

해외 바이오의약품 임상 현황 (2020.06.15~2020.06.21)

한국바이오의약품협회, 2020.6.23.
출처: ClinicalTrials.gov

○ 미국 27건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04399889	hCT-MSCs for COVID19 ARDS	COVID Corona Virus Infection COVID19	Biological: human cord tissue mesenchymal stromal cells	Joanne Kurtzberg, MD The Marcus Foundation Duke University	Phase 1 Phase 2
NCT04207190	Talazoparib and Gemtuzumab Ozogamicin for the Treatment of CD33 Positive Relapsed or Refractory Acute Myeloid Leukemia	Recurrent Acute Myeloid Leukemia Refractory Acute Myeloid Leukemia	Drug: Gemtuzumab Ozogamicin Other: Quality-of-Life Assessment Other: Questionnaire Administration Drug: Talazoparib Drug: Talazoparib Tosylate	Roswell Park Cancer Institute National Cancer Institute (NCI)	Phase 1 Phase 2
NCT04083183	Total Body Irradiation and Astatine-211-Labeled BC8-B10 Monoclonal Antibody for the Treatment of Nonmalignant Diseases	Non-Malignant Neoplasm	Biological: Astatine At 211 Anti-CD45 Monoclonal Antibody BC8-B10 Drug: Fludarabine Drug: Cyclophosphamide Biological: Lapine T-Lymphocyte Immune Globulin Radiation: Total-Body Irradiation Procedure: Hematopoietic Cell Transplantation Drug: Mycophenolate Mofetil Drug: Sirolimus	Fred Hutchinson Cancer Research Center National Cancer Institute (NCI)	Phase 1 Phase 2
NCT04206553	A Study to Evaluate the Efficacy and Safety of Dupilumab in Adult Patients With Bullous Pemphigoid	Bullous Pemphigoid	Drug: dupilumab Drug: Matching Placebo Drug: Oral corticosteroids (OCS)	Regeneron Pharmaceuticals Sanofi	Phase 2 Phase 3
NCT04438824	Palbociclib and INCMGA00012 in People With Advanced Liposarcoma	Well Differentiated Liposarcoma Dedifferentiated Liposarcoma	Drug: INCMGA00012 Drug: Palbociclib	Memorial Sloan Kettering Cancer Center Incyte Corporation	Phase 2
NCT04433117	Bone Material Comparison in Maxillary Sinus Augmentation	Alveolar Bone Resorption Sequela Tooth Extrusion	Biological: Shefabone Biological: Bio-Oss	Rachad Kudsij University of Kentucky	Phase 2
NCT04431635	Dose De-escalation Study of the PI3k Alpha/Delta Inhibitor, Copanlisib Given in Combination With the Immunotherapeutic Agents, Nivolumab and Rituximab in Patients With Relapsed/Refractory Indolent Lymphoma	Indolent Lymphoma	Drug: Copanlisib Drug: Nivolumab Drug: Rituximab	Big Ten Cancer Research Consortium	Phase 1
NCT04393350	Lenvatinib and Pembrolizumab Before Surgery for the Treatment of Locally Advanced Non-Metastatic Kidney Cancer	Kidney Cancer Stage III Renal Cell Cancer AJCC v8 Stage IV Renal Cell Cancer AJCC v8	Drug: Lenvatinib Drug: Lenvatinib Mesylate Biological: Pembrolizumab Other: Quality-of-Life Assessment Other: Questionnaire Administration	Emory University Merck Sharp & Dohme Corp.	Phase 2
NCT04390399	Combination Immunotherapy Plus Standard-of-Care Chemotherapy Versus Standard-of-Care Chemotherapy for First and Second Line Treatment of Locally Advanced or Metastatic Pancreatic Cancer	Pancreatic Cancer	Biological: N-803 Drug: Aldoxorubicin HCl Biological: PD-L1 t-haNK Drug: Nab-paclitaxel Drug: Gemcitabine Drug: Cyclophosphamide Drug: 5-Fluorouracil Drug: Leucovorin Procedure: SBRT Drug: Irinotecan liposome	ImmunityBio, Inc.	Phase 2
NCT04163432	Staggered, Chemo-Immunotherapy With Durvalumab, MEDI4736 Pemetrexed & Carboplatin (PC) for Metastatic Non-Squamous NSCLC	Non-Small Cell Lung Cancer Metastatic	Drug: Durvalumab Drug: Pemetrexed Drug: Carboplatin	University of Utah AstraZeneca	Phase 2
NCT03760575	Pembrolizumab in Combination With Chemotherapy and Image-Guided Surgery for Malignant Pleural Mesothelioma (MPM)	Mesotheliomas Pleural	Drug: Pembrolizumab Procedure: Indocyanine Green (ICG) Image-Guided Surgery Drug: Cisplatin Drug: Pemetrexed	Abramson Cancer Center of the University of Pennsylvania	Phase 1
NCT03203525	Combination Chemotherapy and Bevacizumab With the NovoTTF-100L(P) System in Treating Participants With Advanced, Recurrent, or Refractory Hepatic Metastatic Cancer	Advanced Malignant Neoplasm Colorectal Carcinoma Metastatic in the Liver Metastatic Malignant Neoplasm in the Liver Refractory Malignant Neoplasm	Biological: Bevacizumab Drug: Fluorouracil Drug: Leucovorin Drug: Oxaliplatin Drug: Pegylated Liposomal Doxorubicin Hydrochloride Drug: Temsirolimus Procedure: Tumor Treating Fields Therapy	M.D. Anderson Cancer Center National Cancer Institute (NCI)	Phase 1
NCT04205812	Platinum-Based Chemotherapy With/Without INCMGA00012, an Anti-PD-1 Antibody, in Non-Small Cell Lung Cancer (POD1UM-304)	Metastatic Squamous Non-Small Cell Lung Cancer Metastatic Nonsquamous Non-Small Cell Lung Cancer	Drug: Retifanlimab Drug: Placebo Drug: Pemetrexed Drug: Cisplatin Drug: Carboplatin Drug: Paclitaxel Drug: nab-Paclitaxel	Incyte Corporation Zai Lab (Shanghai) Co., Ltd.	Phase 3
NCT04338061	Study of Evobrutinib in Participants With Relapsing Multiple Sclerosis (RMS)	Relapsing Multiple Sclerosis	Drug: Evobrutinib Drug: Placebo (match to Teriflunomide) Drug: Teriflunomide Drug: Placebo (match to Evobrutinib)	Merck Healthcare KGaA, Darmstadt, Germany, an affiliate of Merck KGaA, Darmstadt, Germany EMD Serono Research & Development Institute, Inc.	Phase 3
NCT04190628	Safety of ABM-1310 Monotherapy in Patients With Advanced Solid Tumors	Advanced Solid Tumor BRAF V600 Mutation	Drug: ABM-1310	ABM Therapeutics, Inc.	Phase 1
NCT04442126	A Study of NM21-1480 in Adult Patients With Advanced Solid Tumors	Advanced Solid Tumor	Biological: NM21-1480	Numab Therapeutics AG	Phase 1 Phase 2

해외 바이오의약품 임상 현황 (2020.06.15~2020.06.21)

한국바이오의약품협회, 2020.6.23.
출처: ClinicalTrials.gov

NCT04382664	UV1 Vaccination Plus Nivolumab and Ipilimumab in Treatment of Melanoma	Malignant Melanoma	Biological: UV1 Biological: Sargramostim Biological: Ipilimumab Biological: Nivolumab	Ultimovacs ASA	Phase 2
NCT04398433	INO-3107 With Electroporation (EP) in Participants With HPV-6- and/or HPV-11-Associated Recurrent Respiratory Papillomatosis (RRP)	Respiratory Papillomatosis	Drug: INO-3107 Device: CELLECTRA™2000	Inovio Pharmaceuticals	Phase 1 Phase 2
NCT04440163	MenABCWY Noninferiority Study in Healthy Participants ≥10 to <26 Years of Age	Meningococcal Vaccine	Biological: MenABCWY Biological: Saline Biological: Trumenba Biological: MenACWY-CRM	Pfizer	Phase 3
NCT04440176	A Trial to Describe the Safety and Immunogenicity of MenABCWY When Administered on 2 Schedules	Meningococcal Vaccine	Biological: MenABCWY Biological: Saline	Pfizer	Phase 2
NCT04424316	A Trial to Evaluate the Efficacy and Safety of RSVpreF in Infants Born to Women Vaccinated During Pregnancy.	Respiratory Tract Infection	Biological: RSVpreF Biological: Placebo	Pfizer	Phase 3
NCT04396236	A Study of Lasmiditan (LY573144) Treatment in Children Aged 6 to 17 With Migraine	Migraine	Drug: Lasmiditan Drug: Placebo	Eli Lilly and Company	Phase 3
NCT04267822	Study of RV521 in the Treatment of Adult Subjects Who Have Undergone HCT With an URTI With RSV	RSV Infection Stem Cell Transplant Complications Lower Resp Tract Infection	Drug: RV521 oral tablet Drug: Placebo oral tablet	ReViral Ltd	Phase 2
NCT04345367	Study of Abrocitinib Compared With Dupilumab in Adults With Moderate to Severe Atopic Dermatitis on Background Topical Therapy	Atopic Dermatitis	Drug: Abrocitinib 200 mg Combination Product: Dupilumab 300 mg	Pfizer	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	Oncolimmune, Inc.	Phase 3
NCT04404140	A Study Evaluating The Safety, Efficacy and Pharmacokinetics Of Ipatasertib In Combination With Atezolizumab And Docetaxel In Metastatic Castration-Resistant Prostate Cancer (mCRPC).	Castration-Resistant Prostatic Cancer	Drug: Ipatasertib Drug: Atezolizumab Drug: Docetaxel	Hoffmann-La Roche	Phase 1
NCT04311710	A Study Evaluating the Drug Levels of Iplimumab Given Under the Skin Alone and in Combination With Nivolumab in Multiple Tumor Types	Tumor	Drug: ipilimumab Drug: nivolumab Drug: ENHANZE (rHuPH20)	Bristol-Myers Squibb	Phase 1 Phase 2

○ 영국 2건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04393246	multi-Arm Therapeutic Study in Pre-ICU Patients Admitted With Covid-19 - Experimental Drugs and Mechanisms	COVID-19	Drug: EDP1815 Drug: Dapagliflozin Drug: Ambrisentan Other: Standard of care	Cambridge University Hospitals NHS Foundation Trust	Phase 2 Phase 3
NCT04264806	A Study of Cusatuzumab in Combination With Azacitidine Compared With Azacitidine Alone in Patients With Higher-risk Myelodysplastic Syndrome (MDS) or Chronic Myelomonocytic Leukemia (CMML) and Who Are Not Candidates for Hematopoietic Stem Cell Transplantation (HSCT)	Myelodysplastic Syndromes Leukemia, Myelomonocytic, Chronic	Drug: Azacitidine Drug: Cusatuzumab	Janssen Research & Development, LLC argenx BVBA	Phase 2

○ 프랑스 4건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04413838	Efficiency and Security of NIVOLUMAB Therapy in Obese Individuals With COVID-19(CORona Virus Disease) Infection	Obesity, COVID-19 Infection	Drug: NIVOLUMAB Other: Routine standard of care	Hospices Civils de Lyon	Phase 2
NCT04311710	A Study Evaluating the Drug Levels of Iplimumab Given Under the Skin Alone and in Combination With Nivolumab in Multiple Tumor Types	Tumor	Drug: ipilimumab Drug: nivolumab Drug: ENHANZE (rHuPH20)	Bristol-Myers Squibb	Phase 1 Phase 2
NCT04264806	A Study of Cusatuzumab in Combination With Azacitidine Compared With Azacitidine Alone in Patients With Higher-risk Myelodysplastic Syndrome (MDS) or Chronic Myelomonocytic Leukemia (CMML) and Who Are Not Candidates for Hematopoietic Stem Cell Transplantation (HSCT)	Myelodysplastic Syndromes Leukemia, Myelomonocytic, Chronic	Drug: Azacitidine Drug: Cusatuzumab	Janssen Research & Development, LLC argenx BVBA	Phase 2

해외 바이오의약품 임상 현황 (2020.06.15~2020.06.21)

한국바이오의약품협회, 2020.6.23.
출처: ClinicalTrials.gov

NCT04404140	A Study Evaluating The Safety, Efficacy and Pharmacokinetics Of Ipatasertib In Combination With Atezolizumab And Docetaxel In Metastatic Castration-Resistant Prostate Cancer (mCRPC).	Castration-Resistant Prostatic Cancer	Drug: Ipatasertib Drug: Atezolizumab Drug: Docetaxel	Hoffmann-La Roche	Phase 1
-------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------	------------------------------------------------------	-------------------	---------

○ 독일 2건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04307576	A Treatment Study Protocol for Participants 1-45 Years With Acute Lymphoblastic Leukaemia	Leukemia, Acute Lymphoblastic	Drug: Omitted Doxorubicin Drug: Omitted Vincristine+Dexamethasone pulses Drug: Inotuzumab Ozogamicin+Standard Maintenance Therapy Drug: Imatinib	Mats Heyman The Swedish Research Council The Swedish Childhood Cancer Foundation Pfizer Servier NordForsk Aamu Pediatric Cancer Foundation Gesellschaft fur Padiatrische Onkologie und Hamatologie - Germany Clinical Trial Center North (CTC North GmbH & Co. KG) Belgium Health Care Knowledge Centre Karolinska Institutet Cancer Research UK Fundação Rui Osório de Castro Acreditar - Associação de Pais e Amigos das Crianças com Cancro Grupo Português De Leucemias Pediátricas Karolinska University Hospital	Phase 3
NCT04264806	A Study of Cusatuzumab in Combination With Azacitidine Compared With Azacitidine Alone in Patients With Higher-risk Myelodysplastic Syndrome (MDS) or Chronic Myelomonocytic Leukemia (CMML) and Who Are Not Candidates for Hematopoietic Stem Cell Transplantation (HSCT)	Myelodysplastic Syndromes Leukemia, Myelomonocytic, Chronic	Drug: Azacitidine Drug: Cusatuzumab	Janssen Research & Development, LLC argenx BVBA	Phase 2

○ 중국 7건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04425824	Toripalimab Combine With Rituximab for Treatment of Relapsed Refractory CD20 Positive Diffuse Large B-cell Lymphoma	Diffuse Large B-cell Lymphoma Rituximab Toripalimab	Drug: Toripalimab combine with Rituximab	Chinese Academy of Medical Sciences	Phase 2
NCT04421469	Triprilimab(JS001) and Chemotherapy Combined With Local Treatment for Multiple Metastatic NPC	Nasopharyngeal Carcinoma	Drug: Triprilimab(JS001)	Fujian Cancer Hospital Zhejiang Cancer Hospital Jiangxi Provincial Cancer Hospital	Phase 2
NCT04418154	Neoadjuvant Dose-dense EC Followed by ABX With PD-1 for Triple Negative Breast Cancer Patients	Triple Negative Breast Cancer	Drug: epirubicin hydrochloride Drug: Cyclophosphamide Drug: Albumin bound paclitaxel Drug: Toripalimab	Fudan University	Phase 2
NCT04394975	Study to Evaluate the Efficacy and Safety of Toripalimab in Combination With Axitinib Versus Sunitinib Monotherapy in Advanced Renal Cell Cancer	Primary Disease: Unresectable or Metastatic Renal Cell Carcinoma Focus of the Study:PFS Assessed by IRC Per RECIST 1.1	Combination Product: Biological : Toripalimab Drug: Axitinib sunitinib	Shanghai Junshi Bioscience Co., Ltd.	Phase 3
NCT04072107	EPstein-barr Virus DNA Response to Systemic Therapy for Treatment Adaptation in High Risk NPC (EP-STAR)	Nasopharyngeal Carcinoma	Drug: sintilimab Drug: Capecitabine	Sun Yat-sen University National Cancer Centre, Singapore Wuzhou Red Cross Hospital	Phase 2
NCT04304040	A Study of MIL62 Combined With ICP-022 for the Treatment of R/R CD20+B Cell Lymphoma	B-cell Lymphoma Recurrent B-cell Lymphoma Refractory	Drug: ICP-022 Drug: Recombinant humanized monoclonal antibody MIL62 injection	Beijing InnoCare Pharma Tech Co., Ltd.	Phase 1 Phase 2
NCT04422392	Neoadjuvant PD-1 Antibody Plus Chemotherapy in Resectable Stage IIIA-N2 Non-Small-Cell Lung Cancer	Non Small Cell Lung Cancer	Drug: Carboplatin Drug: Pemetrexed or Nab-paclitaxel Drug: PD-1 antibody	Shanghai Pulmonary Hospital, Shanghai, China	Phase 2

○ 일본 1건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04342325	The Clinical Trial of ADR-001 for IgA Nephropathy	Glomerulonephritis , IGA	Biological: infusion of ADR-001 (Mesenchymal stem cell)	Nagoya University Rohto Pharmaceutical Co., Ltd.	Phase 1