

## 해외 바이오의약품 임상 현황 (2020.08.10~2020.08.16)

한국바이오의약품협회, 2020.8.18.  
출처: ClinicalTrials.gov

### ○ 미국 24건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
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
NCT04432597	HPV Vaccine PRGN-2009 Alone or in Combination With Anti-PDL1/TGF-Beta Trap (M7824) in Subjects With HPV Associated Cancers	HPV Positive Cancer Vulvar, Vaginal, Penile, Rectal Cancer Anal Cancer Oropharyngeal Cancer Cervical Cancer	Biological: PRGN-2009 Biological: M7824	National Cancer Institute (NCI) National Institutes of Health Clinical Center (CC)	Phase 1  Phase 2
NCT03851081	Inotuzumab Ozogamicin and Vincristine Sulfate Liposome in Treating Patients With Relapsed or Refractory CD22+ B-cell Acute Lymphoblastic Leukemia	Allogeneic Hematopoietic Stem Cell Transplantation Recipient Blasts 5 Percent or More of Bone Marrow Nucleated Cells Blasts 5 Percent or More of Peripheral Blood White Cells CD22 Positive Lymphoblasts 20 Percent or More of Bone Marrow Nucleated Cells Lymphoblasts 20 Percent or More of Peripheral Blood White Cells Recurrent B Acute Lymphoblastic Leukemia Refractory B Acute Lymphoblastic Leukemia	Biological: Inotuzumab Ozogamicin Other: Quality-of-Life Assessment Drug: Vincristine Sulfate Liposome	Roswell Park Cancer Institute Pfizer	Phase 1  Phase 2
NCT03735589	Specialized Immune Cells (nCTLs) and a Vaccine (Alpha-type-1 Polarized Dendritic Cells) in Treating Patients With Stage II-IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	Stage II Fallopian Tube Cancer AJCC v8 Stage II Ovarian Cancer AJCC v8 Stage II Primary Peritoneal Cancer AJCC v8 Stage IIA Fallopian Tube Cancer AJCC v8 Stage IIA Ovarian Cancer AJCC v8 Stage IIA Primary Peritoneal Cancer AJCC v8 Stage IIB Fallopian Tube Cancer AJCC v8 Stage IIB Ovarian Cancer AJCC v8 Stage IIB Primary Peritoneal Cancer AJCC v8 Stage III Fallopian Tube Cancer AJCC v8 Stage III Ovarian Cancer AJCC v8 Stage III Primary Peritoneal Cancer AJCC v8 Stage IIIA Fallopian Tube Cancer AJCC v8 Stage IIIA Ovarian Cancer AJCC v8 Stage IIIA Primary Peritoneal Cancer AJCC v8 Stage IIIA1 Fallopian Tube Cancer AJCC v8 Stage IIIA1 Ovarian Cancer AJCC v8 Stage IIIA2 Fallopian Tube Cancer AJCC v8 Stage IIIA2 Ovarian Cancer AJCC v8 Stage IIIB Fallopian Tube Cancer AJCC v8 Stage IIIB Ovarian Cancer AJCC v8 Stage IIIB Primary Peritoneal Cancer AJCC v8 Stage IIIC Fallopian Tube Cancer AJCC v8 Stage IIIC Ovarian Cancer AJCC v8 Stage IIIC Primary Peritoneal Cancer AJCC v8 Stage IV Fallopian Tube Cancer AJCC v8 Stage IV Ovarian Cancer AJCC v8 Stage IV Primary Peritoneal Cancer AJCC v8 Stage IVA Fallopian Tube Cancer AJCC v8 Stage IVA Ovarian Cancer AJCC v8 Stage IVA Primary Peritoneal Cancer AJCC v8 Stage IVB Fallopian Tube Cancer AJCC v8 Stage IVB Ovarian Cancer AJCC v8 Stage IVB Primary Peritoneal Cancer AJCC v8	Biological: Alpha-type-1 Polarized Dendritic Cells Biological: Autologous Natural Killer Cell-like CTLs	Roswell Park Cancer Institute National Cancer Institute (NCI)	Phase 1  Phase 2
NCT04513665	ZW25 in Women With Endometrial Cancers	Endometrial Cancer Carcinosarcoma	Drug: ZW25	Memorial Sloan Kettering Cancer Center Zymeworks Inc.	Phase 2
NCT04510285	Study of Pembrolizumab Plus Trastuzumab or Trastuzumab Alone After Surgery in Patients With Esophagogastric Tumors	Esophagogastric Tumors Gastric Cancer Gastric Tumor Esophageal Cancer Esophageal Neoplasms Esophageal Tumor Gastroesophageal Cancer Gastroesophageal Junction Adenocarcinoma Gastroesophageal Junction Tumor Gastroesophageal Junction Cancer	Drug: Trastuzumab Drug: Pembrolizumab	Memorial Sloan Kettering Cancer Center	Phase 2
NCT04503603	A Study to Determine the Safety, Tolerability, and Pharmacokinetics of Lanadelumab Administered Intravenously in Healthy Adult Volunteer Participants	Healthy Volunteers	Drug: Lanadelumab Other: Placebo	Takeda Takeda Development Center Americas, Inc.	Phase 1
NCT04486001	Study of Intravenous Administration of Allogeneic Adipose Stem Cells for COVID-19	Covid19	Biological: PSC-04	Personalized Stem Cells, Inc. VetStem Biopharma, Inc. Fresno Community Hospital and Medical Center	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
NCT04319198	Rollover Study in Subjects With Metastatic Solid Tumors Benefiting From Therapy With Sacituzumab Govitecan	Solid Tumor Metastatic Cancer	Drug: Sacituzumab Govitecan	Immunomedics, Inc.	Phase 3
NCT04311411	A Study of Tirzepatide in Overweight and Very Overweight Participants	Obesity Overweight	Drug: Tirzepatide Drug: Placebo Drug: Liraglutide	Eli Lilly and Company	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
NCT04349280	A Study to Evaluate the Efficacy and Safety of Bintrafusp Alfa (M7824) Monotherapy in Metastatic or Locally Advanced Urothelial Cancer	Neoplasms	Drug: Bintrafusp alfa	GlaxoSmithKline Merck KGaA, Darmstadt, Germany	Phase 1
NCT04246671	Intravenous TAEK-VAC-HerBy Vaccine Alone and in Combination Treatment in HER2 Cancer Patients	Breast Cancer Gastric Cancer Cancer	Biological: TAEK-VAC-HerBy	Bavarian Nordic	Phase 1  Phase 2
NCT04294472	A Safety, Pharmacokinetics and Efficacy Study of MAU868 for the Treatment of BK Viremia in Kidney Transplant Recipients	BK Virus Infection	Drug: MAU868 Other: Placebo	Amplifyx Pharmaceuticals	Phase 2

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NCT04381650	A Safety and Efficacy Study of TAK-981 Plus Pembrolizumab in Participants With Select Advanced or Metastatic Solid Tumors	Advanced or Metastatic Solid Tumors	Drug: TAK-981 Drug: Pembrolizumab	Takeda Takeda Development Center Americas, Inc.	Phase 1  Phase 2
NCT04437368	EXPLORE: A Phase II Study to Evaluate the Safety and Efficacy of Two Doses of GT005	Dry Age-related Macular Degeneration	Drug: GT005; Dose 1 Drug: GT005; Dose 2	Gyroscope Therapeutics	Phase 2
NCT04394650	A Study of CC-98633, BCMA-targeted Chimeric Antigen Receptor (CAR) T Cells, in Subjects With Relapsed and/or Refractory Multiple Myeloma	Multiple Myeloma	Biological: CC-98633	Juno Therapeutics, a Subsidiary of Celgene	Phase 1
NCT04340193	A Study of Nivolumab and Ipilimumab in Combination With Transarterial ChemoEmbolization (TACE) in Participants With Intermediate Stage Liver Cancer	Liver Cancer	Biological: nivolumab Biological: ipilimumab	Bristol-Myers Squibb	Phase 3
NCT04338269	A Study of Atezolizumab in Combination With Cabozantinib Compared to Cabozantinib Alone in Participants With Advanced Renal Cell Carcinoma After Immune Checkpoint Inhibitor Treatment	Carcinoma, Renal Cell	Drug: Atezolizumab Drug: Cabozantinib	Hoffmann-La Roche Exelixis Chugai	Phase 3
NCT04514653	RGX-314 Gene Therapy Administered in the Suprachoroidal Space for Participants With Neovascular Age-Related Macular Degeneration (nAMD)	Neovascular Age-Related Macular Degeneration (nAMD)	Biological: RGX-314 Dose 1 Biological: RGX-314 Dose 2 Biological: Ranibizumab (LUCENTIS®)	Regenxbio Inc.	Phase 2
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
NCT04456699	Efficacy and Safety of Olaparib, Olaparib + Bevacizumab Compared to Bevacizumab + 5-Fluorouracil (FU)	Metastatic Colorectal Cancer	Drug: Olaparib Drug: 5-FU Drug: Bevacizumab	Merck Sharp & Dohme Corp.	Phase 3
NCT04504669	First Time in Human Study of AZD8701 With or Without Durvalumab in Participants With Advanced Solid Tumours	Clear Cell Renal Cell Cancer Non-Small-Cell Lung Cancer Triple Negative Breast Neoplasms Squamous Cell Cancer of Head and Neck Small Cell Lung Cancer Gastric Cancer Melanoma Cervical Cancer Advanced Solid Tumours	Drug: AZD8701 Biological: Durvalumab	AstraZeneca	Phase 1

### ○ 영국 2건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04360941	PAveMenT: Palbociclib and Avelumab in Metastatic AR+ Triple Negative Breast Cancer	Triple Negative Breast Cancer Locally Advanced Breast Cancer Recurrent Breast Cancer Metastatic Breast Cancer ER+ Breast Cancer HER2-positive Breast Cancer	Drug: Palbociclib Drug: Avelumab	Royal Marsden NHS Foundation Trust Pfizer Breast Cancer Now	Phase 1
NCT04338269	A Study of Atezolizumab in Combination With Cabozantinib Compared to Cabozantinib Alone in Participants With Advanced Renal Cell Carcinoma After Immune Checkpoint Inhibitor Treatment	Carcinoma, Renal Cell	Drug: Atezolizumab Drug: Cabozantinib	Hoffmann-La Roche Exelixis Chugai	Phase 3

### ○ 프랑스 4건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04497298	Clinical Trial to Evaluate the Safety and Immunogenicity of the COVID-19 Vaccine	COVID-19	Biological: Two COVID-19 vaccine candidate (TMV-083) administrations - Low dose Biological: Two COVID-19 vaccine candidate (TMV-083) administrations - High dose Biological: One COVID-19 vaccine candidate (TMV-083) administration - High dose Other: Placebo	Institut Pasteur Themis Bioscience GmbH Coalition for Epidemic Preparedness Innovations (CEPI)	Phase 1
NCT04340193	A Study of Nivolumab and Ipilimumab in Combination With Transarterial ChemoEmbolization (TACE) in Participants With Intermediate Stage Liver Cancer	Liver Cancer	Biological: nivolumab Biological: ipilimumab	Bristol-Myers Squibb	Phase 3
NCT04338269	A Study of Atezolizumab in Combination With Cabozantinib Compared to Cabozantinib Alone in Participants With Advanced Renal Cell Carcinoma After Immune Checkpoint Inhibitor Treatment	Carcinoma, Renal Cell	Drug: Atezolizumab Drug: Cabozantinib	Hoffmann-La Roche Exelixis Chugai	Phase 3
NCT04504669	First Time in Human Study of AZD8701 With or Without Durvalumab in Participants With Advanced Solid Tumours	Clear Cell Renal Cell Cancer Non-Small-Cell Lung Cancer Triple Negative Breast Neoplasms Squamous Cell Cancer of Head and Neck Small Cell Lung Cancer Gastric Cancer Melanoma Cervical Cancer Advanced Solid Tumours	Drug: AZD8701 Biological: Durvalumab	AstraZeneca	Phase 1

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NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04514796	Pharmacokinetics, Safety, Tolerability, and Immunogenicity of Two Formulations of SB5 in Healthy Male Subjects	Healthy	Drug: Adalimumab	Samsung Bioepis Co., Ltd.	Phase 1
NCT03988036	A Study With Pembrolizumab in Combination With Dual Anti-HER2 Blockade With Trastuzumab and Pertuzumab in Early Breast Cancer Patients With Molecular HER2-enriched Intrinsic Subtype (Keyriched-1)	Breast Cancer	Drug: Pembrolizumab Drug: Trastuzumab Biosimilar ABP 980 Drug: Pertuzumab	West German Study Group Merck Sharp & Dohme Corp. NanoString Technologies, Inc.	Phase 2
NCT04340193	A Study of Nivolumab and Ipilimumab in Combination With Transarterial ChemoEmbolization (TACE) in Participants With Intermediate Stage Liver Cancer	Liver Cancer	Biological: nivolumab Biological: ipilimumab	Bristol-Myers Squibb	Phase 3
NCT04338269	A Study of Atezolizumab in Combination With Cabozantinib Compared to Cabozantinib Alone in Participants With Advanced Renal Cell Carcinoma After Immune Checkpoint Inhibitor Treatment	Carcinoma, Renal Cell	Drug: Atezolizumab Drug: Cabozantinib	Hoffmann-La Roche Exelixis Chugai	Phase 3

### ○ 중국 5건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04512534	Sintilimab Combined With Chidamide in Treating Peripheral T Cell Lymphoma	Peripheral T-cell Lymphoma	Drug: PD-1 antibody+ HDAC inhibitor	Fudan University	Phase 2
NCT04508842	CD19/CD22-Dual-STAR-T for Patients With B Cell Acute Leukemia(B-ALL)	Refractory and Relapsed B Cell Acute Leukemia	Biological: CD19/CD22-Dual-STAR-T	Hebei Yanda Ludaopei Hospital China Immunotech (Beijing) Biotechnology Co., Ltd.	Phase 1
NCT04506983	GPC3-CAR-T Cells for the Hepatocellular Carcinoma	Hepatocellular Carcinoma	Biological: GPC3-CAR-T cells	Beijing Tsinghua Chang Gung Hospital China Immunotech (Beijing) Biotechnology Co., Ltd.	Phase 1
NCT04486651	HX008 Plus Irinotecan Versus Placebo Plus Irinotecan as Second-line Treatment in Advanced Gastric Cancer	Stomach Cancer	Drug: Irinotecan Hydrochloride Injection Drug: HX008 Drug: Placebo	Taizhou Hanzhong biomedical co. LTD	Phase 3
NCT04340193	A Study of Nivolumab and Ipilimumab in Combination With Transarterial ChemoEmbolization (TACE) in Participants With Intermediate Stage Liver Cancer	Liver Cancer	Biological: nivolumab Biological: ipilimumab	Bristol-Myers Squibb	Phase 3

### ○ 일본 3건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04509947	A Study of Ad26.COV2.S in Adults (COVID-19)	Healthy	Biological: Ad26.COV2.S Biological: Placebo	Janssen Pharmaceutical K.K.	Phase 1
NCT04340193	A Study of Nivolumab and Ipilimumab in Combination With Transarterial ChemoEmbolization (TACE) in Participants With Intermediate Stage Liver Cancer	Liver Cancer	Biological: nivolumab Biological: ipilimumab	Bristol-Myers Squibb	Phase 3
NCT04338269	A Study of Atezolizumab in Combination With Cabozantinib Compared to Cabozantinib Alone in Participants With Advanced Renal Cell Carcinoma After Immune Checkpoint Inhibitor Treatment	Carcinoma, Renal Cell	Drug: Atezolizumab Drug: Cabozantinib	Hoffmann-La Roche Exelixis Chugai	Phase 3