

해외 바이오의약품 임상 현황 ('23년 10월 2주)

한국바이오의약품협회, 2023.10.17.

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

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- 출처: ClinicalTrials.gov
- 모니터링 기간: 2023.10.09.~2023.10.15.
- 주간 업데이트 제공국가 : 미국, 유럽(영국, 프랑스, 독일), 중국, 일본

○ 미국 21건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
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/NCT05908786
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
NCT06084598	A Study to Evaluate the Safety, Tolerability and Drug Levels of BMS-986446 in Healthy Participants and Healthy Participants of Japanese Ethnicity	Drug: BMS-986446 Other: Placebo	Bristol-Myers Squibb	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06084598
NCT06054776	Acalabrutinib, Obinutuzumab, and Glofitamab for the Treatment of Relapsed or Refractory Mantle Cell Lymphoma	Drug: Acalabrutinib Procedure: Biospecimen Collection Procedure: Bone Marrow Biopsy Procedure: Computed Tomography Procedure: Echocardiography Biological: Glofitamab Procedure: Multigated Acquisition Scan Biological: Obinutuzumab Procedure: Positron Emission Tomography	City of Hope Medical Center National Cancer Institute (NCI)	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06054776
NCT06048250	Mezigidomide (CC-92480) Post Idecabtagene Vicleucel in Treating Patients With Relapsed Multiple Myeloma	Procedure: Biospecimen Collection Procedure: Bone Marrow Aspiration Procedure: Computed Tomography Biological: Mezigidomide Procedure: Positron Emission Tomography	City of Hope Medical Center National Cancer Institute (NCI)	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06048250
NCT06022029	A Dose Escalation and Dose Expansion Study of Intratumoral ONM-501 Alone and in Combination With Cemiplimab in Patients With Advanced Solid Tumors and Lymphomas.	Drug: ONM-501 Drug: Cemiplimab	OncoNano Medicine, Inc.	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06022029
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
NCT05943496	Tafasitamab, Acalabrutinib, and Obinutuzumab for the Treatment of Previously Untreated Chronic Lymphocytic Leukemia	Drug: Acalabrutinib Procedure: Biospecimen Collection Procedure: Bone Marrow Aspiration Procedure: Bone Marrow Biopsy Procedure: Computed Tomography Procedure: Echocardiography Biological: Obinutuzumab Other: Questionnaire Administration Biological: Tafasitamab	OHSU Knight Cancer Institute Oregon Health and Science University Incyte Corporation	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05943496
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

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NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05883449	Phase 2 Study of AFM13 in Combination With AB-101 in Subjects With R/R HL and CD30+ PTCL	Drug: AFM13 Drug: AB-101 Drug: Cyclophosphamide Drug: Fludarabine Drug: Interleukin-2	Affimed GmbH Artiva Biotherapeutics, Inc.	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05883449
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
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 Stemline Therapeutics, Inc.	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05716009
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
NCT05377827	Dose-Escalation and Dose-Expansion Study to Evaluate the Safety and Tolerability of Anti-CD7 Allogeneic CAR T-Cells (WU-CART-007) in Patients With CD7+ Hematologic Malignancies	Biological: WU-CART-007	Washington University School of Medicine Wugen, Inc.	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05377827
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
NCT04777851	Regorafenib-pembrolizumab vs. TACE/TARE in Intermediate Stage HCC Beyond Up-to-7	Drug: Regorafenib in combination with pembrolizumab Procedure: Loco-regional therapy	Translational Research in Oncology Bayer	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT04777851
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/NCT04466475
NCT05687110	Studying the Safety and Determining the Optimal Dose of Novobiocin in Patients With Tumors That Have Alterations in DNA Repair Genes	Procedure: Biopsy Procedure: Biospecimen Collection Procedure: Diagnostic Imaging Biological: Novobiocin Sodium	National Cancer Institute (NCI)	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT05687110
NCT05469802	A Study of Purified Inactivated Zika Virus Vaccine (PIZV) in Healthy Adults	Biological: Purified Inactivated Zika Virus Vaccine (PIZV) Other: Placebo	Takeda	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05469802
NCT06079190	Efficacy and Safety of GSK4527226 [AL101] in Participants With Early Alzheimer's Disease	Drug: GSK4527226 Other: Placebo	GlaxoSmithKline Alector Inc.	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06079190
NCT06045689	A Study to Assess Luspatercept in Lower-risk Myelodysplastic Syndrome Participants	Drug: Luspatercept	Bristol-Myers Squibb	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06045689

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○ 영국 3건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06080048	A Clinical Trial to Assess the Safety of SOR102 in Healthy Participants and Patients With Ulcerative Colitis	Drug: SOR102 Drug: Placebo	Sorriso Pharmaceuticals, Inc.	Phase 1	https://clinicaltrials.gov/ct2/show/study/NCT06080048
NCT06079190	Efficacy and Safety of GSK4527226 [AL101] in Participants With Early Alzheimer's Disease	Drug: GSK4527226 Other: Placebo	GlaxoSmithKline Alector Inc.	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06079190
NCT05257083	A Study of Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucl 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

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NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06067061	"neoBREASTIM": Atezolizumab Plus RP1 Oncolytic Immunotherapy in the NeoAdjuvant Setting of Triple-Negative Breast Cancer	Combination Product: Atezolizumab + RP1	Institut Curie Replimune Inc. Roche Pharma AG	Phase 1 Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06067061
NCT05726916	Eculizumab in Hypertensive Emergency-associated Hemolytic Uremic Syndrome	Drug: Soliris® Drug: Renin angiotensin system blockers	Assistance Publique - Hôpitaux de Paris	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05726916
NCT05946486	Evaluation of the Efficacy of Immunomodulatory Therapy in Case of Psychiatric Disorders With Proven Dysimmunity.	Drug: immunomodulatory treatment by rituximab	University Hospital, Bordeaux	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT05946486
NCT05300035	Phase II Trial of ART + Dual bNAbs vs. ART + Placebo During Primary HIV-1 Infection-impact on Post-ART Control	Drug: Recombinant human monoclonal antibody (bNAbs) Drug: Placebo	ANRS, Emerging Infectious Diseases Rockefeller University Institut Pasteur	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT05300035
NCT06079190	Efficacy and Safety of GSK4527226 [AL101] in Participants With Early Alzheimer's Disease	Drug: GSK4527226 Other: Placebo	GlaxoSmithKline Alector Inc.	Phase 2	https://clinicaltrials.gov/ct2/show/study/NCT06079190
NCT06045689	A Study to Assess Luspatercept in Lower-risk Myelodysplastic Syndrome Participants	Drug: Luspatercept	Bristol-Myers Squibb	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06045689
NCT05257083	A Study of Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucl 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

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NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06045689	A Study to Assess Luspatercept in Lower-risk Myelodysplastic Syndrome Participants	Drug: Luspatercept	Bristol-Myers Squibb	Phase 3	https://clinicaltrials.gov/ct2/show/study/NCT06045689

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NCT05257083	A Study of Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucl 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	
NCT06079190	Efficacy and Safety of GSK4527226 [AL101] in Participants With Early Alzheimer's Disease	Drug: GSK4527226 Other: Placebo	GlaxoSmithKline Alector Inc.	Phase 2	

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NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06081920	A Study of IBI363 in Subjects With Advanced Melanoma	Biological: IBI363	Innovent Biologics (Suzhou) Co. Ltd.	Phase 1 Phase 2	
NCT06079112	9MW2821 Combined With Toripalimab Injection in Subjects With Local Advanced or Metastatic Urothelial Cancer	Drug: 9MW2821 Drug: Toripalimab	Mabwell (Shanghai) Bioscience Co., Ltd.	Phase 1 Phase 2	
NCT06080984	The Application of Novel Oncolytic Virus in Late Stage Solid Tumors	Drug: Oncolytic Virus SDJ001 Drug: Oncolytic Virus YD06-1	West China Hospital	Phase 1	
NCT06055738	Zimberelimab Combined With Albumin-bound Paclitaxel and Cisplatin in Neoadjuvant Treatment of LACC	Drug: Zimberelimab Drug: Albumin-bound Paclitaxel Drug: Cisplatin	Tang-Du Hospital	Phase 2	
NCT05980507	An Open Label, Single-arm Clinical Study Evaluating the Safety and Efficacy of ICI201 Infusion in Relapsed/Refractory Multiple Myeloma	Drug: ICI201	The First Affiliated Hospital of Soochow University	Phase 1	
NCT05866354	To Evaluate Pharmacokinetics of Tisotumab Vedotin in Chinese Subjects With Metastatic or Recurrent Solid Malignancies	Drug: Tisotumab Vedotin	Zai Lab (Shanghai) Co., Ltd. Zai Lab (Hong Kong), Ltd.	Phase 1	
NCT06056804	Neoadjuvant Chemoradiotherapy Combined With PD-1 Inhibitor and Thymalfasin for pMMR/MSS Locally Advanced Mid-low Rectal Cancer	Drug: capecitabine Drug: tislelizumab Drug: thymalfasin Radiation: long-term radiotherapy	Beijing Friendship Hospital Peking Union Medical College Hospital	Phase 2	
NCT06084936	A Study to Evaluate Glofitamab as a Single Agent vs. Investigator's Choice in Participants With Relapsed/Refractory Mantle Cell Lymphoma	Drug: Obinutuzumab Drug: Glofitamab Drug: Rituximab Drug: Bendamustine Drug: Lenalidomide Drug: Tocilizumab	Hoffmann-La Roche	Phase 3	

○ 일본 1건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05257083	A Study of Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucl 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	