

해외 바이오의약품 임상 현황 ('23년 12월 2주)

한국바이오의약품협회, 2023.12.19.

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

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- 출처: ClinicalTrials.gov

- 모니터링 기간: 2023.12.11.~2023.12.17.

- 주간 업데이트 제공국가 : 미국, 유럽(영국, 프랑스, 독일), 중국, 일본

○ 미국 15건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT03735589	Specialized Immune Cells (nCTLs) and a Vaccine (Alpha-type-1 Polarized Dendritic Cells) in Treating Patients With Stage II-IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	Biological: Alpha-type-1 Polarized Dendritic Cells Biological: Autologous Natural Killer Cell-like CTLs	Roswell Park Cancer Institute National Cancer Institute (NCI)	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT03735589
NCT06083844	Phase II Investigation of Pembrolizumab in Combination With Bevacizumab and Oral Cyclophosphamide in Patients With High Grade Ovarian Cancer and Surgically Documented Minimal Residual Disease After Frontline Therapy	Drug: Pembrolizumab Drug: Bevacizumab Drug: Cyclophosphamide	M.D. Anderson Cancer Center	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06083844
NCT05969496	Neoadjuvant Pembrolizumab and Axitinib in Renal Cell Carcinoma With Inferior Vena Cava Tumor Thrombus	Drug: Axitinib Drug: Pembrolizumab	University of Colorado, Denver Cancer League of Colorado	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05969496
NCT05835505	Detoxification of the Liver In PSC (Dolphin)	Drug: BRS201 Drug: Placebo	Brigham and Women's Hospital	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05835505
NCT05786404	Study to Evaluate the Fecal Microbiota Transplantation (FMT) in the Treatment of Ulcerative Colitis	Drug: PRIM-DJ2727 - FROZEN Drug: PRIM-DJ2727 - CAPSULES	The University of Texas Health Science Center, Houston	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05786404
NCT05741164	Propranolol and Pembrolizumab for Tumor Re-sensitization and Treatment of Patients With Checkpoint Inhibitor Refractory Metastatic or Unresectable Triple Negative Breast Cancer	Procedure: Biopsy Procedure: Biospecimen Collection Procedure: Computed Tomography Biological: Pembrolizumab Drug: Propranolol Other: Questionnaire Administration	Roswell Park Cancer Institute	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05741164
NCT05518032	Pembrolizumab and Autologous Dendritic Cells for the Treatment of Refractory Colorectal Cancer (CRC)	Procedure: Biopsy Biological: Pembrolizumab Biological: Therapeutic Autologous Dendritic Cells	Roswell Park Cancer Institute	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05518032
NCT04876248	Belantamab Mafodotin and Lenalidomide for the Treatment of Multiple Myeloma in Patients With Minimal Residual Disease Positive After Stem Cell Transplant	Biological: Belantamab Mafodotin Drug: Lenalidomide	Roswell Park Cancer Institute GlaxoSmithKline	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT04876248
NCT06141473	Efficacy and Safety Studies of Frexalimab (SAR441344) in Adults With Relapsing Forms of Multiple Sclerosis	Drug: Frexalimab Drug: Teriflunomide Drug: Placebo infusion Drug: Placebo tablet Drug: MRI contrast-enhancing agents Drug: Cholestyramine Drug: Activated charcoal	Sanofi	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06141473
NCT06091865	A Study to Compare How Well Odronexamab Combined With Chemotherapy Works and How Safe it is Against Rituximab Combined With Chemotherapy, in Patients With Previously Untreated Diffuse Large B-cell Lymphoma	Drug: Odronexamab Drug: Rituximab Drug: Cyclophosphamide Drug: Doxorubicin Drug: Vincristine Drug: Prednisone Prednisolone	Regeneron Pharmaceuticals	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06091865

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NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06091254	A Trial to Learn if Odronektamab is Safe and Well-tolerated and How Well it Works Compared to Rituximab Combined With Different Types of Chemotherapy for Participants With Follicular Lymphoma	Drug: Odronektamab Drug: Rituximab Drug: Cyclophosphamide Drug: Doxorubicin Drug: Vincristine Drug: Prednisone/prednisolone Drug: Bendamustine	Regeneron Pharmaceuticals	Phase 3	https://clinicaltrials.gov/ct2/show/study?term=NCT06091254&rank=1
NCT05954871	Study to Evaluate the Safety, Pharmacokinetics, and Activity of GDC-1971 in Combination With Either Osimertinib in Participants With Unresectable, Locally Advanced, or Metastatic Non-Small Cell Lung Cancer, or With Cetuximab in Participants With Metastatic Colorectal Cancer	Drug: GDC-1971 Drug: Osimertinib Drug: Cetuximab	Genentech, Inc.	Phase 1	https://clinicaltrials.gov/ct2/show/study?term=NCT05954871&rank=1
NCT05908786	A Study Evaluating The Efficacy and Safety of Neoadjuvant Immunotherapy Combinations in Patients With Surgically Resectable Hepatocellular Carcinoma	Drug: Atezolizumab Drug: Bevacizumab Drug: Tiragolumab Drug: Tobemstomig	Hoffmann-La Roche	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT05908786&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
NCT05096481	PEP-CMV Vaccine Targeting CMV Antigen to Treat Newly Diagnosed Pediatric HGG and DIPG and Recurrent Medulloblastoma	Biological: PEP-CMV Drug: Temozolomide Biological: Tetanus Diphtheria Vaccine	Nationwide Children's Hospital	Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT05096481&rank=1

○ 프랑스 1건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05821231	Study Evaluating the Safety and Efficacy of MEDI5752 in Combination With Stereotactic Radiotherapy in Patients With Metastatic Sarcoma	Combination Product: SBRT + MEDI5752	Institut Claudius Regaud National Cancer Institute, France AstraZeneca	Phase 1	https://clinicaltrials.gov/ct2/show/study?term=NCT05821231&rank=1

○ 중국 6건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06152978	A Perioperative Sintilimab and Chemotherapy in Esophageal Squamous Cell Carcinoma	Drug: Sintilimab Drug: Chemotherapy	Fudan University Innovent Biologics (Suzhou) Co. Ltd.	Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT06152978&rank=1
NCT06143748	Combination of Cadonilimab and Chemoradiotherapy in Esophageal Cancer (EC-CRT-006)	Drug: Cadonilimab Drug: Paclitaxel and cisplatin Radiation: intensity-modulated radiotherapy	Sun Yat-sen University	Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT06143748&rank=1
NCT06123754	Phase III Study of Envafoimab Versus Placebo Plus Chemotherapy in Resectable Stage III NSCLC	Drug: Envafoimab subcutaneously injected+Platinum-based doublet chemotherapy intravenous injection Drug: placebo subcutaneously injected +Platinum-based doublet chemotherapy intravenous injection	3D Medicines (Sichuan) Co., Ltd. 3D Medicines	Phase 3	https://clinicaltrials.gov/ct2/show/study?term=NCT06123754&rank=1
NCT06026891	Study of MG-K10 Humanized Monoclonal Antibody Injection in Patients With Atopic Dermatitis	Drug: MG-K10/Placebo	Shanghai Mabgeek Biotech.Co.Ltd	Phase 3	https://clinicaltrials.gov/ct2/show/study?term=NCT06026891&rank=1

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NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05872685	Perioperative Chemotherapy Combined With Serplulimab or Placebo for pMMR Locally Advanced Gastric Adenocarcinoma (FOCUS-05)	Drug: S1 Drug: Oxaliplatin Drug: Serplulimab Drug: Placebo	Yu jiren First Affiliated Hospital of Zhejiang University	Phase 2	https://clinicaltrials.gov/study/NCT05872685
NCT06166472	A Study to Evaluate the Safety, Tolerance, Pharmacokinetics, and Preliminary Antineoplastic Activity of AK132 in Advanced Malignant Solid Tumor	Drug: AK132	Akeso	Phase 1	https://clinicaltrials.gov/study/NCT06166472