

해외 바이오의약품 임상 현황 ('23년 5월 4주)

한국바이오의약품협회, 2023.05.30.

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

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- 출처: ClinicalTrials.gov

- 모니터링 기간: 2023.05.22.~2023.05.28.

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

○ 미국 11건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05716009	Tagraxofusp-erzs, an IL-3 Diphtheria Fusion Protein, in Combination With Gemtuzumab Ozogamicin in Patients With Relapsed/Refractory AML	Drug: Dose Escalation -tagraxofusp-erzs Drug: Dose Expansion at RP2D -tagraxofusp-erzs	Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins StemlineTherapeutics, Inc.	Phase 1	https://clinicaltrials.gov/ct2/show/study?term=NCT05716009&rank=1
NCT05675579	A Phase II Study of Neoadjuvant Sacituzumab Govitecan and Pembrolizumab Therapy for Immunotherapy-resistant Early-stage Triple-negative Breast Cancer (TNBC)	Drug: Sacituzumab Govitecan Drug: Pembrolizumab	M.D. Anderson Cancer Center Gilead Sciences	Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT05675579&rank=1
NCT05650749	GPC2 CAR T Cells for Relapsed or Refractory Neuroblastoma	Biological: GPC2 CAR T cells	Stephan Grupp MD PhD Children's Hospital of Philadelphia Tmunity Therapeutics University of Pennsylvania	Phase 1	https://clinicaltrials.gov/ct2/show/study?term=NCT05650749&rank=1
NCT04466475	Radioimmunotherapy (211At-OKT10-B10) and Chemotherapy (Melphalan) Before Stem Cell Transplantation for the Treatment of Multiple Myeloma	Biological: Astatine At 211 Anti-CD38 Monoclonal Antibody OKT10-B10 Drug: Melphalan Procedure: Peripheral Blood Stem Cell Transplantation	Fred Hutchinson Cancer Center National Cancer Institute (NCI) National Institutes of Health (NIH)	Phase 1	https://clinicaltrials.gov/ct2/show/study?term=NCT04466475&rank=1
NCT04128176	Efficacy and Safety of Rituximab Combined With Omalizumab in Patients With Bullous Pemphigoid	Drug: Rituximab combined with Omalizumab	University of California, Davis	Phase 3	https://clinicaltrials.gov/ct2/show/study?term=NCT04128176&rank=1
NCT05553639	HB-302/HB-301 Therapy in Participants With Metastatic Castration-Resistant Prostate Cancer	Biological: HB-302/HB-301 Alternating 2-Vector Therapy	Hookipa Biotech GmbH	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT05553639&rank=1
NCT05606757	A Study to Evaluate Adverse Events and Effectiveness of OnabotulinumtoxinA in Participants Undergoing Open Abdominal Ventral Hernia Repair for the Achievement of Primary Fascial Closure Without the Use of Component Separation Technique	Drug: BOTOX Dose A Drug: Placebo for BOTOX Drug: BOTOX Dose B Drug: BOTOX Dose C	AbbVie	Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT05606757&rank=1
NCT05765851	A Study of DS-1103a Combination Therapy in Participants With Advanced Solid Tumors	Drug: DS-1103a Drug: T-DXd	Daiichi Sankyo, Inc. AstraZeneca	Phase 1	https://clinicaltrials.gov/ct2/show/study?term=NCT05765851&rank=1
NCT05671757	Daratumumab in Primary Antiphospholipid Syndrome	Biological: Daratumumab	National Institute of Allergy and Infectious Diseases (NIAID) Immune Tolerance Network (ITN) PPD Rho Federal Systems Division, Inc.	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT05671757&rank=1
NCT04716231	Atacept in Subjects With IgA Nephropathy	Biological: Atacept Other: Placebo to match Atacept	Vera Therapeutics, Inc.	Phase 2 Phase 3	https://clinicaltrials.gov/ct2/show/study?term=NCT04716231&rank=1
NCT05626322	Effects of Maplirpacept (PF-07901801), Tafasitamab, and Lenalidomide in People With Relapsed or Refractory Diffuse Large B-cell Lymphoma	Drug: Maplirpacept Drug: Tafasitamab Drug: Lenalidomide	Pfizer MorphoSys AG Incyte Corporation	Phase 2	https://clinicaltrials.gov/ct2/show/study?term=NCT05626322&rank=1

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○ 영국 2건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05646082	Preliminary Assessment of Safety and Tolerability of Dostarlimab in Combination Antiretroviral Therapy (cART) Refractory HIV Associated Kaposi Sarcoma	Drug: Dostarlimab in Combination Antiretroviral Therapy	Imperial College London	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05646082
NCT04716231	Atacicept in Subjects With IgA Nephropathy	Biological: Atacicept Other: Placebo to match Atacicept	Vera Therapeutics, Inc.	Phase 2 Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT04716231

○ 독일 1건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT04716231	Atacicept in Subjects With IgA Nephropathy	Biological: Atacicept Other: Placebo to match Atacicept	Vera Therapeutics, Inc.	Phase 2 Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT04716231

○ 중국 4건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05858853	Phase II/III of Recombinant Human Serum Albumin	Drug: Recombinant Human Serum Albumin Drug: Human serum albumin	Protgen Ltd	Phase 2 Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05858853
NCT05821452	Immunotherapy Plus Chemotherapy vs. Chemoradiotherapy for Thoracic Squamous Esophageal Carcinoma	Drug: Camrelizumab Drug: Paclitaxel Drug: Cisplatin Radiation: Radiotherapy	Fujian Medical University Union Hospital	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05821452
NCT05584137	Evaluate the Efficacy, Safety and Tolerability of HLX26 and HLX10 in Patients With Metastatic Colorectal Carcinoma That Have Received 3 Prior Lines of Therapy	Drug: HLX26 Drug: HLX10	Shanghai Henlius Biotech	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05584137
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 1건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05626322	Effects of Maplirpacept (PF-07901801), Tafasitamab, and Lenalidomide in People With Relapsed or Refractory Diffuse Large B-cell Lymphoma	Drug: Maplirpacept Drug: Tafasitamab Drug: Lenalidomide	Pfizer MorphoSys AG Incyte Corporation	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05626322