

## 해외 바이오의약품 임상 현황 (2020.09.14~2020.09.20)

한국바이오의약품협회, 2020.9.22.  
출처: ClinicalTrials.gov

### ○ 미국 28건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04555837	Alisertib and Pembrolizumab for the Treatment of Patients With Rb-deficient Head and Neck Squamous Cell Cancer	Head and Neck Squamous Cell Carcinoma Malignant Solid Neoplasm	Drug: Alisertib Biological: Pembrolizumab	M.D. Anderson Cancer Center National Cancer Institute (NCI)	Phase 1  Phase 2
NCT04497389	Safety and Feasibility of Amniotic Fluid as a Treatment for COVID-19 Patients	SARS CoV-2	Biological: Human Amniotic Fluid	University of Utah	Phase 1  Phase 2
NCT04524962	Study of Descartes-30 in Acute Respiratory Distress Syndrome	Acute Respiratory Distress Syndrome Covid19	Biological: Descartes 30	Cartesian Therapeutics	Phase 1  Phase 2
NCT04556266	A Phase I Trial of Donor-Derived 19-28z CAR T Cells Following Allogeneic Transplant for the Treatment of CD19 Malignancies	Leukemia Lymphoma Lymphoma, B-Cell	Biological: CAR T-Cell Infusion	Memorial Sloan Kettering Cancer Center	Phase 1
NCT04552288	Study of Benralizumab in People With Skin Side Effects Caused by Cancer Therapies	Solid Tumor Solid Carcinoma Solid Tumor, Adult Hematologic Malignancy	Drug: Benralizumab	Memorial Sloan Kettering Cancer Center	Phase 2
NCT04528719	A Dose Escalation Study to Evaluate Safety, Reactogenicity, and Immunogenicity of mRNA-1345 in Healthy Adults Aged 18 to 49 Years and in Children Aged 12 to 36 Months Who Are Respiratory Syncytial Virus Seropositive	Respiratory Syncytial Virus	Biological: mRNA-1345 Drug: Placebo	ModernaTX, Inc.	Phase 1
NCT04510051	CAR T Cells After Lymphodepletion for the Treatment of IL13Rα2 Positive Recurrent or Refractory Brain Tumors in Children	Malignant Brain Neoplasm Recurrent Malignant Brain Neoplasm Refractory Malignant Brain Neoplasm	Drug: Cyclophosphamide Drug: Fludarabine Biological: IL13Rα2-specific Hinge-optimized 41BB-co-stimulatory CAR Truncated CD19-expressing Autologous T-Lymphocytes	City of Hope Medical Center National Cancer Institute (NCI)	Phase 1
NCT04441905	Phase 1 Study of SAR440894 vs Placebo	Chikungunya Virus Infection	Other: Placebo Biological: SAR440894	National Institute of Allergy and Infectious Diseases (NIAID)	Phase 1
NCT04417361	Galcanezumab for Vestibular Migraine	Vestibular Migraine	Drug: Galcanezumab Prefilled Syringe Drug: Placebo	University of California, San Francisco Eli Lilly and Company	Phase 2
NCT04407234	A Study to Measure Stomach Emptying in Overweight Non-diabetic and Diabetic Participants Using Tirzepatide	Overweight Obesity Diabetes Mellitus, Type 2	Drug: Tirzepatide Drug: Acetaminophen	Eli Lilly and Company	Phase 1
NCT04370509	Pembrolizumab With or Without Axitinib for Treatment of Locally Advanced or Metastatic Clear Cell Kidney Cancer in Patients Undergoing Surgery	Metastatic Clear Cell Renal Cell Carcinoma Recurrent Clear Cell Renal Cell Carcinoma Stage III Renal Cell Cancer AJCC v8 Stage IV Renal Cell Cancer AJCC v8 Clear Cell Renal Cell Carcinoma	Drug: Axitinib (VEGF-TKI) Procedure: Cytoreductive Nephrectomy (CN) Procedure: Metastectomy (MET) Biological: Pembrolizumab	University of California, San Francisco Merck Sharp & Dohme Corp.	Phase 2
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
NCT04131413	HPV DNA Vaccine Via Electroporation for HPV16 Positive Cervical Neoplasia	Human Papillomavirus Type 16 Cervical Intraepithelial Neoplasia Grade II Cervical Intraepithelial Neoplasia, Grade III	Drug: pNGVL4aCRTE6E7L2	Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins National Cancer Institute (NCI)	Phase 1
NCT04119830	Rintatolimod and Pembrolizumab for the Treatment of Refractory Metastatic or Unresectable Colorectal Cancer	Metastatic Colorectal Adenocarcinoma Microsatellite Stable Mismatch Repair Proficient Refractory Colorectal Adenocarcinoma Stage III Colorectal Cancer AJCC v8 Stage IIIA Colorectal Cancer AJCC v8 Stage IIIB Colorectal Cancer AJCC v8 Stage IIIC Colorectal Cancer AJCC v8 Stage IV Colorectal Cancer AJCC v8 Stage IVA Colorectal Cancer AJCC v8 Stage IVB Colorectal Cancer AJCC v8 Stage IVC Colorectal Cancer AJCC v8 Unresectable Colorectal Carcinoma	Biological: Pembrolizumab Other: Questionnaire Administration Drug: Rintatolimod	Roswell Park Cancer Institute National Cancer Institute (NCI) AIM BioPharma	Phase 2
NCT03982004	Epicutaneous Cryoimmunotherapy Combined With Pembrolizumab for Cutaneous Metastatic Breast Cancer	Metastatic Breast Cancer	Device: Epicutaneous cryoimmunotherapy Drug: Topical imiquimod Drug: Pembrolizumab Other: Dermatologic Quality of Life Index Other: Functional Assessment of Cancer Therapy Drug: Intra-lesional GM-CSF Device: Cryo-AC Procedure: Cutaneous tumor biopsy Procedure: Peripheral blood draw for research	Washington University School of Medicine Merck Sharp & Dohme Corp.	Phase 1
NCT04372433	IO-202 as Monotherapy in Patients in AML and CMML	AML M5 AML M4 AML, NOS Acute Myelogenous Leukemia in Relapse Myelomonocytic Leukemia, Chronic	Drug: IO-202 Dose Escalation Drug: IO-202 Dose Expansion	Immune-Onc Therapeutics Inc	Phase 1
NCT04519749	An Open-label, Phase 1/2 Trial of Gene Therapy 4D-310 in Adult Males With Classic Fabry Disease	Fabry Disease	Biological: 4D-310	4D Molecular Therapeutics	Phase 1  Phase 2
NCT04544267	Study on a High-Dose Quadrivalent Influenza Vaccine Compared With Standard-Dose Quadrivalent Influenza Vaccine in Children 6 Months Through 35 Months of Age	Influenza	Biological: Quadrivalent influenza vaccine, high-dose Biological: Quadrivalent influenza vaccine, standard dose	Sanofi Pasteur, a Sanofi Company Sanofi	Phase 3
NCT04524871	A Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients With Advanced Liver Cancers (Morpheus-Liver)	Advanced Liver Cancers	Drug: Atezolizumab Drug: Bevacizumab Drug: Tiragolumab Drug: Tocilizumab	Hoffmann-La Roche	Phase 1  Phase 2
NCT04298918	A Study Evaluating the Safety and Efficacy of Venetoclax in Combination With Trastuzumab Emtansine in Patients With Previously Treated HER2-Positive Locally Advanced or Metastatic Breast Cancer	Breast Cancer	Drug: Placebo Drug: Venetoclax Drug: Trastuzumab emtansine	Hoffmann-La Roche	Phase 1  Phase 2
NCT04557098	A Study of Teclistamab, in Participants With Relapsed or Refractory Multiple Myeloma	Hematological Malignancies	Drug: Teclistamab	Janssen Research & Development, LLC	Phase 2

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NCT04546724	Pivotal Study to Evaluate Safety and Immunogenicity of a Live-Attenuated Chikungunya Virus Vaccine Candidate in Adults	Chikungunya Virus Infection	Biological: VLA1553 Biological: Placebo	Valneva Austria GmbH	Phase 3
NCT04479436	A Study to Evaluate U3-1402 in Subjects With Advanced or Metastatic Colorectal Cancer	Metastatic Colorectal Cancer	Drug: U3-1402	Daiichi Sankyo, Inc.	Phase 2
NCT04526691	DS-1062a in Combination With Pembrolizumab in Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations (TROPION-Lung02)	Advanced or Metastatic NSCLC	Drug: DS-1062a Drug: Pembrolizumab	Daiichi Sankyo, Inc. Merck Sharp & Dohme Corp.	Phase 1
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	Oncolimmune, Inc.	Phase 3
NCT04551950	Bintrafusp Alfa Combination Therapy in Participants With Cervical Cancer	Cervical Cancer	Drug: M7824 Drug: Carboplatin Drug: Paclitaxel Drug: Bevacizumab Drug: Cisplatin Radiation: Radiotherapy	EMD Serono Research & Development Institute, Inc. Merck KGaA, Darmstadt, Germany EMD Serono	Phase 1
NCT04088500	A Study of Combination Nivolumab and Ipilimumab Retreatment in Patients With Advanced Renal Cell Carcinoma	Renal Cell Carcinoma	Biological: Nivolumab Biological: Ipilimumab	Bristol-Myers Squibb	Phase 2
NCT04439539	A Study of JNJ-73763989 + JNJ-56136379 + Nucleos(t)ide Analog (NA) Regimen With or Without Pegylated Interferon Alpha-2a (PegIFN-α2a) in Treatment-Naive Participants With Hepatitis B e Antigen (HBeAg) Positive Chronic Hepatitis B Virus (HBV) Infection and Normal Alanine Aminotransferase (ALT)	Hepatitis B, Chronic	Drug: JNJ-73763989 Drug: JNJ-56136379 Drug: PegIFN-α2a Drug: Tenofovir disoproxil	Janssen Research & Development, LLC	Phase 2

### ○ 영국 5건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04557098	A Study of Teclistamab, in Participants With Relapsed or Refractory Multiple Myeloma	Hematological Malignancies	Drug: Teclistamab	Janssen Research & Development, LLC	Phase 2
NCT04479436	A Study to Evaluate U3-1402 in Subjects With Advanced or Metastatic Colorectal Cancer	Metastatic Colorectal Cancer	Drug: U3-1402	Daiichi Sankyo, Inc.	Phase 2
NCT04439539	A Study of JNJ-73763989 + JNJ-56136379 + Nucleos(t)ide Analog (NA) Regimen With or Without Pegylated Interferon Alpha-2a (PegIFN-α2a) in Treatment-Naive Participants With Hepatitis B e Antigen (HBeAg) Positive Chronic Hepatitis B Virus (HBV) Infection and Normal Alanine Aminotransferase (ALT)	Hepatitis B, Chronic	Drug: JNJ-73763989 Drug: JNJ-56136379 Drug: PegIFN-α2a Drug: Tenofovir disoproxil	Janssen Research & Development, LLC	Phase 2
NCT04318093	Study of the Safety of BMS-986259 in Participants With Post-acute Decompensated Heart Failure	Acute Decompensated Heart Failure	Drug: BMS-986259 Other: Placebo	Bristol-Myers Squibb	Phase 2
NCT04515849	A Study of Cotadutide in Participants Who Have Chronic Kidney Disease With Type 2 Diabetes Mellitus	Type 2 Diabetes Mellitus Chronic Kidney Diseases	Drug: Cotadutide 100 micrograms Drug: Cotadutide 300 micrograms Drug: Cotadutide 600 micrograms Drug: Semaglutide Drug: Placebo	AstraZeneca	Phase 2

### ○ 프랑스 6건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04529278	Efficacy and Tolerance of Liraglutide for Weight Loss in Obese Type 2 Diabetic Hemodialysis Patients	Diabetes Mellitus, Type 2 Hemodialysis Obese	Drug: Liraglutide	Groupe Hospitalier Paris Saint Joseph	Phase 2
NCT04524871	A Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients With Advanced Liver Cancers (Morpheus-Liver)	Advanced Liver Cancers	Drug: Atezolizumab Drug: Bevacizumab Drug: Tiragolumab Drug: Tocilizumab	Hoffmann-La Roche	Phase 1  Phase 2
NCT04348045	Phase II Study to Evaluate Maintenance Therapy With Olaparib or Selumetinib Plus Durvalumab According to BRCAness and KRAS Somatic Status Personalized in Metastatic Pancreatic Adenocarcinoma Patients	Metastatic Pancreatic Adenocarcinoma	Drug: Arm A - Olaparib Drug: ARM B - durvalumab plus selumetinib Drug: ARM C FOLFIRI	GERCOR - Multidisciplinary Oncology Cooperative Group AstraZeneca	Phase 2
NCT04439539	A Study of JNJ-73763989 + JNJ-56136379 + Nucleos(t)ide Analog (NA) Regimen With or Without Pegylated Interferon Alpha-2a (PegIFN-α2a) in Treatment-Naive Participants With Hepatitis B e Antigen (HBeAg) Positive Chronic Hepatitis B Virus (HBV) Infection and Normal Alanine Aminotransferase (ALT)	Hepatitis B, Chronic	Drug: JNJ-73763989 Drug: JNJ-56136379 Drug: PegIFN-α2a Drug: Tenofovir disoproxil	Janssen Research & Development, LLC	Phase 2
NCT04557098	A Study of Teclistamab, in Participants With Relapsed or Refractory Multiple Myeloma	Hematological Malignancies	Drug: Teclistamab	Janssen Research & Development, LLC	Phase 2
NCT04479436	A Study to Evaluate U3-1402 in Subjects With Advanced or Metastatic Colorectal Cancer	Metastatic Colorectal Cancer	Drug: U3-1402	Daiichi Sankyo, Inc.	Phase 2

### ○ 독일 4건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04554836	MoLiMoR - A Study With FOLFIRI-based First-line Therapy With or Without Intermittent Cetuximab	Adenocarcinoma of the Colon Adenocarcinoma of the Rectum	Drug: Cetuximab Other: FOLFIRI	TheraOp	Phase 2
NCT04515849	A Study of Cotadutide in Participants Who Have Chronic Kidney Disease With Type 2 Diabetes Mellitus	Type 2 Diabetes Mellitus Chronic Kidney Diseases	Drug: Cotadutide 100 micrograms Drug: Cotadutide 300 micrograms Drug: Cotadutide 600 micrograms Drug: Semaglutide Drug: Placebo	AstraZeneca	Phase 2

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NCT04557098	A Study of Teclistamab, in Participants With Relapsed or Refractory Multiple Myeloma	Hematological Malignancies	Drug: Teclistamab	Janssen Research & Development, LLC	Phase 2
NCT04439539	A Study of JNJ-73763989 + JNJ-56136379 + Nucleos(t)ide Analog (NA) Regimen With or Without Pegylated Interferon Alpha-2a (PegIFN-α2a) in Treatment-Naïve Participants With Hepatitis B e Antigen (HBeAg) Positive Chronic Hepatitis B Virus (HBV) Infection and Normal Alanine Aminotransferase (ALT)	Hepatitis B, Chronic	Drug: JNJ-73763989 Drug: JNJ-56136379 Drug: PegIFN-α2a Drug: Tenofovir disoproxil	Janssen Research & Development, LLC	Phase 2

### ○ 중국 6건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04552366	A Clinical Trial of a Recombinant Adenovirus 5 Vectored COVID-19 Vaccine (Ad5-nCoV) With Two Doses in Healthy Adults	COVID-19	Biological: Ad5-nCoV	Institute of Biotechnology, Academy of Military Medical Sciences, PLA of China Zhongnan Hospital	Phase 1
NCT04547907	Comparing the Efficacy of Nab-PHP and TCBHP in Neoadjuvant Therapy for HER2 Positive Operable Breast Cancer, A Multicenter, Randomized, Phase III Clinical Trial	Breast Cancer, Her2 Positive	Drug: Albumin binding paclitaxel+ trastuzumab+ patuzumab Drug: Docetaxel+ carboplatin+ trastuzumab + patuzumab	Henan Cancer Hospital	Phase 3
NCT04527068	QL1101 in Combination With JS001 in Patients With pMMR/MSS Refractory Metastatic Colorectal Cancer	Refractory Metastatic Colorectal Cancer pMMR MSS	Drug: Bevacizumab Drug: Tripletriumab	Second Affiliated Hospital, School of Medicine, Zhejiang University Qilu Pharmaceutical Co., Ltd. Shanghai Junshi Bioscience Co., Ltd.	Phase 2
NCT04518852	TACE, Sorafenib and PD-1 Monoclonal Antibody in the Treatment of HCC	Hepatocellular Carcinoma Liver Neoplasms Digestive System Neoplasms Sorafenib Molecular Mechanisms of Pharmacological Action Liver Diseases Antineoplastic Agents Protein Kinase Inhibitors	Combination Product: TACE combined with sorafenib and PD-1 mAb	Sichuan Cancer Hospital and Research Institute	Phase 2
NCT04474119	KN046 in Subjects With Advanced Squamous Non-small Cell Lung Cancer	Squamous Non-small-cell Lung Cancer	Drug: KN046 Drug: KN046 placebo	Jiangsu Alphamab Biopharmaceuticals Co., Ltd	Phase 3
NCT04524871	A Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients With Advanced Liver Cancers (Morpheus-Liver)	Advanced Liver Cancers	Drug: Atezolizumab Drug: Bevacizumab Drug: Tiragolumab Drug: Tocilizumab	Hoffmann-La Roche	Phase 1 Phase 2

### ○ 일본 7건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04546074	Imatinib Mesylate in Combination With Pembrolizumab in Patients With Melanoma	Melanoma	Drug: Pembrolizumab and Imatinib mesylate	Keio University Merck Sharp & Dohme Corp. OHARA Pharmaceutical Co., Ltd.	Phase 1 Phase 2
NCT04530838	20-valent Pneumococcal Conjugate Vaccine Safety and Immunogenicity Study in Healthy Japanese Infants	Pneumococcal Disease	Biological: 20-valent pneumococcal conjugate vaccine Biological: 13-valent pneumococcal conjugate vaccine	Pfizer	Phase 3
NCT04479436	A Study to Evaluate U3-1402 in Subjects With Advanced or Metastatic Colorectal Cancer	Metastatic Colorectal Cancer	Drug: U3-1402	Daiichi Sankyo, Inc.	Phase 2
NCT04551950	Bintrafusp Alfa Combination Therapy in Participants With Cervical Cancer	Cervical Cancer	Drug: M7824 Drug: Carboplatin Drug: Paclitaxel Drug: Bevacizumab Drug: Cisplatin Radiation: Radiotherapy	EMD Serono Research & Development Institute, Inc. Merck KGaA, Darmstadt, Germany EMD Serono	Phase 1
NCT04439539	A Study of JNJ-73763989 + JNJ-56136379 + Nucleos(t)ide Analog (NA) Regimen With or Without Pegylated Interferon Alpha-2a (PegIFN-α2a) in Treatment-Naïve Participants With Hepatitis B e Antigen (HBeAg) Positive Chronic Hepatitis B Virus (HBV) Infection and Normal Alanine Aminotransferase (ALT)	Hepatitis B, Chronic	Drug: JNJ-73763989 Drug: JNJ-56136379 Drug: PegIFN-α2a Drug: Tenofovir disoproxil	Janssen Research & Development, LLC	Phase 2
NCT04515849	A Study of Cotadutide in Participants Who Have Chronic Kidney Disease With Type 2 Diabetes Mellitus	Type 2 Diabetes Mellitus Chronic Kidney Diseases	Drug: Cotadutide 100 micrograms Drug: Cotadutide 300 micrograms Drug: Cotadutide 600 micrograms Drug: Semaglutide Drug: Placebo	AstraZeneca	Phase 2
NCT04526691	DS-1062a in Combination With Pembrolizumab in Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations (TROPION-Lung02)	Advanced or Metastatic NSCLC	Drug: DS-1062a Drug: Pembrolizumab	Daiichi Sankyo, Inc. Merck Sharp & Dohme Corp.	Phase 1