

해외 바이오의약품 임상 현황 (2020.2.10~2020.2.16)

한국바이오의약품협회, 2020.2.18.
출처: ClinicalTrials.gov

○ 미국 14건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
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
NCT04162210	Study of Single Agent Belantamab Mafodotin Versus Pomalidomide Plus Low-dose Dexamethasone (Pom/Dex) in Participants With Relapsed/Refractory Multiple Myeloma (RRMM)	Multiple Myeloma	Drug: Belantamab mafodotin Drug: Pom/dex (Pomalidomide plus low dose Dexamethasone)	GlaxoSmithKline	Phase 3
NCT04032418	Pembrolizumab Every 12 Weeks Versus Every 3 Weeks in Treating Patients With Non-small Cell Lung Cancer	Lung Non-Small Cell Carcinoma	Biological: Pembrolizumab	Roswell Park Cancer Institute National Cancer Institute (NCI)	Phase 2
NCT04212091	Evaluating the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of the Monoclonal Antibody PGT121.414.LS Administered Alone and in Combination With VRC07-523LS Via Intravenous or Subcutaneous Infusions in Healthy, HIV-uninfected Adult Participants	HIV Infections	Biological: PGT121.414.LS Biological: VRC07-523LS	National Institute of Allergy and Infectious Diseases (NIAID) HIV Vaccine Trials Network HIV Prevention Trials Network	Phase 1
NCT04268498	A Study of Daratumumab, Carfilzomib, Lenalidomide, and Dexamethasone in Patients With Newly-Diagnosed Multiple Myeloma	Multiple Myeloma	Drug: Bortezomib Drug: Dexamethasone Drug: Lenalidomide Drug: Acetaminophen Drug: Diphenhydramine Drug: Montelukast Drug: Carfilzomib Drug: Daratumumab	Memorial Sloan Kettering Cancer Center	Phase 2
NCT04258995	A TRIAL TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF A BOOSTER DOSE OF A GROUP B STREPTOCOCCUS 6 VALENT POLYSACCHARIDE CONJUGATE VACCINE (GBS6) IN HEALTHY ADULTS	Group B Streptococcal Infections	Biological: Group B streptococcus 6-valent polysaccharide conjugate vaccine (GBS6)	Pfizer	Phase 2
NCT04254783	A Study to Evaluate the Effect of Intravenous (IV) Infusions of Risankizumab on Pharmacokinetics of Cytochrome P450 Substrates in Adult Participants With Moderately to Severely Active Ulcerative Colitis or Crohn's Disease	Ulcerative Colitis (UC) Crohn's Disease	Drug: Risankizumab Drug: Cytochrome P450 (CYP) Substrates	AbbVie	Phase 1
NCT04007744	Sonidegib and Pembrolizumab in Treating Patients With Advanced Solid Tumors	Clinical Stage III Cutaneous Melanoma AJCC v8 Clinical Stage III Gastric Cancer AJCC v8 Clinical Stage III Gastroesophageal Junction Adenocarcinoma AJCC v8 Clinical Stage IV Cutaneous Melanoma AJCC v8 Clinical Stage IV Gastric Cancer AJCC v8 Clinical Stage IV Gastroesophageal Junction Adenocarcinoma AJCC v8 Clinical Stage IVA Gastric Cancer AJCC v8 Clinical Stage IVA Gastroesophageal Junction Adenocarcinoma AJCC v8 Clinical Stage IVB Gastric Cancer AJCC v8 Clinical Stage IVB Gastroesophageal Junction Adenocarcinoma AJCC v8 High-Frequency Microsatellite Instability Locally Advanced Urothelial Carcinoma Metastatic Gastric Adenocarcinoma Metastatic Gastroesophageal Junction Adenocarcinoma Metastatic Head and Neck Squamous Cell Carcinoma Metastatic Lung Non-Small Cell Carcinoma Metastatic Malignant Solid Neoplasm Metastatic Melanoma Metastatic Pancreatic Adenocarcinoma Metastatic Urothelial Carcinoma Mismatch Repair Deficiency Pathologic Stage III Cutaneous Melanoma AJCC v8 Pathologic Stage III Gastric Cancer AJCC v8 Pathologic Stage III Gastroesophageal Junction Adenocarcinoma AJCC v8 Pathologic Stage IIIA Gastric Cancer AJCC v8 Pathologic Stage IIIA Gastroesophageal Junction Adenocarcinoma AJCC v8 Pathologic Stage IIIB Gastric Cancer AJCC v8 Pathologic Stage IIIB Gastroesophageal Junction Adenocarcinoma AJCC v8 Pathologic Stage IIIC Gastric Cancer AJCC v8 Pathologic Stage IV Cutaneous Melanoma AJCC v8 Pathologic Stage IV Gastric Cancer AJCC v8 Pathologic Stage IV Gastroesophageal Junction Adenocarcinoma AJCC v8 Pathologic Stage IVA Gastroesophageal Junction Adenocarcinoma AJCC v8 Pathologic Stage IVB Gastroesophageal Junction Adenocarcinoma AJCC v8 PD-L1 Positive Progressive Disease Recurrent Head and Neck Squamous Cell Carcinoma Refractory Lung Non-Small Cell Carcinoma Refractory Pancreatic Adenocarcinoma Stage II Pancreatic Cancer AJCC v8 Stage IIA Pancreatic Cancer AJCC v8 Stage IIB Pancreatic Cancer AJCC v8 Stage III Pancreatic Cancer AJCC v8 Stage IV Cutaneous Squamous Cell Carcinoma of the Head and Neck AJCC v8 Stage IV Lung Cancer AJCC v8 Stage IV Pancreatic Cancer AJCC v8 Stage IVA Lung Cancer AJCC v8 Stage IVB Lung Cancer AJCC v8 Unresectable Malignant Solid Neoplasm Unresectable Melanoma Unresectable Pancreatic Adenocarcinoma	Biological: Pembrolizumab Drug: Sonidegib	Mayo Clinic National Cancer Institute (NCI)	Phase 1

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NCT03983395	Study of ISB 1302 (CD3 Bispecific Ab) in HER2-positive Metastatic Breast Cancer	Breast Cancer	Biological: ISB 1302 250 ng/kg Biological: ISB 1302 325 ng/kg Biological: ISB 1302 325 ng/kg-D1;425 ng/kg - D8,D15,D22 Biological: ISB 1302 325 ng/kg-D1;550 ng/kg - D8,D15,D22 Biological: ISB 1302 325ng/kgD1;550 ng/kg D8;700 ng/kgD15,22 Biological: ISB 1302 325ng/kg D1;550 ng/kg D8;900 ng/kg D15,22 Biological: ISB 1302 escalating doses,1200 ng/kg D15,22 Biological: ISB 1302 at the MTD and/or RP2D dose	Ichnos Sciences SA Glenmark Pharmaceuticals S.A.	Phase 1 Phase 2
NCT04221477	A Study To Evaluate The Efficacy And Safety Of Obinutuzumab In Patients With ISN/RPS 2003 Class III Or IV Lupus Nephritis	Lupus Nephritis	Drug: Obinutuzumab Drug: Mycophenolate Mofetil Drug: Prednisone Drug: Placebo Drug: Methylprednisolone Drug: Acetaminophen Drug: Diphenhydramine	Hoffmann-La Roche	Phase 3
NCT04095858	CD24Fc for the Prevention of Acute GVHD Following Myeloablative HSCT	Hematopoietic Stem Cell Transplantation Acute Graft Versus Host Disease Acute Myeloid Leukemia Acute Lymphoblastic Leukemia Myelodysplastic Syndromes	Drug: CD24Fc Drug: Placebo Drug: Methotrexate Drug: Tacrolimus	OncoImmune, Inc.	Phase 3
NCT04268771	A Phase III Transition Study of DRL Rituximab to Reference Medicinal Products	Rheumatoid Arthritis	Biological: Experimental: Arm A: DRL_RI Biological: Arm B: Rituxan 璉/Mabthera璉	Dr. Reddy's Laboratories Limited PPD	Phase 3
NCT04158648	A Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of Emicizumab in Participants With Mild or Moderate Hemophilia A Without FVIII Inhibitors	Mild Hereditary Factor VIII Deficiency Disease Without Inhibitor Moderate Hereditary Factor VIII Deficiency Disease Without Inhibitor Hemophilia A	Drug: Emicizumab	Hoffmann-La Roche	Phase 3
NCT04272203	A Study to Determine Safety, Tolerability, Pharmacokinetics, and Recommended Phase 2 Dose (RP2D) of Intravenous ABBV-184 in Adult Participants With Previously Treated Cancers	Acute Myeloid Leukemia (AML) Non Small Cell Lung Cancer Cancer	Drug: ABBV-184	AbbVie	Phase 1

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NCT04272203	A Study to Determine Safety, Tolerability, Pharmacokinetics, and Recommended Phase 2 Dose (RP2D) of Intravenous ABBV-184 in Adult Participants With Previously Treated Cancers	Acute Myeloid Leukemia (AML) Non Small Cell Lung Cancer Cancer	Drug: ABBV-184	AbbVie	Phase 1
NCT04158648	A Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of Emicizumab in Participants With Mild or Moderate Hemophilia A Without FVIII Inhibitors	Mild Hereditary Factor VIII Deficiency Disease Without Inhibitor Moderate Hereditary Factor VIII Deficiency Disease Without Inhibitor Hemophilia A	Drug: Emicizumab	Hoffmann-La Roche	Phase 3

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NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04243499	First-in-Human Study of ICT01 in Patients With Advanced Cancer	Solid Tumor, Adult Hematopoietic/Lymphoid Cancer	Biological: IV ICT01	ImCheck Therapeutics	Phase 1
NCT03946358	Combination of UCPVax Vaccine and Atezolizumab for the Treatment of Human Papillomavirus Positive Cancers (VolATIL)	Squamous Cell Carcinoma of the Head and Neck Anal Canal Cancer Cervical Cancer	Biological: Blood sample collection Procedure: Tumor biopsies Other: CT scan Drug: Atezolizumab Drug: UCPVax	Centre Hospitalier Universitaire de Besancon Roche Pharma AG National Cancer Institute, France	Phase 2
NCT04272203	A Study to Determine Safety, Tolerability, Pharmacokinetics, and Recommended Phase 2 Dose (RP2D) of Intravenous ABBV-184 in Adult Participants With Previously Treated Cancers	Acute Myeloid Leukemia (AML) Non Small Cell Lung Cancer Cancer	Drug: ABBV-184	AbbVie	Phase 1
NCT04221477	A Study To Evaluate The Efficacy And Safety Of Obinutuzumab In Patients With ISN/RPS 2003 Class III Or IV Lupus Nephritis	Lupus Nephritis	Drug: Obinutuzumab Drug: Mycophenolate Mofetil Drug: Prednisone Drug: Placebo Drug: Methylprednisolone Drug: Acetaminophen Drug: Diphenhydramine	Hoffmann-La Roche	Phase 3
NCT04158648	A Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of Emicizumab in Participants With Mild or Moderate Hemophilia A Without FVIII Inhibitors	Mild Hereditary Factor VIII Deficiency Disease Without Inhibitor Moderate Hereditary Factor VIII Deficiency Disease Without Inhibitor Hemophilia A	Drug: Emicizumab	Hoffmann-La Roche	Phase 3

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NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04221477	A Study To Evaluate The Efficacy And Safety Of Obinutuzumab In Patients With ISN/RPS 2003 Class III Or IV Lupus Nephritis	Lupus Nephritis	Drug: Obinutuzumab Drug: Mycophenolate Mofetil Drug: Prednisone Drug: Placebo Drug: Methylprednisolone Drug: Acetaminophen Drug: Diphenhydramine	Hoffmann-La Roche	Phase 3
NCT04158648	A Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of Emicizumab in Participants With Mild or Moderate Hemophilia A Without FVIII Inhibitors	Mild Hereditary Factor VIII Deficiency Disease Without Inhibitor Moderate Hereditary Factor VIII Deficiency Disease Without Inhibitor Hemophilia A	Drug: Emicizumab	Hoffmann-La Roche	Phase 3

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NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04264936	A Study of RC48-ADC(Antibody Drug Conjugate) and JS001 to Evaluate the Safety and Pharmacokinetics of Subjects With Locally Advanced or Metastatic Urothelial Cancer	Urothelial Carcinoma	Drug: RC48-ADC and JS001	Beijing Cancer Hospital	Phase 1 Phase 2
NCT04271813	An Phase II Study of First-line Treatment of Advanced Colorectal Cancer With Anlotinib Plus Sintilimab	Colorectal Cancer Immunotherapy Anlotinib Sintilimab Chemo-free Therapy First-line Treatment	Drug: Anlotinib plus Sintilimab	Shanghai Changzheng Hospital	Phase 2
NCT04260945	CD19/CD20 Dual-CAR-T in B-cell Leukemia Patients	B-cell Leukemia	Biological: CD19/CD20 Dual-CAR-T cells	Hebei Yanda Ludaopei Hospital China Immunotech Co., Ltd.	Phase 1
NCT04260932	CD19/CD20 Dual-CAR-T in B-cell Lymphoma Patients	B-cell Lymphoma	Biological: CD19/CD20 Dual-CAR-T cells	Hebei Yanda Ludaopei Hospital China Immunotech Co., Ltd.	Phase 1
NCT04220307	A Study of a PD-1/CTLA-4 Bispecific Antibody AK104 in Patients With Metastatic Nasopharyngeal Carcinoma	Nasopharyngeal Carcinoma	Biological: AK-104	Akeso Akeso Pharmaceuticals, Inc.	Phase 2
NCT04175847	A Phase I Study of RC88-ADC in Subjects With Advanced Malignant Solid Tumors	Solid Tumor	Drug: RC88	RemeGen	Phase 1

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NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04272203	A Study to Determine Safety, Tolerability, Pharmacokinetics, and Recommended Phase 2 Dose (RP2D) of Intravenous ABBV-184 in Adult Participants With Previously Treated Cancers	Acute Myeloid Leukemia (AML) Non Small Cell Lung Cancer Cancer	Drug: ABBV-184	AbbVie	Phase 1