

## 해외 바이오의약품 임상 현황 (2020.07.06~2020.07.12)

한국바이오의약품협회, 2020.7.14.  
출처: ClinicalTrials.gov

### ○ 미국 19건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04441047	Universal Anti-Viral Vaccine for Healthy Elderly Adults	Virus Diseases	Drug: AlloStim	Immunovative Therapies, Ltd. Mirror Biologics, Inc.	Phase 1  Phase 2
NCT04465643	Neoadjuvant Nivolumab Plus Ipilimumab for Newly Diagnosed Malignant Peripheral Nerve Sheath Tumor	Nerve Sheath Tumors	Drug: Nivolumab Drug: Ipilimumab	Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Bristol-Myers Squibb	Phase 1
NCT04464200	19(T2)28z1xx Chimeric Antigen Receptor (CAR) T Cells in People With B-Cell Cancers	Diffuse Large B Cell Lymphoma Primary Mediastinal Large B Cell Lymphoma Transformed Follicular Lymphoma to Diffuse Large B Cell Lymphoma Chronic Lymphocytic Leukemia Indolent Non-Hodgkin Lymphoma Marginal Zone Lymphoma Waldenstrom Macroglobulinemia Burkitt's Lymphoma Primary CNS Lymphoma	Drug: 19(T2)28z1xx CAR T cells	Memorial Sloan Kettering Cancer Center Takeda	Phase 1
NCT04456452	Study of Ampion for the Treatment of Adult COVID-19 Patients Requiring Oxygen Supplementation	COVID-19	Biological: Ampion Other: Standard of Care	Ampio Pharmaceuticals. Inc.	Phase 1
NCT04450732	Safety of GQ1001 in Adult Patients With HER2-Positive Advanced Solid Tumors	HER2-positive Breast Cancer HER2-positive Gastric Cancer Advanced Solid Tumor	Drug: GQ1001	GeneQuantum Healthcare (Suzhou) Co., Ltd. CRC Oncology	Phase 1
NCT04445844	INCMGA00012 and Pelareorep for the Treatment of Metastatic Triple Negative Breast Cancer, IRENE Study	Anatomic Stage IV Breast Cancer AJCC v8 Locally Advanced Breast Carcinoma Metastatic Triple-Negative Breast Carcinoma Prognostic Stage IV Breast Cancer AJCC v8 Triple-negative Breast Cancer	Biological: Pelareorep Other: Quality-of-Life Assessment Other: Questionnaire Administration Biological: Retifanlimab	Rutgers, The State University of New Jersey Incyte Corporation Oncolytics Biotech National Cancer Institute (NCI)	Phase 2
NCT04438057	Evaluating the Efficacy of Convalescent Plasma in Symptomatic Outpatients Infected With COVID-19	COVID-19	Biological: CCP	Metro Infectious Disease Consultants	Phase 2
NCT04435184	Crizanlizumab for Treating COVID-19 Vasculopathy	COVID-19	Drug: Crizanlizumab Other: 0.9% saline	Johns Hopkins University Novartis Socar Research SA Brigham and Women's Hospital	Phase 2
NCT04433546	PB1046, a Long-acting, Sustained Release Human VIP Analogue, Intended to Provide Clinical Improvement to Hospitalized COVID-19 Patients at High Risk for Rapid Clinical Deterioration and Acute Respiratory Distress Syndrome (ARDS).	Acute Respiratory Distress Syndrome Coronavirus Hypoxic Respiratory Failure Hypoxemic Respiratory Failure Respiratory Complication Respiratory Insufficiency Cardiac Dysfunction Pneumonia Pulmonary Edema Pulmonary Inflammation Respiratory Failure Cytokine Storm COVID 19 SARS-CoV-2 Cardiac Event Cardiac Complication Cardiac Failure Cardiac Infarct	Drug: PB1046 Drug: Low Dose (10 mg) Control	PhaseBio Pharmaceuticals Inc.	Phase 2
NCT04369937	HPV-16 Vaccination and Pembrolizumab Plus Cisplatin for "Intermediate Risk" HPV-16-associated Head and Neck Squamous Cell Carcinoma	HPV-Related Squamous Cell Carcinoma Head and Neck Squamous Cell Carcinoma	Radiation: IMRT (Intensity Modulated Radiotherapy) Drug: Pembrolizumab Drug: Cisplatin Biological: ISA101b	Robert Ferris Merck Sharp & Dohme Corp. ISA Pharmaceuticals University of Pittsburgh	Phase 2
NCT04015336	E7 TCR Cell Induction Immunotherapy for Stage II and Stage III HPV-Associated Oropharyngeal Cancer	Papillomavirus Infections Oropharyngeal Neoplasms	Biological: E7 TCR	National Cancer Institute (NCI) National Institutes of Health Clinical Center (CC)	Phase 2
NCT03920631	Microtransplantation and Checkpoint Blockade Immunotherapy for Relapsed or Refractory B Cell Lymphomas	B Cell Lymphomas	Drug: Nivolumab Biological: Microtransplantation	Ahmed Galal, MD Duke University	Phase 1
NCT03571334	Botulinum Toxin A for the Treatment of Chemotherapy Induced Peripheral Neuropathy	Peripheral Neuropathy Due to Chemotherapy	Drug: IncobotulinumtoxinA (Xeomin ®, Merz) (INA) Drug: Normal saline	Medical College of Wisconsin	Phase 2
NCT04457778	First in Human Study of M6223 in Participants With Metastatic or Locally Advanced Solid Unresectable Tumors	Metastatic Solid Tumors	Drug: M6223 Drug: Bintrafusp alfa	EMD Serono Research & Development Institute, Inc. Merck KGaA, Darmstadt, Germany EMD Serono	Phase 1
NCT04260698	Expanded Access of Omidubicel, for Allogeneic Transplantation in Patients With Hematological Malignancies	Hematological Malignancies	Biological: omidubicel	Gamida Cell Ltd	Phase 3
NCT03266653	EBV-specific Cytotoxic T-lymphocytes (CTLs) for Refractory EBV Infection	Epstein-Barr Virus Infections Primary Immune Deficiency Disorder	Drug: cytotoxic t-lymphocytes	New York Medical College Children's Hospital of Philadelphia Medical College of Wisconsin	Phase 2
NCT04322708	A Study of Antolimax (AK002) in Patients With Active Eosinophilic Esophagitis	Eosinophilic Esophagitis	Other: Placebo Drug: antolimax (AK002)	Allakos, Inc.	Phase 2  Phase 3
NCT04450407	A Study of LY3209590 in Participants With Type 1 Diabetes	Type 1 Diabetes Mellitus	Drug: LY3209590 Drug: Insulin Degludec	Eli Lilly and Company	Phase 2
NCT04450394	A Phase 2 Study of LY3209590 in Participants With Type 2 Diabetes Mellitus	Type 2 Diabetes Mellitus	Drug: LY3209590 Drug: Insulin Degludec	Eli Lilly and Company	Phase 2

### ○ 프랑스 1건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04453384	Study to Evaluate the Safety and Efficacy of XAV-19 in Patients With COVID-19 Induced Moderate Pneumonia	SARS Virus	Drug: XAV-19 Drug: Placebo	Nantes University Hospital BPIfrance Xenothera SAS	Phase 2

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### ○ 독일 3건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04457778	First in Human Study of M6223 in Participants With Metastatic or Locally Advanced Solid Unresectable Tumors	Metastatic Solid Tumors	Drug: M6223 Drug: Bintrafusp alfa	EMD Serono Research & Development Institute, Inc. Merck KGaA, Darmstadt, Germany EMD Serono	Phase 1
NCT04450394	A Phase 2 Study of LY3209590 in Participants With Type 2 Diabetes Mellitus	Type 2 Diabetes Mellitus	Drug: LY3209590 Drug: Insulin Degludec	Eli Lilly and Company	Phase 2
NCT04450407	A Study of LY3209590 in Participants With Type 1 Diabetes	Type 1 Diabetes Mellitus	Drug: LY3209590 Drug: Insulin Degludec	Eli Lilly and Company	Phase 2

### ○ 중국 3건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04465695	Dual Therapy With Interferon Beta-1b and Clofazimine for COVID-19	COVID-19	Drug: Interferon beta-1b Drug: Clofazimine	The University of Hong Kong	Phase 2
NCT04416035	A Study to Compare the Similarity in Efficacy and Safety Between TRS003 and China-approved Bevacizumab® in NSCLC	Advanced Non-squamous Non-small-cell Lung Cancer	Biological: TRS003 Biological: China-approved Bevacizumab Drug: Carboplatin Drug: Paclitaxel	Zhejiang Teruisi Pharmaceutical Inc.	Phase 3
NCT04449588	Efficacy and Safety Study of BDB-001 in Severe COVID-19 With ALI/ARDS	COVID-19 Pneumonia	Drug: BDB-001 Injection Other: Conventional treatment	Staidson (Beijing) Biopharmaceuticals Co., Ltd Beijing Defengrui Biotechnology Co. Ltd	Phase 2  Phase 3

### ○ 일본 1건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04451720	Study of Subcutaneous Risankizumab Injection to Assess Change in Palmoplantar Pustulosis Area and Severity Index [PPPASi] in Adult Japanese Participants With Palmoplantar Pustulosis	Palmoplantar Pustulosis (PPP)	Drug: Risankizumab Drug: Placebo	AbbVie	Phase 3