

해외 바이오의약품 임상 현황 (2020.11.16~2020.11.22)

한국바이오의약품협회, 2020.11.24
출처: ClinicalTrials.gov

○ 미국 26건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04620681	CD8 Depleted, Non-engrafting, HLA Mismatched Unrelated Infusion With MDS and Secondary AML	Myelodysplastic Syndromes Secondary Acute Myeloid Leukemia	Biological: CD8 Depleted, Non-engrafting,HLA mismatched unrelated donor lymphocytes Drug: Standard of Care Chemotherapy	H. Lee Moffitt Cancer Center and Research Institute	Phase 1 Phase 2
NCT04588545	Radiation Therapy Followed by Intrathecal Trastuzumab/Pertuzumab in HER2+ Breast Leptomeningeal Disease	HER2-positive Breast Cancer Leptomeningeal Metastasis Leptomeningeal Disease	Radiation: Radiation Therapy Drug: Pertuzumab Drug: Trastuzumab	H. Lee Moffitt Cancer Center and Research Institute Genentech, Inc.	Phase 1 Phase 2
NCT04445220	A Study of Cell Therapy in COVID-19 Subjects With Acute Kidney Injury Who Are Receiving Renal Replacement Therapy	COVID-19 Acute Kidney Injury	Biological: SBI-101	Sentien Biotechnologies, Inc.	Phase 1 Phase 2
NCT04331067	Cabiralizumab in Combination With Nivolumab and Neoadjuvant Chemotherapy in Patients With Localized Triple-negative Breast Cancer	Triple Negative Breast Cancer	Drug: Paclitaxel Drug: Carboplatin Biological: Nivolumab Biological: Cabiralizumab Procedure: Tumor biopsy Procedure: Bone marrow Procedure: Blood draw	Washington University School of Medicine Bristol-Myers Squibb	Phase 1 Phase 2
NCT04607954	Durvalumab and Topotecan for the Treatment of Relapsed or Refractory Small Cell Lung Cancer	Platinum-Sensitive Lung Small Cell Carcinoma Recurrent Extensive Stage Lung Small Cell Carcinoma Refractory Extensive Stage Lung Small Cell Carcinoma	Biological: Durvalumab Drug: Topotecan Hydrochloride	Mayo Clinic National Cancer Institute (NCI)	Phase 2
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	Plasma Cell Myeloma Recurrent Plasma Cell Myeloma Refractory Plasma Cell 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 Research Center National Cancer Institute (NCI)	Phase 1
NCT04231877	Polatuzumab Vedotin and Combination Chemotherapy for the Treatment of Untreated Aggressive Large B-cell Lymphoma	Aggressive Non-Hodgkin Lymphoma ALK-Positive Large B-Cell Lymphoma B-Cell Lymphoma, Unclassifiable, With Features Intermediate Between Diffuse Large B-Cell Lymphoma and Classic Hodgkin Lymphoma Diffuse Large B-Cell Lymphoma, Not Otherwise Specified EBV-Positive Diffuse Large B-Cell Lymphoma, Not Otherwise Specified High Grade B-Cell Lymphoma With MYC and BCL2 and/or BCL6 Rearrangements High Grade B-Cell Lymphoma, Not Otherwise Specified Primary Mediastinal (Thymic) Large B-Cell Lymphoma T-Cell/Histiocyte-Rich Large B-Cell Lymphoma	Drug: Polatuzumab Vedotin Biological: Rituximab Drug: Prednisone Drug: Etoposide Drug: Doxorubicin Drug: Cyclophosphamide Biological: Filgrastim	University of Washington National Cancer Institute (NCI) Genentech, Inc.	Phase 1
NCT04623671	Intravenous Infusion of CAP-1002 in Patients With COVID-19	Covid19	Biological: CAP-1002 Biological: Placebo	Capricor Inc.	Phase 2
NCT04609579	Study of SNX281 in Subjects With Advanced Solid Tumors and Lymphoma	Advanced Solid Tumor Advanced Lymphoma	Drug: SNX281 Drug: Pembrolizumab	Silicon Therapeutics	Phase 1
NCT04592549	This is a Phase 1 Clinical Trial to Evaluate the Safety, Pharmacokinetics, and Immunogenicity of ADM03820, a Monoclonal Antibody Cocktail Being Tested for the Treatment and Prevention of COVID-19	SARS-CoV-2	Drug: ADM03820 Other: Placebo	Ology Bioservices Enabling Biotechnologies (EB)	Phase 1
NCT04634149	A Study to Evaluate the Drug Levels, Safety, and Tolerability of BMS-986036 in Participants With Normal Liver Function and Participants With Moderate and Severe Liver Impairment	Moderate Liver Impairment Severe Liver Impairment	Biological: BMS-986036	Bristol-Myers Squibb	Phase 1
NCT04527991	Study of Sacituzumab Govitecan (IMMU-132) in Metastatic or Locally Advanced Unresectable Urothelial Cancer	Urothelial Carcinoma Bladder Cancer Metastatic Urothelial Carcinoma Locally Advanced Urothelial Cancer Transitional Cell Carcinoma	Drug: sacituzumab govitecan 10 mg/kg IV q21 day dosing Drug: Treatment of Physician's Choice of either paclitaxel 175 mg/m2, docetaxel 75 mg/m2 or vinflunine 320 mg/m2	Immunomedics, Inc.	Phase 3
NCT04631588	Intradermal (ID) BOTOX in the Treatment of Facial Fine Lines	Facial Fine Lines	Drug: Botox Drug: Placebo	Allergan	Phase 1
NCT04498910	A Study of LY3451838 in Participants With Migraine	Migraine	Drug: LY3451838 Drug: Placebo	Eli Lilly and Company	Phase 2
NCT04557384	A Study of Ramucirumab (LY3009806) Given by Injection Under the Skin in Participants With Advanced Cancer	Advanced Solid Tumor	Drug: Ramucirumab	Eli Lilly and Company	Phase 1
NCT04626297	A Study of Lebrikizumab (LY3650150) on Vaccine Response in Adults With Atopic Dermatitis (ADopt-VA)	Atopic Dermatitis	Drug: Lebrikizumab Drug: Placebo	Eli Lilly and Company	Phase 3
NCT04619420	A Study of JNJ-63733657 in Participants With Early Alzheimer's Disease	Alzheimer Disease Cognitive Dysfunction Dementia	Drug: JNJ-63733657 Drug: Placebo	Janssen Research & Development, LLC	Phase 2
NCT04548999	A Study to Evaluate the Efficacy, Safety and Pharmacokinetics of a Higher Dose of Ocrelizumab in Adults With Primary Progressive Multiple Sclerosis (PPMS)	Multiple Sclerosis	Drug: Ocrelizumab Drug: Antihistamine Drug: Methylprednisolone	Hoffmann-La Roche	Phase 3
NCT04539275	COVID-19 (VA CURES-1)	COVID-19	Drug: Convalescent Plasma Other: Masked Saline Placebo	VA Office of Research and Development	Phase 3
NCT04631016	A Phase II, Randomized, Double-blind, Placebo-controlled Study to Assess MEDI3506 in Participants With COPD and Chronic Bronchitis	Chronic Obstructive Pulmonary Disease (COPD) Chronic Bronchitis	Biological: MEDI3506 Other: Placebo	AstraZeneca	Phase 2
NCT04511013	A Study to Compare the Administration of Encorafenib + Binimetinib + Nivolumab Versus Ipilimumab + Nivolumab in BRAF-V600 Mutant Melanoma With Brain Metastases	Acral Lentiginous Melanoma Clinical Stage IV Cutaneous Melanoma AJCC v8 Metastatic Cutaneous Melanoma Metastatic Malignant Neoplasm in the Brain Metastatic Melanoma Metastatic Mucosal Melanoma Pathologic Stage IV Cutaneous Melanoma AJCC v8	Drug: Binimetinib Drug: Encorafenib Biological: Ipilimumab Biological: Nivolumab	Southwest Oncology Group National Cancer Institute (NCI)	Phase 2
NCT04539470	Study to Evaluate the Safety and Pharmacokinetics of UTR1147A in Combination With Standard of Care in Participants Undergoing Allogeneic Hematopoietic Stem Cell Transplantation	Acute Graft-versus-host Disease	Drug: UTR1147A	Genentech, Inc.	Phase 1

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NCT04299048	Safety, Tolerability, PK and PD Following SC PF-06946860 in Patients With NSCLC and Cachexia	Cachexia Non-Small-Cell Lung Cancer	Drug: PF-06946860	Pfizer	Phase 1
NCT04457284	Temozolomide, Cisplatin, and Nivolumab in People With Colorectal Cancer	Colorectal Adenocarcinoma	Drug: Temozolomide (TMZ) Drug: Cisplatin Drug: Nivolumab	Memorial Sloan Kettering Cancer Center Bristol-Myers Squibb	Phase 2
NCT04350138	Safety and Efficacy Study of Meningococcal Group B Vaccine rMenB+OMV NZ (Bexsero) to Prevent Gonococcal Infection	Gonococcal Infection	Biological: Meningococcal Group B Vaccine Other: Placebo	National Institute of Allergy and Infectious Diseases (NIAID)	Phase 2
NCT04580121	A Dose Escalation and Expansion Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of RO7283420.	Acute Myeloid Leukemia	Drug: RO7283420 Drug: Tocilizumab Drug: Dasatinib	Hoffmann-La Roche	Phase 1

○ 영국 1건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04548999	A Study to Evaluate the Efficacy, Safety and Pharmacokinetics of a Higher Dose of Ocrelizumab in Adults With Primary Progressive Multiple Sclerosis (PPMS)	Multiple Sclerosis	Drug: Ocrelizumab Drug: Antihistamine Drug: Methylprednisolone	Hoffmann-La Roche	Phase 3

○ 프랑스 2건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04547504	pEmbrolizumab verSus chEmotherapy and pEmbrolizumab in Non-small-cell Lung Cancers (NSCLC) With PDL1 ≥ 50 %	Non-small-cell Lung Cancer	Drug: Pembrolizumab Drug: Pembrolizumab and Chemotherapy drugs	University Hospital, Brest Groupe Français de Pneumo-Cancérologie	Phase 3
NCT04548999	A Study to Evaluate the Efficacy, Safety and Pharmacokinetics of a Higher Dose of Ocrelizumab in Adults With Primary Progressive Multiple Sclerosis (PPMS)	Multiple Sclerosis	Drug: Ocrelizumab Drug: Antihistamine Drug: Methylprednisolone	Hoffmann-La Roche	Phase 3

○ 독일 3건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04633148	Dose-escalating Trial With UniCAR02-T Cells and PSMA Target Module (TmPSPMA) in Patients With Progressive Disease After Standard Systemic Therapy in Cancers With Positive PSMA Marker	Renal Cancer Transitional Cell Cancer of the Renal Pelvis and Ureter Prostate Cancer Non-small Cell Lung Cancer Breast Cancer Colorectal Cancer	Drug: Cyclophosphamide (Non-IMP) Drug: Fludarabine (Non-IMP) Drug: UniCAR02-T-pPSMA Drug: UniCAR02-T (IMP)	Cellex Patient Treatment GmbH PHARMALOG Institut für klinische Forschung GmbH	Phase 1
NCT04548999	A Study to Evaluate the Efficacy, Safety and Pharmacokinetics of a Higher Dose of Ocrelizumab in Adults With Primary Progressive Multiple Sclerosis (PPMS)	Multiple Sclerosis	Drug: Ocrelizumab Drug: Antihistamine Drug: Methylprednisolone	Hoffmann-La Roche	Phase 3
NCT04631016	A Phase II, Randomized, Double-blind, Placebo-controlled Study to Assess MEDI3506 in Participants With COPD and Chronic Bronchitis	Chronic Obstructive Pulmonary Disease (COPD) Chronic Bronchitis	Biological: MEDI3506 Other: Placebo	AstraZeneca	Phase 2

○ 중국 9건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04636008	Sintilimab Plus Hypofractionated Radiotherapy for MSI-H/dMMR Rectal Cancer	Anti-PD-1 Antibody Radiotherapy Rectal Cancer MSI-H Mmr Deficiency	Drug: Sintilimab Radiation: Hypofractionated Radiotherapy	West China Hospital First Affiliated Hospital of Chongqing Medical University Yunnan Cancer Hospital Sichuan Cancer Hospital and Research Institute Chengdu Third People's Hospital The Affiliated Hospital Of Southwest Medical University	Phase 1 Phase 2
NCT04626908	Clinical Study of Targeting CD19 and CD22 Chimeric Antigen Receptor T Lymphocytes in the Treatment of Recurrent or Refractory B Cell Non-Hodgkin Lymphoma	Relapsed and Refractory Lymphoid Hematological Malignancies	Drug: GC022F CAR-T cells	He Huang Gracell Biotechnology Ltd. Zhejiang University	Phase 1 Phase 2
NCT04624217	A Trial of SHR-1701 in Combination With Gemcitabine and Albumin Paclitaxel in Patients With Pancreatic Cancer	Pancreatic Cancer	Drug: SHR-1701	Jiangsu HengRui Medicine Co., Ltd.	Phase 1 Phase 2
NCT04611321	Study of IBI318 in Patients With Advanced Cutaneous Squamous Cell Carcinoma	Advanced Cutaneous Squamous Cell Carcinoma	Drug: IBI318	Innovent Biologics (Suzhou) Co. Ltd.	Phase 1 Phase 2
NCT04640402	A Phase II Clinical Trial of Recombinant Corona Virus Disease-19 (COVID-19) Vaccine (Sf9 Cells)	COVID-19	Biological: Low-dose Recombinant COVID-19 vaccine (Sf9 cells) (18-59 years) & Two dose regimen Biological: Low-dose Recombinant COVID-19 vaccine (Sf9 cells) (18-59 years) & Three dose regimen Biological: High-dose Recombinant COVID-19 vaccine (Sf9 cells) (18-59 years) & Two dose regimen Biological: High-dose Recombinant COVID-19 vaccine (Sf9 cells) (18-59 years) & Three dose regimen Biological: Low-dose Recombinant COVID-19 vaccine (Sf9 cells) (60-85 years) & Two dose regimen Biological: Low-dose Recombinant COVID-19 vaccine (Sf9 cells) (60-85 years) & Three dose regimen Biological: High-dose Recombinant COVID-19 vaccine (Sf9 cells) (60-85 years) & Two dose regimen Biological: High-dose Recombinant COVID-19 vaccine (Sf9 cells) (60-85 years) & Three dose regimen	Jiangsu Province Centers for Disease Control and Prevention West China Hospital	Phase 2

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NCT04635527	A Study on the Safety and Effectiveness of IBI318 Combined With Conventional TACE (cTACE) as a Perioperative Treatment for Potentially Resected Hepatocellular Carcinoma	Hepatocellular Carcinoma	Drug: IBI318 Procedure: cTACE Drug: placebo	Innovent Biologics (Suzhou) Co. Ltd.	Phase 1
NCT04612673	A Phase II Study of Anti-PD-1 Antibody, Sintilimab, as Second-line Therapy for Biomarker-selected Advanced or Metastatic NSCLC	Non-small Cell Lung Cancer	Drug: Sintilimab	China Medical University, China Shengjing Hospital The First People's Hospital of Jingzhou The People's Hospital of Liaoning Province Liaoning Cancer Hospital & Institute Anshan Tumor Hospital Benxi Central Hospital The Second Affiliated Hospital of Dalian Medical University The First Affiliated Hospital of Dalian Medical University	Phase 2
NCT04516551	Anti-CD19 Allo-CAR-T Cells for Relapsed B Cell Malignancies After HSCT	Relapsed Adult ALL B Cell Leukemia	Biological: anti-CD19 allo-CAR-T cells	Xinqiao Hospital of Chongqing Gracell Biotechnologies (Shanghai) Co., Ltd First Affiliated Hospital of Zhejiang University The Second Affiliated Hospital of Chongqing Medical University The Affiliated Hospital Of Guizhou Medical University The General Hospital of Western Theater Command Chongqing University Cancer Hospital The First Affiliated Hospital of Anhui Medical University Tang-Du Hospital 920th Hospital of Joint Logistics Support Force First	Phase 1
NCT04637503	4SCAR-T Therapy Targeting GD2, PSMA and CD276 for Treating Neuroblastoma	Neuroblastoma	Biological: GD2, PSMA and CD276 CAR-T cells	Shenzhen Geno-Immune Medical Institute Shenzhen Children's Hospital	Phase 1 Phase 2

○ 일본 1건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04557384	A Study of Ramucirumab (LY3009806) Given by Injection Under the Skin in Participants With Advanced Cancer	Advanced Solid Tumor	Drug: Ramucirumab	Eli Lilly and Company	Phase 1