988372	Sulfatinib and Serplulimab Combined With AG Regimen Compare With AG Regimen as Conversion Therapy for Patients With Locally Advanced Pancreatic Cancer (SAGE)	Drug: Sulfatinib + Serplulimab+Albumin-paclitaxel + Gemcitabine Drug: Albumin-paclitaxel + Gemcitabine	Sun Yat-sen University	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05988372
NCT05985109	KN 046 Plus Regorafenib in MSS Metastatic Colorectal Cancer	Drug: KN046 Drug: regorafenib	Peking University Cancer Hospital & Institute	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05985109
NCT05980689	Combination of AK104 and Neoadjuvant Chemoradiotherapy in pMMR/MSS Locally Advanced Rectal Cancer	Drug: AK104 Drug: Capecitabine Radiation: Neoadjuvant Radiotherapy	Sun Yat-sen University Akeso Haplox Biotechnology Co., Ltd.	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05980689
NCT05061277	Study to Evaluate the Pharmacokinetics, Safety and Tolerability of Recifercept in Healthy Chinese Participants	Drug: Recifercept	Pfizer	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05061277
NCT06082102	Efficacy and Safety of Orelabrutinib Plus Lenalidomide and Rituximab (R2) Compared to Placebo Plus R2 in r/r Marginal Zone Lymphoma	Drug: Orelabrutinib Drug: Lenalidomide Drug: Rituximab Drug: Orelabrutinib Placebo	Beijing InnoCare Pharma Tech Co., Ltd.	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06082102
NCT05046314	A Clinical Study of TK216 in Patients With Relapsed or Refractory Ewing's Sarcoma	Biological: TK216+Vincristin	Shanghai Pharmaceuticals Holding Co., Ltd	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05046314

○ 일본 2건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05784246	A Study of Mirikizumab (LY3074828) in Pediatric Participants With Moderately to Severely or Active Ulcerative Colitis	Drug: Mirikizumab IV Drug: Mirikizumab SC	Eli Lilly and Company	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05784246
NCT05784246	A Study of Mirikizumab (LY3074828) in Pediatric Participants With Moderately to Severely or Active Ulcerative Colitis	Drug: Mirikizumab IV Drug: Mirikizumab SC	Eli Lilly and Company	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05784246