

## 해외 바이오의약품 임상 현황 (2021.3.22~2021.3.28)

한국바이오의약품협회, 2021.3.30.  
출처: ClinicalTrials.gov

### ○ 미국 10건

| NCT Number  | Title  | Conditions  | Interventions  | Sponsor/Collaborators  | Phases              | 출처 URL |
|-------------|--|---|--|--|---------------------|--------|
| NCT04685499 | Phase 2 Study of OBP-301 (Telomelysin™ in Combination With Pembrolizumab and SBRT in Patients With HNSCC With Inoperable, Recurrent or Progressive Disease   | Head and Neck Squamous Cell Carcinoma With Inoperable Recurrent or Progressive Disease  | Drug: OBP-301 Drug: Pembrolizumab  | Weill Medical College of Cornell University Oncolys BioPharma Inc  | Phase 2             | ————   |
| NCT04579523 | <sup>213</sup> At-OKT10-B10 and Fludarabine Alone or in Combination With Cyclophosphamide and Low-Dose TBI Before Donor Stem Cell Transplant for the Treatment of Newly Diagnosed, Recurrent, or Refractory High-Risk Multiple Myeloma | Plasma Cell Myeloma Recurrent Plasma Cell Myeloma Refractory Plasma Cell Myeloma  | Procedure: Allogeneic Hematopoietic Stem Cell Transplantation Biological: Astatine At 211 Anti-CD38 Monoclonal Antibody OKT10-B10 Drug: Cyclophosphamide Drug: Fludarabine Phosphate Radiation: Total-Body Irradiation | Fred Hutchinson Cancer Research Center National Cancer Institute (NCI)   | Phase 1             | ————   |
| NCT04174560 | Phase I Norovirus Challenge Model  | Gastroenteritis Norovirus   | Biological: Norovirus GIL4 Challenge Pool  | National Institute of Allergy and Infectious Diseases (NIAID)  | Phase 1             | ————   |
| NCT04761198 | A Study of Etigilimab and Nivolumab in Subjects With Locally Advanced or Metastatic Tumors.  | Solid Tumor, Adult Advanced Solid Tumor Metastatic Solid Tumor  | Drug: Etigilimab dosing Drug: Nivolumab  | Mereo BioPharma CON Clinical Research  | Phase 1<br> Phase 2 | ————   |
| NCT04677777 | Safety Study of PP-007 in Subjects With Acute Ischemic Stroke  | Acute Ischemic Stroke   | Biological: PP-007 Other: Standard of care   | Prolong Pharmaceuticals  | Phase 1             | ————   |
| NCT04083170 | Cord Blood Transplant With OTS for the Treatment of HIV Positive Hematologic Cancers   | Acute Erythroid Leukemia Acute Lymphoblastic Leukemia Acute Megakaryoblastic Leukemia Acute Myeloid Leukemia Chronic Myelogenous Leukemia, BCR-ABL1 Positive Hematopoietic and Lymphoid Cell Neoplasm HIV Infection Myelodysplastic Syndrome Myelodysplastic Syndrome With Excess Blasts Non-Hodgkin Lymphoma Refractory Anemia | Drug: Fludarabine Drug: Cyclophosphamide Drug: Thiotepa Radiation: Total-Body Irradiation Procedure: Umbilical Cord Blood Transplantation Other: Cellular Therapy  | Fred Hutchinson Cancer Research Center National Cancer Institute (NCI) National Heart, Lung, and Blood Institute (NHLBI) | Phase 2             | ————   |
| NCT04811664 | A Study of SARS CoV-2 Infection and Potential Transmission in University Students Immunized With Moderna COVID-19 Vaccine  | SARS-CoV-2 Infection  | Biological: Moderna COVID-19 Vaccine   | National Institute of Allergy and Infectious Diseases (NIAID)  | Phase 3             | ————   |
| NCT04795531 | A Research Study to Compare Two Types of Insulin, a New Insulin, Insulin Icodec and an Available Insulin, Insulin Degludec, in People With Type 2 Diabetes Who Have Not Used Insulin Before (ONWARDS 3)                                | Diabetes Mellitus, Type 2   | Drug: Insulin icodec Drug: Placebo insulin icodec Drug: Insulin degludec Drug: Placebo insulin degludec  | Novo Nordisk A/S   | Phase 3             | ————   |
| NCT04791319 | A Study of Bermekimab (JNJ-77474462) in the Treatment of Participants With Moderate to Severe Atopic Dermatitis  | Dermatitis, Atopic  | Drug: Placebo Drug: Bermekimab Drug: Dupilumab   | Janssen Research & Development, LLC  | Phase 2             | ————   |
| NCT04740970 | A Study of JNJ-64304500 in Participants With Alopecia Areata   | Alopecia Areata   | Drug: JNJ-64304500 Drug: Placebo   | Janssen Research & Development, LLC  | Phase 2             | ————   |

### ○ 프랑스 3건

| NCT Number  | Title   | Conditions                | Interventions   | Sponsor/Collaborators               | Phases  | 출처 URL |
|-------------|---|---------------------------|---|-------------------------------------|---------|--------|
| NCT04795531 | A Research Study to Compare Two Types of Insulin, a New Insulin, Insulin Icodec and an Available Insulin, Insulin Degludec, in People With Type 2 Diabetes Who Have Not Used Insulin Before (ONWARDS 3) | Diabetes Mellitus, Type 2 | Drug: Insulin icodec Drug: Placebo insulin icodec Drug: Insulin degludec Drug: Placebo insulin degludec | Novo Nordisk A/S                    | Phase 3 | ————   |
| NCT04791319 | A Study of Bermekimab (JNJ-77474462) in the Treatment of Participants With Moderate to Severe Atopic Dermatitis   | Dermatitis, Atopic        | Drug: Placebo Drug: Bermekimab Drug: Dupilumab  | Janssen Research & Development, LLC | Phase 2 | ————   |
| NCT04740970 | A Study of JNJ-64304500 in Participants With Alopecia Areata  | Alopecia Areata           | Drug: JNJ-64304500 Drug: Placebo  | Janssen Research & Development, LLC | Phase 2 | ————   |

### ○ 독일 2건

| NCT Number  | Title  | Conditions               | Interventions                                  | Sponsor/Collaborators               | Phases  | 출처 URL |
|-------------|--|--------------------------|--|-------------------------------------|---------|--------|
| NCT04816890 | A Trial to Assess the Efficacy and Safety of M1 Pram P037 Prandial Insulin in Subjects With Type 1 Diabetes (T1DM) | Type 1 Diabetes Mellitus | Drug: M1 Pram P037 Drug: Insulin lispro        | Adocia                              | Phase 2 | ————   |
| NCT04791319 | A Study of Bermekimab (JNJ-77474462) in the Treatment of Participants With Moderate to Severe Atopic Dermatitis    | Dermatitis, Atopic       | Drug: Placebo Drug: Bermekimab Drug: Dupilumab | Janssen Research & Development, LLC | Phase 2 | ————   |

### ○ 중국 4건

| NCT Number  | Title   | Conditions                        | Interventions   | Sponsor/Collaborators   | Phases  | 출처 URL |
|-------------|---|-----------------------------------|---|---|---------|--------|
| NCT04813562 | Immunogenicity and Safety of Recombinant COVID-19 Vaccine (CHO Cells)   | COVID-19                          | Biological: a middle-dose recombinant COVID-19 vaccine (CHO Cell) (18-59 years) at the schedule of day 0, 28, 56 Biological: a high-dose recombinant COVID-19 vaccine (CHO Cell) (18-59 years) at the schedule of day 0, 28, 56 Biological: a middle-dose recombinant COVID-19 vaccine (CHO Cell) (60-85 years) at the schedule of day 0, 28, 56 Biological: a high-dose recombinant COVID-19 vaccine (CHO Cell) (60-85 years) at the schedule of day 0, 28, 56 Biological: a middle-dose placebo (18-59 years) at the schedule of day 0, 28, 56 Biological: a high-dose placebo (18-59 years) at the schedule of day 0, 28, 56 Biological: a middle-dose placebo (60-85 years) at the schedule of day 0, 28, 56 Biological: a high-dose placebo (60-85 years) at the schedule of day 0, 28, 56 | Jiangsu Province Centers for Disease Control and Prevention Academy of Military Medical Sciences , Academy of Military Sciences , PLA ZHONGYANKE Biotech Co, Ltd. LIAONINGMAOKANGYUAN Biotech Co, Ltd | Phase 2 | ————   |
| NCT04805736 | Microwave Ablation Combined With Camrelizumab in the Treatment of Early Breast Cancer   | Breast Cancer                     | Procedure: Microwave Ablation Drug: Camrelizumab Procedure: Breast Surgery  | The First Affiliated Hospital with Nanjing Medical University Jiangsu HengRui Medicine Co., Ltd.  | Phase 2 | ————   |
| NCT04756648 | Phase I Clinical Trial of CT0180 Cells in the Treatment of Hepatocellular Carcinoma   | Advanced Hepatocellular Carcinoma | Drug: CT0180 Cells  | Zhejiang University Carsgen Therapeutics, Ltd.  | Phase 1 | ————   |
| NCT04795531 | A Research Study to Compare Two Types of Insulin, a New Insulin, Insulin Icodec and an Available Insulin, Insulin Degludec, in People With Type 2 Diabetes Who Have Not Used Insulin Before (ONWARDS 3) | Diabetes Mellitus, Type 2         | Drug: Insulin icodec Drug: Placebo insulin icodec Drug: Insulin degludec Drug: Placebo insulin degludec   | Novo Nordisk A/S  | Phase 3 | ————   |

### ○ 일본 4건

| NCT Number  | Title  | Conditions                         | Interventions  | Sponsor/Collaborators               | Phases  | 출처 URL |
|-------------|--|------------------------------------|--|-------------------------------------|---------|--------|
| NCT04721977 | A Study of Tucatinib (MK-7119) in Combination With Trastuzumab and Capecitabine in Participants With Previously Treated Locally Advanced Unresectable or Metastatic Human Epidermal Growth Factor Receptor 2 Positive (HER2+) Breast Carcinoma (MK-7119-001) | Breast Cancer                      | Drug: Tucatinib Biological: Trastuzumab Drug: Capecitabine | Merck Sharp & Dohme Corp.           | Phase 2 | ————   |
| NCT04738942 | A Study of Intravenous Vedolizumab Administered Every 4 Weeks in Japanese Participants With Moderate to Severe Ulcerative Colitis or Crohn's Disease   | Ulcerative Colitis Crohn's Disease | Drug: Vedolizumab  | Takeda                              | Phase 3 | ————   |
| NCT04740970 | A Study of JNJ-64304500 in Participants With Alopecia Areata   | Alopecia Areata                    | Drug: JNJ-64304500 Drug: Placebo                           | Janssen Research & Development, LLC | Phase 2 | ————   |
| NCT04791319 | A Study of Bermekimab (JNJ-77474462) in the Treatment of Participants With Moderate to Severe Atopic Dermatitis  | Dermatitis, Atopic                 | Drug: Placebo Drug: Bermekimab Drug: Dupilumab             | Janssen Research & Development, LLC | Phase 2 | ————   |