

해외 바이오의약품 임상 현황 (2021.1.25~2021.1.31)

한국바이오의약품협회, 2021.2.2.
출처: ClinicalTrials.gov

○ 미국 32건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases	출처 URL
NCT04624113	Tazemetostat and Pembrolizumab in Patients With Pembrolizumab- or Nivolumab-Resistant, Recurrent or Metastatic Head and Neck Squamous-Cell Carcinoma	Head and Neck Squamous Cell Carcinoma	Drug: Tazemetostat[Drug: Pembrolizumab	Washington University School of Medicine Epizyme, Inc.	Phase 1 Phase 2	
NCT04729725	Strategic Alliance: Phase 1b Trial Assessing Combination of TGF-β Inhibitor and PD-1 Inhibitor Cemiplimab	Advanced Malignant Solid Neoplasm Metastatic Malignant Solid Neoplasm Unresectable Malignant Solid Neoplasm	Biological: Anti-TGF-beta Monoclonal Antibody SAR-439459 Biological: Cemiplimab	M.D. Anderson Cancer Center	Phase 1	
NCT04714983	DNX-2440 for Resectable Colorectal Liver Metastasis	Liver Metastases Liver Metastasis Colon Cancer Colorectal Cancer Breast Cancer Gastric Cancer Periapillary Cancer Melanoma Renal Cell Cancer Sarcoma Squamous Cell Carcinoma Gastrointestinal Stromal Tumors	Biological: DNX-2440	DNAtrix, Inc. H. Lee Moffitt Cancer Center and Research Institute	Phase 1	
NCT04712851	Pembrolizumab for the Treatment of High-Grade Vulvar, Vaginal, or Cervical Intraepithelial Neoplasia	Cervical Intraepithelial Neoplasia Cervical Squamous Cell Carcinoma In Situ Cervical Squamous Intraepithelial Neoplasia 2 Vaginal Intraepithelial Neoplasia Vulvar Intraepithelial Neoplasia	Biological: Pembrolizumab	Jonsson Comprehensive Cancer Center Merck Sharp & Dohme Corp.	Phase 2	
NCT04708054	Venetoclax, Busulfan, Cladribine, and Fludarabine for the Treatment of High-Risk Acute Myeloid Leukemia or Myelodysplastic Syndrome	Acute Myeloid Leukemia Chronic Myelomonocytic Leukemia Myelodysplastic Syndrome	Drug: Busulfan Drug: Cladribine Drug: Fludarabine Phosphate Procedure: Hematopoietic Cell Transplantation Drug: Thiotepa Drug: Venetoclax	M.D. Anderson Cancer Center	Phase 2	
NCT04701307	Niraparib and Dostarlimab for the Treatment of Small Cell Lung Cancer and Other High-Grade Neuroendocrine Carcinomas	Lung Small Cell Carcinoma Neuroendocrine Carcinoma Stage III Lung Cancer AJCC v8 Stage IIIA Lung Cancer AJCC v8 Stage IIIB Lung Cancer AJCC v8 Stage IIIC Lung Cancer AJCC v8	Biological: Dostarlimab Drug: Niraparib	M.D. Anderson Cancer Center	Phase 2	
NCT04697628	Tisotumab Vedotin vs Chemotherapy in Recurrent or Metastatic Cervical Cancer	Cervical Cancer	Drug: tisotumab vedotin Drug: topotecan Drug: vinorelbine Drug: gemcitabine Drug: irinotecan Drug: pemetrexed	Seagen Inc. Genmab	Phase 3	
NCT04696575	Lamivudine in Combination With Chemoimmunotherapy for the Treatment of Extensive Stage Small Cell Lung Cancer	Extensive Stage Lung Small Cell Carcinoma	Biological: Atezolizumab Drug: Carboplatin Drug: Etoposide Drug: Lamivudine	Roswell Park Cancer Institute	Phase 2	
NCT04675710	Pembrolizumab, Dabrafenib, and Trametinib Before Surgery for the Treatment of BRAF-Mutated Anaplastic Thyroid Cancer	Thyroid Gland Anaplastic Carcinoma Thyroid Gland Squamous Cell Carcinoma	Procedure: Conventional Surgery Drug: Dabrafenib Radiation: Intensity-Modulated Radiation Therapy Biological: Pembrolizumab Other: Quality-of-Life Assessment Drug: Trametinib	M.D. Anderson Cancer Center	Phase 2	
NCT04659811	Stereotactic Radiosurgery and Immunotherapy (Pembrolizumab) for the Treatment of Recurrent Meningioma	Grade I Meningioma, Adult Grade II Meningioma, Adult Grade III Meningioma, Adult Recurrent Meningioma	Drug: Pembrolizumab Procedure: Stereotactic Radiosurgery	Nancy Ann Oberheim Bush, MD Merck Sharp & Dohme Corp. University of California, San Francisco	Phase 2	
NCT04643379	Olaparib in Combination With Pembrolizumab and Carboplatin as First-Line Treatment of Recurrent or Metastatic Head and Neck Squamous-Cell Carcinoma	Recurrent Head and Neck Squamous Cell Carcinoma Metastatic Head and Neck Squamous Cell Carcinoma	Drug: Olaparib Drug: Pembrolizumab Drug: Carboplatin Procedure: Peripheral blood draw	Washington University School of Medicine Merck Sharp & Dohme Corp. Joseph Sanchez Foundation	Phase 2	
NCT04611880	Crizanlizumab for Treatment of Retinal Vasculopathy With Cerebral Leukoencephalopathy (RVCL)	RVCL - Retinal Vasculopathy Cerebral Leukoencephalopathy	Drug: Crizanlizumab	Washington University School of Medicine	Phase 2	
NCT04605731	Durvalumab and Tremelimumab After Radioembolization for the Treatment of Unresectable, Locally Advanced Liver Cancer	BCLC Stage B Hepatocellular Carcinoma BCLC Stage C Hepatocellular Carcinoma Locally Advanced Hepatocellular Carcinoma Stage III Hepatocellular Carcinoma AJCC v8 Stage IIIA Hepatocellular Carcinoma AJCC v8 Stage IIIB Hepatocellular Carcinoma AJCC v8 Stage IV Hepatocellular Carcinoma AJCC v8 Stage IVA Hepatocellular Carcinoma AJCC v8 Stage IVB Hepatocellular Carcinoma AJCC v8 Unresectable Hepatocellular Carcinoma	Biological: Durvalumab Biological: Tremelimumab	City of Hope Medical Center National Cancer Institute (NCI)	Phase 1	
NCT04582864	Flotetuzumab for Relapsed Acute Myeloid Leukemia (AML) Following Allogeneic Hematopoietic Cell Transplantation (Allo-HCT)	Relapsed Acute Myeloid Leukemia	Drug: MGD006 Procedure: Donor lymphocyte infusion	Washington University School of Medicine MacroGenics	Phase 2	
NCT04536077	Immunologic Effects of CDX-301 and CDX-1140 in Resectable Pancreatic Cancer Patients	Pancreatic Cancer Cancer of the Pancreas Pancreas Cancer	Drug: CDX-301 Drug: CDX-1140 Procedure: Research blood draw	Washington University School of Medicine Celldex Therapeutics	Phase 2	
NCT04498377	Study of F-652 (IL-22IgG2 Fusion Protein) in Patients With Moderate to Severe COVID-19	Covid19	Biological: F-652 Biological: Placebo	Generon (Shanghai) Corporation Ltd.	Phase 2	
NCT04477512	Cabozantinib and Abiraterone With Checkpoint Inhibitor Immunotherapy in Metastatic Hormone Sensitive Prostate Cancer (CABIOS Trial)	Metastatic Hormone Refractory Prostate Cancer	Drug: Cabozantinib Drug: Nivolumab Drug: Abiraterone acetate Drug: Prednisone Procedure: Peripheral blood collection	Washington University School of Medicine Bristol-Myers Squibb Exelixis	Phase 1	
NCT04463771	Safety and Efficacy of Retifanlimab (INCMGA00012) Alone or in Combination With Other Therapies in Participants With Advanced or Metastatic Endometrial Cancer Who Have Progressed on or After Platinum-based Chemotherapy.	Endometrial Cancer	Drug: retifanlimab Drug: epacadostat Drug: pemigatinib	Incyte Corporation Gynecologic Oncology Group European Network for Gynaecological Oncological Trial groups(ENGOT)	Phase 2	
NCT04397003	Personalized Neoantigen Vaccine in Combination With Durvalumab (MED4736) and Tremelimumab in Extensive Stage Small Cell Lung Cancer	Extensive-stage Small Cell Lung Cancer	Biological: Neoantigen DNA vaccine Drug: Durvalumab Drug: Tremelimumab Device: TDS-IM v1.0 System Procedure: Peripheral blood draws	Washington University School of Medicine AstraZeneca	Phase 2	
NCT04594707	A Study to Evaluate Long Term Safety and Efficacy of Recombinant Human Pentraxin-2 (rhPTX-2; PRM-151) in Participants With Idiopathic Pulmonary Fibrosis	Idiopathic Pulmonary Fibrosis	Drug: PRM-151	Hoffmann-La Roche	Phase 3	
NCT04398680	A Study of Belantamab Mafodotin (GSK2857916) in Multiple Myeloma Participants With Normal and Impaired Hepatic Function	Multiple Myeloma	Drug: Belantamab mafodotin	GlaxoSmithKline	Phase 1	
NCT03979742	Umbilical Cord Blood Cell Transplant Into Injured Spinal Cord With Lithium Carbonate or Placebo Followed by Locomotor Training	Spinal Cord Injuries	Biological: Umbilical Cord Blood Mononuclear Cell Drug: Lithium Carbonate Other: Placebo Other: Locomotor Training	StemCyte, Inc. Amarex Clinical Research	Phase 2	
NCT04643002	Isatuximab in Combination With Novel Agents in RMM	Plasma Cell Myeloma Refractory	Drug: Isatuximab SAR650984 Drug: Dexamethasone Drug: Pomalidomide Drug: SAR439459	Sanofi	Phase 1 Phase 2	
NCT04499924	Tucatinib, Trastuzumab, Ramucirumab, and Paclitaxel Versus Paclitaxel and Ramucirumab in Previously Treated HER2+ Gastroesophageal Cancer	Gastric Adenocarcinoma Gastroesophageal Junction Adenocarcinoma Esophageal Adenocarcinoma	Drug: tucatinib Drug: trastuzumab Drug: ramucirumab Drug: paclitaxel Other: tucatinib placebo Other: trastuzumab placebo	Seagen Inc.	Phase 2 Phase 3	
NCT04315246	177Lu-DTPA-Omburtamab Radioimmunotherapy for Leptomeningeal Metastasis From Solid Tumors	Leptomeningeal Metastasis Solid Tumor, Adult	Biological: radiolabeled DPTA-omburtamab	Y-mAbs Therapeutics	Phase 1 Phase 2	
NCT04696055	Regorafenib Plus Pembrolizumab in Patients With Advanced or Spreading Liver Cancer Who Have Been Previously Treated With PD-1/PD-L1 Immune Checkpoint Inhibitors	Carcinoma, Hepatocellular	Drug: Pembrolizumab Drug: Regorafenib (Stivarga, BAY73-4506)	Bayer Merck Sharp & Dohme Corp.	Phase 2	
NCT04655807	A Study of JNJ-64304500 as Add-on Therapy in Participants With Active Crohn's Disease	Crohn Disease	Drug: JNJ-64304500 Drug: Placebo Drug: Adalimumab Drug: Ustekinumab	Janssen Research & Development, LLC	Phase 2	
NCT04630028	A Study of Ustekinumab in Pediatric Participants With Moderately to Severely Active Ulcerative Colitis (UC)	Colitis, Ulcerative	Drug: Ustekinumab Dose Based on BSA and Body Weight Drug: Matching Placebo	Janssen Research & Development, LLC	Phase 3	
NCT04552899	A Study to Evaluate the Efficacy and Safety of Recombinant Human Pentraxin-2 (rhPTX-2; PRM-151) in Participants With Idiopathic Pulmonary Fibrosis	Idiopathic Pulmonary Fibrosis	Drug: PRM-151 Drug: Placebo	Hoffmann-La Roche	Phase 3	
NCT04716946	Treating Early-stage Non-Small Cell Lung Cancer With Durvalumab and Radiation Therapy	NSCLC Non-small Cell Lung Cancer Lung Cancer Non-small Cell Lung Cancer Stage I Non-small Cell Lung Cancer Stage II Non-small Cell Lung Cancer Stage III Non-small Cell Lung Cancer Stage IIIA PD-L1 Gene Mutation	Drug: Durvalumab Radiation: Stereotactic Body Radiation Therapy	Memorial Sloan Kettering Cancer Center AstraZeneca	Phase 2	
NCT04683003	A Continuation Study of Prophylactic and On-demand Treatment of Congenital Thrombotic Thrombocytopenic Purpura (cTTP) With TAK-755	Congenital Thrombotic Thrombocytopenic Purpura	Biological: TAK-755	Baxalta now part of Shire Baxalta Innovations GmbH, now part of Shire Takeda	Phase 3	
NCT04686305	Phase Ib Study of the Safety of T-DXd and Durvalumab With Chemotherapy in Advanced or Metastatic HER2+ Non-squamous NSCLC	Locally Advanced or Metastatic Non-Small Cell Lung Cancer	Drug: Trastuzumab deruxtecan Biological: Durvalumab Drug: Cisplatin Drug: Carboplatin Drug: Pemetrexed	AstraZeneca Daiichi Sankyo, Inc.	Phase 1	

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○ 영국 4건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases	출처 URL
NCT04552899	A Study to Evaluate the Efficacy and Safety of Recombinant Human Pentraxin-2 (rhPTX-2; PRM-151) in Participants With Idiopathic Pulmonary Fibrosis	Idiopathic Pulmonary Fibrosis	Drug: PRM-151 Drug: Placebo	Hoffmann-La Roche	Phase 3	_____
NCT04630028	A Study of Ustekinumab in Pediatric Participants With Moderately to Severely Active Ulcerative Colitis (UC)	Colitis, Ulcerative	Drug: Ustekinumab Dose Based on BSA and Body Weight Drug: Matching Placebo	Janssen Research & Development, LLC	Phase 3	_____
NCT04315246	177Lu-DTPA-Omburtamab Radioimmunotherapy for Leptomeningeal Metastasis Solid Tumor, Adult	Leptomeningeal Metastasis Solid Tumor, Adult	Biological: radiolabeled DPTA-omburtamab	Y-mAbs Therapeutics	Phase 1 Phase 2	_____
NCT04683003	A Continuation Study of Prophylactic and On-demand Treatment of Congenital Thrombotic Thrombocytopenic Purpura (cTTP) With TAK-755	Congenital Thrombotic Thrombocytopenic Purpura	Biological: TAK-755	Baxalta now part of Shire Baxalta Innovations GmbH, now part of Shire Takeda	Phase 3	_____

○ 프랑스 5건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases	출처 URL
NCT02912897	Trial to Assess the Safety and Feasibility of Adoptive Cell Therapy With Autologous EBV-specific Cytotoxic T Lymphocytes (CTL) in Patients With a First Clinical Episode Highly Suggestive of Multiple Sclerosis	Multiple Sclerosis	Biological: Cellular therapy with EBV specific autologous CTL infusion	Nantes University Hospital	Phase 1	_____
NCT04552899	A Study to Evaluate the Efficacy and Safety of Recombinant Human Pentraxin-2 (rhPTX-2; PRM-151) in Participants With Idiopathic Pulmonary Fibrosis	Idiopathic Pulmonary Fibrosis	Drug: PRM-151 Drug: Placebo	Hoffmann-La Roche	Phase 3	_____
NCT04655807	A Study of JNJ-64304500 as Add-on Therapy in Participants With Active Crohn's Disease	Crohn Disease	Drug: JNJ-64304500 Drug: Placebo Drug: Adalimumab Drug: Ustekinumab	Janssen Research & Development, LLC	Phase 2	_____
NCT04696055	Regorafenib Plus Pembrolizumab in Patients With Advanced or Spreading Liver Cancer Who Have Been Previously Treated With PD-1/PD-L1 Immune Checkpoint Inhibitors	Carcinoma, Hepatocellular	Drug: Pembrolizumab Drug: Regorafenib (Stivarga, BAY73-4506)	Bayer Merck Sharp & Dohme Corp.	Phase 2	_____
NCT04683003	A Continuation Study of Prophylactic and On-demand Treatment of Congenital Thrombotic Thrombocytopenic Purpura (cTTP) With TAK-755	Congenital Thrombotic Thrombocytopenic Purpura	Biological: TAK-755	Baxalta now part of Shire Baxalta Innovations GmbH, now part of Shire Takeda	Phase 3	_____

○ 독일 5건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases	출처 URL
NCT04552899	A Study to Evaluate the Efficacy and Safety of Recombinant Human Pentraxin-2 (rhPTX-2; PRM-151) in Participants With Idiopathic Pulmonary Fibrosis	Idiopathic Pulmonary Fibrosis	Drug: PRM-151 Drug: Placebo	Hoffmann-La Roche	Phase 3	_____
NCT04655807	A Study of JNJ-64304500 as Add-on Therapy in Participants With Active Crohn's Disease	Crohn Disease	Drug: JNJ-64304500 Drug: Placebo Drug: Adalimumab Drug: Ustekinumab	Janssen Research & Development, LLC	Phase 2	_____
NCT04696055	Regorafenib Plus Pembrolizumab in Patients With Advanced or Spreading Liver Cancer Who Have Been Previously Treated With PD-1/PD-L1 Immune Checkpoint Inhibitors	Carcinoma, Hepatocellular	Drug: Pembrolizumab Drug: Regorafenib (Stivarga, BAY73-4506)	Bayer Merck Sharp & Dohme Corp.	Phase 2	_____
NCT04630028	A Study of Ustekinumab in Pediatric Participants With Moderately to Severely Active Ulcerative Colitis (UC)	Colitis, Ulcerative	Drug: Ustekinumab Dose Based on BSA and Body Weight Drug: Matching Placebo	Janssen Research & Development, LLC	Phase 3	_____
NCT04683003	A Continuation Study of Prophylactic and On-demand Treatment of Congenital Thrombotic Thrombocytopenic Purpura (cTTP) With TAK-755	Congenital Thrombotic Thrombocytopenic Purpura	Biological: TAK-755	Baxalta now part of Shire Baxalta Innovations GmbH, now part of Shire Takeda	Phase 3	_____

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NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases	출처 URL
NCT04714827	Targeting CD19 and BCMA CAR-T Cells Immunotherapy in Patients With Relapsed or Refractory Multiple Myeloma	Multiple Myeloma	Biological: CD19-CD22 CAR-T cells	Shanxi Province Cancer Hospital Shanghai Ultra-T Immune Therapeutics Co. LTD	Phase 1 Phase 2	_____
NCT04728334	Phase 1, Dose Escalation and Dose Expansion Study of AK117, a CD47 Antibody	Neoplasms Malignant	Drug: AK117	Akeso	Phase 1	_____
NCT04728321	A Study of Anti-PD-1/CTLA-4 Bispecific AK104 Alone or in Combination With Lenvatinib in Advanced Hepatocellular Carcinoma	Hepatocellular Carcinoma	Biological: AK104 lenvatinib Biological: AK104	Akeso Akeso Pharmaceuticals, Inc.	Phase 2	_____
NCT04720716	A Study to Compare the Effectiveness and Safety of IB1310 Combined With Sintilimab Versus Sorafenib in the First-line Treatment of Advanced HCC	Hepatocellular Carcinoma	Drug: IB1310 Drug: Sintilimab Drug: Sorafenib	Innovent Biologics (Suzhou) Co. Ltd.	Phase 3	_____
NCT04718415	Neoadjuvant Sintilimab in Combination With Carboplatin and Nab-paclitaxel in Untreated Oral Cavity Squamous Cell Carcinoma	Oral Squamous Cell Carcinoma(OSCC)	Drug: sintilimab, paclitaxel, carboplatin Procedure: Surgical resection	Sun Yat-Sen Memorial Hospital of Sun Yat-Sen University	Phase 2	_____
NCT04714190	A Study of RC48-ADC in Local Advanced or Metastatic Gastric Cancer With the HER2-Overexpression	Gastric Cancer HER2 Overexpressing Gastric Carcinoma	Drug: RC48-ADC Drug: Paclitaxel injection Drug: Irinotecan Hydrochloride Injection	RemeGen	Phase 3	_____
NCT04672356	A Study to Evaluate the Safety, Tolerability and Efficacy of IB1939 in Combination With Sintilimab in Patients With Advanced Lung Cancer	Advanced Lung Cancer	Biological: IB1939 Biological: Sintilimab	Innovent Biologics (Suzhou) Co. Ltd.	Phase 1	_____
NCT04552899	A Study to Evaluate the Efficacy and Safety of Recombinant Human Pentraxin-2 (rhPTX-2; PRM-151) in Participants With Idiopathic Pulmonary Fibrosis	Idiopathic Pulmonary Fibrosis	Drug: PRM-151 Drug: Placebo	Hoffmann-La Roche	Phase 3	_____
NCT04712643	A Study of TACE Combined With Atezolizumab Plus Bevacizumab or TACE Alone in Patients With Untreated Hepatocellular Carcinoma	Hepatocellular Carcinoma	Drug: Atezolizumab Drug: Bevacizumab Device: Transarterial chemoembolization (TACE)	Hoffmann-La Roche	Phase 3	_____

○ 일본 7건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases	출처 URL
NCT04683029	A Study of Guselkumab in Participants With Systemic Sclerosis	Scleroderma, Systemic	Drug: Guselkumab Dose 1 Drug: Guselkumab Dose 2 Drug: Placebo	Janssen Pharmaceutical K.K.	Phase 2	_____
NCT04655092	Extension Study After Completion of Phase 2 Study for P1101 With Polycythemia Vera (PV) Patients (Study A19-201)	Polycythemia Vera (PV)	Biological: P1101 (Ropeginterferon alfa-2b)	PharmaEssentia Japan K.K.	Phase 2	_____
NCT04712643	A Study of TACE Combined With Atezolizumab Plus Bevacizumab or TACE Alone in Patients With Untreated Hepatocellular Carcinoma	Hepatocellular Carcinoma	Drug: Atezolizumab Drug: Bevacizumab Device: Transarterial chemoembolization (TACE)	Hoffmann-La Roche	Phase 3	_____
NCT04630028	A Study of Ustekinumab in Pediatric Participants With Moderately to Severely Active Ulcerative Colitis (UC)	Colitis, Ulcerative	Drug: Ustekinumab Dose Based on BSA and Body Weight Drug: Matching Placebo	Janssen Research & Development, LLC	Phase 3	_____
NCT04655807	A Study of JNJ-64304500 as Add-on Therapy in Participants With Active Crohn's Disease	Crohn Disease	Drug: JNJ-64304500 Drug: Placebo Drug: Adalimumab Drug: Ustekinumab	Janssen Research & Development, LLC	Phase 2	_____
NCT04683003	A Continuation Study of Prophylactic and On-demand Treatment of Congenital Thrombotic Thrombocytopenic Purpura (cTTP) With TAK-755	Congenital Thrombotic Thrombocytopenic Purpura	Biological: TAK-755	Baxalta now part of Shire Baxalta Innovations GmbH, now part of Shire Takeda	Phase 3	_____
NCT04696055	Regorafenib Plus Pembrolizumab in Patients With Advanced or Spreading Liver Cancer Who Have Been Previously Treated With PD-1/PD-L1 Immune Checkpoint Inhibitors	Carcinoma, Hepatocellular	Drug: Pembrolizumab Drug: Regorafenib (Stivarga, BAY73-4506)	Bayer Merck Sharp & Dohme Corp.	Phase 2	_____