

Antibody News You Should Know

July 1 - July 15, 2021



Have you missed some antibody news?

As a service to the community, The Antibody Society offers access to past “Antibody News You Should Know”, which have been compiled into PDFs for your convenience. The PDFs, [which can be downloaded here](#), include links to the original source and can be searched by keywords (e.g., SARS-CoV-2, bispecific, antibody-drug conjugate).

[COVID-19 intervention news](#)

AR-712 cocktail neutralizes Delta variant, will enter clinical study soon

On July 12, 2021, [Aridis Pharmaceuticals, Inc. announced](#) that its COVID-19 monoclonal antibody (mAb) cocktail, AR-712, binds and neutralizes the Delta variant virus SARS-CoV-2 at a highly effective level (~20 ng/mL). AR-712 is being developed as a self-administered, at-home inhaled treatment for COVID-19 patients who are not yet hospitalized. The company remains on track to initiate a clinical study in 2H 2021.

- AR-712 is a cocktail of two human immunoglobulin G1 mAbs discovered from screening the antibody-secreting B cells of convalescent SARS-CoV-2-infected patients.
-
-
-

Updates on non-COVID-19 interventions

GlaxoSmithKline plc and Alector enter collaboration

On July 2, 2021, **GlaxoSmithKline plc and Alector announced a strategic global collaboration** for the development and commercialization of two clinical-stage, potential first-in-class mAbs (AL001 and AL101) designed to elevate progranulin (PGRN) levels. The companies will develop the antibodies for a range of neurodegenerative diseases, including frontotemporal dementia, amyotrophic lateral sclerosis, Parkinson's disease, and Alzheimer's disease. Alector will receive \$700 million in upfront payments and up to \$1.5 billion in potential milestone payments, profit sharing and royalties.

- AL001 and AL101 are human mAbs that elevate levels of PGRN by blocking the sortilin receptor responsible for PGRN degradation.

First in humans study of AGEN1777 to start soon

On July 6, 2021, Agenus Inc. announced the U.S. Food and Drug Administration (FDA) **clearance of an Investigational New Drug (IND) application for their bispecific antibody AGEN1777**. The company also announced the closing of its global exclusive license with Bristol Myers Squibb (BMS) for this asset. Under the terms of the agreement with BMS, Agenus receives a \$200 million upfront payment in connection with the closing. The agreement also includes up to \$1.36 billion in development, regulatory and commercial milestones in addition to tiered double-digit royalties on net product sales.

- AGEN1777 is an Fc-enhanced, anti-TIGIT bispecific antibody that co-targets another inhibitor receptor not yet disclosed, but also expressed on T cells and natural killer cells.

First-in-humans studies started

On July 6, 2021, NextCure, Inc. announced the [initiation of a Phase 1/2 clinical trial \(NCT04875806\) for NC762](#). The Phase 1 dose-escalation portion of this open-label trial is designed to evaluate the safety and tolerability of NC762 in patients with advanced or metastatic solid tumors and to determine its pharmacologically active and/or maximum tolerated dose. The study is expected to enroll 176 patients, and has a primary completion date in October 2024.

- NC762 is a humanized anti-B7-H4 monoclonal antibody.

On July 07, 2021, [NGM Biopharmaceuticals, Inc. announced](#) it has dosed the first patient in a Phase 1/2 study (NCT04913337) to evaluate the efficacy, safety and pharmacokinetics/pharmacodynamics of NGM707 when given alone or in combination with KEYTRUDA® (pembrolizumab), an anti- PD-1 antibody. The study is expected to enroll 179 patients, and has a primary completion date in February 2025.

- NGM707 is a dual antagonist antibody that inhibits the Immunoglobulin-like Transcript 2 (ILT2) and Immunoglobulin-like Transcript 4 (ILT4) receptors, which are overexpressed on myeloid cells in the tumor microenvironment.

On July 8, 2021, details were posted on [clinicaltrials.gov](#) for a Phase 1 study ([NCT04954456](#)) of bispecific antibody QLS31901 in patients with advanced or metastatic malignancies. Sponsored by Qilu Pharmaceutical Co., Ltd., the study is expected to enroll 96 patients, and has a primary completion date in December 2022.

- QLS31901 is a bispecific antibody targeting PD-L1 and TGF-β.

On July 9, 2021, Molecular Templates, Inc announced the [dosing of the first subject in a Phase 1 study \(NCT04795713\) investigating MT-6402](#) in patients with PD-L1-positive solid tumors. The starting dose is 16 mcg/kg. Following determination of the maximum tolerated dose or recommended Phase 2 dose, expansion cohorts are planned to evaluate MT-6402 as a monotherapy in tumor-specific and tumor-agnostic cohorts.

- MT-6402 is composed of a single-chain variable fragment with affinity for PD-L1, fused to the enzymatically active de-immunized Shiga-like toxin-A subunit and a class I antigen derived from the human cytomegalovirus pp65 protein.

On July 12, 2021, details were posted on clinicaltrials.gov for a Phase 1 study ([NCT04958434](#)) dose escalation and dose expansion study of TST005 in patients with locally advanced or metastatic solid tumors. Sponsored by Transcenta Therapeutics, the study is expected to enroll 55 patients, and has a primary completion date in July 2023.

- TST005 is a bispecific IgG1 antibody consisting of a PD-L1 mAb and a transforming growth factor beta (TGF- β) trap.

On July 11, 2021, [Innovent Biologics, Inc. announced](#) that the first patient has been dosed in a Phase 1 study (NCT04916119) of their bispecific antibody IBI323. In Phase Ia of the study, seven dose levels of IBI323 (0.03, 0.1, 0.3, 1, 3, 10 and 20 mg/kg) administered by iv infusion day 1 of every 14 days will be tested. After the dose escalation stage completed, two dose levels (10 and 20mg/kg) will be expanded. The study is expected to enroll 322 patients, and has a primary completion date in June 2022.

- IBI323 is bispecific antibody targeting LAG-3 and PD-L1.

YH001 and YH003 poised to enter Phase 2 clinical studies

On July 6, 2021, Eucure Biopharma, a wholly owned subsidiary of Biocytogen, announced that the [FDA has approved two Phase 2 clinical trials for their](#)

mAb therapeutics YH001 and YH003 in the United States. YH001 will be evaluated in combination with Junshi Biosciences' anti-PD-1 monoclonal antibody toripalimab for the treatment of advanced non-small cell lung cancer and hepatocellular carcinoma. YH003 will be evaluated in combination with toripalimab for the treatment of PD-1-resistant unresectable/metastatic melanoma and pancreatic ductal adenocarcinoma. Both trials are multi-regional clinical trials, and will be conducted in the United States, Australia and China.

- YH001 is a humanized IgG1 mAb targeting CTLA-4.
- YH003 is a humanized IgG2 agonistic mAb targeting CD40.

Tezepelumab biologics license application granted priority review

On July 7, 2021, Amgen announced that the **BLA for tezepelumab has been accepted and granted Priority Review** for the treatment of asthma from the FDA. Tezepelumab is being developed by AstraZeneca in collaboration with AstraZeneca. A decision by the FDA is anticipated during the first quarter of 2022. Tezepelumab was granted Breakthrough Therapy Designation for patients with severe asthma without an eosinophilic phenotype in September 2018.

- Tezepelumab is a human IgG2 mAb that targets and blocks thymic stromal lymphopoietin.

FDA issues complete response letter for teplizumab BLA

On July 6, 2021, Provention Bio, Inc. announced that the **FDA has issued a Complete Response Letter for the company's BLA for teplizumab** for the delay of clinical type 1 diabetes (T1D) in at-risk individuals. The company expects relevant additional PK/PD data being, or to be, collected from a PK/PD substudy in patients receiving 12-days of therapy in the ongoing Phase 3 PROTECT trial in newly diagnosed T1D patients later this quarter.

- Teplizumab is a humanized IgG1 mAb that targets CD3.

Antibody News You Should Know

July 15 - August 1, 2021

JOIN US FOR THE:

Emerging Immunotherapeutics for Ovarian Cancer Symposium

SEPTEMBER 23, 2021 | 8:00 - 12:00 PDT

SPONSORS:

ANTI
BODY
SOCI
ETY

OCRA ovarian cancer
research alliance

Registration fees will be donated to the Ovarian Cancer Research Alliance

Come network with your fellow Society members!

Registration is free using code [tabs100](#).

[COVID-19 intervention news](#)

Development update: As of the end of July 2021, over 25 anti-SARS-CoV-2 antibodies, or cocktails of such antibodies, have entered clinical studies and 4 products have emergency use authorizations in at least one country. Details can be found on our [COVID-19 Biologics Tracker webpage](#).

First clinical study of IMM-BCP-01 to start soon

On July 20, 2021, [Immunome, Inc.](#) announced that its three-antibody cocktail (IMM-BCP-01) has demonstrated potent neutralizing activity against the SARS-CoV-2

Delta variant in pre-clinical pseudovirus testing. The company plans to submit an IND application with the U.S. Food and Drug Administration (FDA) by the end of September 2021.

- IMM-BCP-01 targets at least three non-overlapping epitopes of SARS-CoV-2.

Phase 2 study to evaluate nasal administration of COVIDROPS started

On July 21, 2021, Sorrento Therapeutics, Inc. announced that a [Phase 2 efficacy trial \(NCT04900428\) of COVIDROPS has started](#). Approximately 350 outpatients with COVID-19 who are asymptomatic or have mild symptoms will be enrolled in this large double-blind, randomized clinical trial evaluating intranasal administration of COVIDROPS doses of 10 mg or 20 mg vs. placebo.

- COVIDROPS (STI-2099) comprises a human SARS-CoV-2 neutralizing monoclonal antibody with an Fc region that was modified to reduce binding affinity to Fc receptors. As COVI-AMG™ (STI-2020), intravenous administration is also being evaluated.

Studies of BI 767551 stopped

On July 28, 2021, the status of Phase 2/3 study ([NCT04822701](#)) of anti-SARS-COV-2 antibody BI 767551, also known as DZIF-10c, was updated to terminated and another Phase 2/3 study withdrawn due to project termination, suggesting Boehringer Ingelheim has discontinued their involvement in the development of this molecule. The project had included scientists at Cologne University Hospital and the German Center for Infection Research.

Sotrovimab to become more readily available in the EU for treatment of COVID-19

On July 28, 2020, [GlaxoSmithKline plc and Vir Biotechnology, Inc. announced](#) they signed a Joint Procurement Agreement with the European Commission to supply up to 220,000 doses of sotrovimab, an investigational single dose SARS-CoV-2 monoclonal antibody for the treatment of adults and adolescents (aged 12 years and over and weighing at least 40 kg) with COVID-19 who do not require oxygen supplementation

and who are at risk of progressing to severe COVID-19.

FDA authorizes REGEN-COV for emergency use as post-exposure prophylaxis of COVID-19

On July 30, 2021, FDA authorized Regeneron's combo of anti-SARS-CoV-2 antibodies [casirivimab and imdevimab for emergency use as post-exposure prophylaxis](#) of COVID-19, in addition to the authorization for treatment of mild-to-moderate COVID-19. The authorization was based in part on the review of the topline analysis of Phase 3 data from COV-2069 (NCT04452318), a randomized, double-blind, placebo-controlled trial in household contacts with close exposure to a household member known to be infected with SARS-CoV-2, but who were themselves asymptomatic.

[Updates on non-COVID-19 interventions](#)

Innovative antibody-based therapeutics queue to enter clinic

On July 21, 2021, [Sorrento Therapeutics, Inc. announced](#) its partner Escugen Biotechnology Co, Ltd. and Sorrento's subsidiary Levena (Suzhou) Biopharma Co., Ltd. received an approval letter from China's National Medical Products Administration for its application for clinical trial of their antibody-drug conjugate (ADC) ESG-401. Sorrento intends to file a US Investigational New Drug (IND) application for ESG-401 before the end of 2021. The ADC is a potential treatment of multiple solid tumors, including triple-negative breast cancer and urothelial carcinoma.

- ESG-401 is a recombinant humanized anti-Trop2 antibody conjugated to the DNA polymerase inhibitor SN38.

On July 16, 2021, details were posted on [clinicaltrials.gov](#) for a Phase 1 dose-escalation study ([NCT04965077](#)) to evaluate the safety, tolerability, pharmacokinetics and efficacy of MIL97 in subjects with advanced or metastatic solid tumors. Sponsored

by Beijing Mabworks Biotech Co., Ltd., the study will enroll an estimated 62 patients. The study's estimated start and primary completion dates are July 2021 and December 2022, respectively.

- MIL97 is a recombinant humanized monoclonal antibody targeting CD40.

On July 22, 2021, details were posted on clinicaltrials.gov for a Phase 1 ([NCT04972981](#)) dose-escalation and dose-expansion study to evaluate the safety, tolerability, pharmacokinetics, and antitumor activity of ADCT-901 as monotherapy in patients with selected advanced solid tumors. Sponsored by ADC Therapeutics S.A., the study will enroll an estimated 70 patients. The study's estimated start and primary completion dates are August 2021 and April 2024, respectively.

- ADCT-901 is an ADC composed of a humanized monoclonal antibody targeting KAAG1 that is conjugated through a cathepsin-cleavable linker to SG3199, a PBD-dimer cytotoxin.

On July 27, 2021, details were posted on clinicaltrials.gov for a Phase 1/2 ([NCT04977453](#)) study to evaluate safety, tolerability, PK, and therapeutic activity of GI-101 as a single agent and in combination with pembrolizumab, lenvatinib or local radiotherapy in patients with advanced, metastatic solid tumors. Sponsored by GI Innovation, Inc., the study will enroll an estimated 374 patients. The study's estimated start and primary completion dates are July 2021 and September 2025, respectively.

- GI-101 is a novel bispecific Fc fusion protein containing the CD80 ectodomain as an N-terminal moiety and an interleukin-2 variant as a C-terminal moiety configured via a human IgG4 Fc.

On July 28, 2021, Fusion Pharmaceuticals Inc. announced that the [FDA cleared their IND applications for \[225Ac\]-FPI-1966 \(FPI-1966\) and imaging agent \[111In\]-FPI-1967 \(FPI-1967\)](#). The company plans to initiate a Phase 1, non-randomized, open-label clinical trial of these investigational antibodies in patients with solid tumors expressing fibroblast growth factor 3 (FGFR3).

- FPI-1966 is a targeted alpha therapy using vofatamab, a human monoclonal antibody, to target and deliver actinium-225 to tumor sites expressing FGFR3, a protein that is overexpressed in multiple tumor types, particularly head and neck and bladder cancers.

Phase 2 study of anti-TL1A PRA023 started

On July 19, 2021, Prometheus Biosciences, Inc. announced the [initiation of the Phase 2 ARTEMIS-UC clinical trial evaluating PRA023](#) for moderate-to-severe ulcerative colitis (UC), with first patient enrollment. The study is placebo-controlled and statistically powered to evaluate the efficacy and safety of PRA023 in UC patients. Initiation of a Phase 2a study in Crohn's disease is on track for Q3 2021.

- PRA023 is an IgG1 humanized monoclonal antibody that blocks TNF-like ligand 1A, also known as TNF superfamily member 15.

Phase 3 study of anti-PD-L1 socazolimab started

On July 23, 2021, Sorrento Therapeutics, Inc. and Lee's Pharmaceutical Holdings Limited announced that, on July 15, 2021, China Oncology Focus Limited, a subsidiary of Lee's Pharm, enrolled the first patient in China in the [Phase 3 \(NCT04878016\) placebo controlled clinical trial of socazolimab](#) (formerly known as ZKAB001) combined with chemotherapy in the first-line treatment of extensive-stage small-cell lung cancer.

- Socazolimab is a human anti-PD-L1 monoclonal antibody identified by Sorrento using its proprietary G-MAB™ library platform.

Incyte receives a complete response letter for retifanlimab's BLA

On July 23, 2021, Incyte Corporation announced that the [FDA issued a Complete Response Letter \(CRL\) regarding its Biologics License Application for retifanlimab](#) for the treatment of adult patients with locally advanced or metastatic squamous cell carcinoma of the anal canal (SCAC) who have progressed on, or who are intolerant of, platinum-based chemotherapy. On June 24, 2021, FDA's Oncologic

Drug Advisory Committee had voted 13 to 4 for the deferral of the FDA approval of retifanlimab. FDA's letter indicates that the application cannot be approved in its present form and additional data are needed to demonstrate the clinical benefit of retifanlimab for the treatment of patients with advanced or metastatic SCAC.

- Retifanlimab is a humanized, hinge-stabilized IgG4k monoclonal antibody targeting programmed cell death protein 1 (PD-1).

Attending a virtual meeting soon?

The Antibody Society members save up to 20% on registration fees to attend:

World Bispecific, September 29 - October 1, 2021

- Use code ABS10 for a 10% discount

World ADC, October 11-14, 2021

- Use code TABS10 for a 10% discount

PEGS Europe, November 2-4, 2021

- Use code TAS20 for a 20% discount

Festival of Biologics, November 9-11, 2021

Antibody News You Should Know

August 1 - 15, 2021

Do you know about these resources, all available via

The Antibody Society's website?

[AIRR Community Working Groups](#)

[Approved Antibody Therapeutics Data](#)

[Webinars](#)

[Career Center](#)

Meeting Discount Codes ([log into](#) Members Only)

[COVID-19 intervention news](#)

Development update: Over 25 anti-SARS-CoV-2 monoclonal antibodies, or cocktails of such antibodies, are currently in clinical studies and 4 products have emergency use authorizations in at least one country. Details can be found on our [COVID-19 Biologics Tracker webpage](#).

First clinical study of GIGA-2050 started

On August 11, 2021, GigaGen Inc., a subsidiary of Grifols, announced the [first patient was dosed in its Phase 1 clinical trial \(NCT04883138\) of GIGA-2050](#).

In this study, up to 18 hospitalized patients with confirmed COVID-19 will be divided into three cohorts who will receive a single intravenous (IV) infusion dose of GIGA-2050 at 5, 15 or 50 mg (or as determined by the safety review committee) per kg of body weight.

- GIGA-2050 is a recombinant hyperimmune polyclonal antibody drug composed of more than 12,000 antibodies designed to provide passive immunity to COVID-19 patients.
-
-
-

Updates on non-COVID-19 interventions

Innovative antibody-based therapeutics queued to enter clinic

On August 2, 2021, Hummingbird Bioscience announced that the **UK Medicines and Healthcare Products Regulatory Agency has approved the clinical trial application to initiate a first-in-human Phase 1 trial of HMBD-001** in patients with advanced cancers. Under a clinical development partnership agreement, Cancer Research UK will fund and conduct the Phase 1 trial in the UK.

- HMBD-001 is a humanized IgG1 antibody that inhibits HER3 by binding an epitope on the heterodimerization interface, accessible irrespective of receptor conformation.

On August 2, 2021, Avidity Biosciences, Inc. announced that the U.S. Food and Drug Administration (**FDA**) **cleared the company to proceed with the Phase 1/2 MARINA™ clinical trial of AOC 1001** in adults with myotonic dystrophy type 1. The company is developing RNA-containing therapeutics called Antibody Oligonucleotide Conjugates (AOCs™). Myotonic dystrophy type 1 is a progressive and often fatal disease caused by a triplet-repeat on the DMPK gene, resulting in a toxic gain of function mRNA.

- AOC 1001 consists of a proprietary monoclonal antibody that binds to the transferrin receptor 1 conjugated with a small interfering RNA that targets DMPK mRNA.

On August 4, 2021, ABL Bio, Inc. announced that the [Investigational New Drug application for ABL501 has been approved by South Korea's Ministry of Food and Drug Safety](#). The Phase 1 study will evaluate the safety, tolerability, maximum tolerated dose and preliminary efficacy of ABL501 in patients with advanced or metastatic solid tumors.

- ABL501 is a bispecific antibody that blocks PD-L1 and LAG-3-mediated T cell inhibition.

On August 12, 2021, Immune-Onc Therapeutics, Inc. announced that [FDA has cleared the company's Investigational New Drug application for IO-108](#), a novel antagonist antibody targeting Leukocyte Immunoglobulin-Like Receptor B2 (LILRB2, also known as ILT4) for the treatment of solid tumors.

- IO-108 binds to LILRB2 with high affinity and specificity and blocks the interaction of LILRB2 with ligands that are involved in cancer-associated immune suppression

On August 2, 2021, details were posted on clinicaltrials.gov for a Phase 1 study ([NCT04985812](#)) to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of JNJ-67484703 in participants with active rheumatoid arthritis despite methotrexate therapy. Sponsored by Janssen Research & Development, LLC, the study will enroll an estimated 42 patients. The study's estimated start and primary completion dates are August 25, 2021, and November 17, 2022, respectively.

- JNJ-67484703 is a humanized immunoglobulin G1 kappa antibody that targets an undisclosed antigen.

On August 4, 2021, details were posted on clinicaltrials.gov for a Phase 1 study ([NCT04989387](#)) of INCA00186 as monotherapy or in combination with immunotherapy in participants with advanced solid tumors. Sponsored by Incyte Corporation, the study will enroll an estimated 230 patients. The study's

estimated start and primary completion dates are August 21, 2021, and May 21, 2024, respectively.

- INCA00186 is a humanized monoclonal antibody that binds and inhibits CD73 function.

On August 5, 2021, details were posted on clinicaltrials.gov for a Phase 1 study ([NCT04991740](#)) of JNJ-78306358 for advanced-stage solid tumors. Sponsored by Janssen Research & Development, LLC the study will enroll an estimated 140 patients. The study's estimated start and primary completion dates are October 3, 2021, and February 22, 2024, respectively.

- JNJ-78306358 is a bispecific antibody that binds CD3 on T cells and human leukocyte antigen G (HLA-G) on cancer cells.

FDA issues complete response letter for oportuzumab monatox

On August 13, 2021, Sesen Bio announced that it received a [Complete Response Letter from the FDA regarding the BLA for Vicineum™](#) (oportuzumab monatox-qqs) for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). The FDA provided recommendations specific to additional clinical/statistical data and analyses in addition to Chemistry, Manufacturing and Controls (CMC) issues pertaining to a recent pre-approval inspection and product quality.

- Oportuzumab monatox is a humanized single-chain antibody fragment specific for the epithelial cell adhesion molecule antigen linked to ETA(252-608) Pseudomonas exotoxin.

Penpulimab approved in China for Hodgkin's lymphoma

On August 5, 2021, Akeso, Inc. announced that [penpulimab has obtained marketing approval by China's National Medical Products](#) for treatment of patients with relapsed or refractory classic Hodgkin's lymphoma after at least second-line systemic chemotherapy treatment. Akeso co-developed the drug with

Sino Biopharmaceutical Limited. A Biologics License Application for penpulimab for third-line treatment of metastatic nasopharyngeal carcinoma was submitted to the FDA through the Real-Time Oncology Review program in May 2021.

- Penpulimab is a humanized IgG1 monoclonal antibody that targets PD-1. The antibody was engineered to eliminate Fc-mediated effector function and have a slower off-rate on antigen binding, resulting in improved receptor occupancy.

Attending a virtual meeting soon?

The Antibody Society members save up to 20% on registration fees to attend:

World Bispecific, September 29 - October 1, 2021

- Use code ABS10 for a 10% discount

World ADC, October 11-14, 2021

- Use code TABS10 for a 10% discount

PEGS Europe, November 2-4, 2021

- Use code TAS20 for a 20% discount

Antibody News You Should Know

August 15 - September 1, 2021

Want your news faster? Follow us on [LinkedIn!](#)

[COVID-19 intervention news](#)

New anti-SARS-CoV-2 antibodies enter the clinic

On August 23, 2021, details were posted on clinical trials.gov for a Phase 1 randomized, double-blind, placebo-controlled, parallel group, single ascending dose study (NCT05017168) to evaluate the safety, tolerability and pharmacokinetics of Celltrion's CT-P63 in healthy subjects. After verifying safety in phase 1 study, the [company plans to proceed with additional clinical trials using a combination treatment](#) comprising CT-P63 and anti-SARS-CoV-2 Regkirona (CT-P59), which is currently under review by the European Medicines Agency (EMA). Celltrion is in talks with the US Food and Drug Administration (FDA) for Emergency Use Authorization of Regkirona.

- CT-P63 is a monoclonal antibody targeted against SARS-CoV-2 spike receptor binding domain.

On August 18, 2021, [ExeVir announced that the first subjects have been dosed in a Phase I clinical study of XVR011](#), its llama-derived antibody for the treatment and prevention of COVID-19, and on September 1, they announced that the first patient has been treated in a Phase 1b/2 global clinical study of XVR011. EXEVIR0101 (NCT04884295) is a dose-finding, safety, and efficacy study of XVR011 added to standard of care in patients hospitalized for COVID-19.

- XVR011 is a single domain-based anti-SARS-CoV-2 antibody (VHH-Fc) optimized for stability, safety, broad neutralizing capability and excellent manufacturability.

Sotrovimab granted marketing authorization in Australia

On August 23, 2021, Vir Biotechnology, Inc. announced the **first marketing authorization, granted in Australia, for its first commercial product, sotrovimab (Xevudy®)**, developed in partnership with GlaxoSmithKline. In April 2021, the Australian Therapeutic Goods Administration (TGA) had granted provisional marketing authorization for sotrovimab for the treatment of adults and adolescents (aged 12 years and over and weighing at least 40 kg) with COVID-19 who do not require initiation of oxygen due to COVID-19 and who are at increased risk of progression to hospitalization or death. Globally, sotrovimab is authorized for emergency use in the U.S., received a positive scientific opinion from the EMA, and has been granted temporary authorization in Bahrain, Canada, Egypt, Italy, Kuwait, Qatar, Singapore and the United Arab Emirates.

- Sotrovimab is an anti-SARS-CoV-2 monoclonal antibody that incorporates Xencor's Xtend™ technology, and has been designed to achieve high concentration in the lungs to ensure optimal penetration into airway tissues affected by SARS-CoV-2 and to have an extended half-life.

Updates on non-COVID-19 interventions

New antibody therapeutics queued to enter clinic

On August 18, 2021, details were posted on clinicaltrials.gov for a Phase 1 trial ([NCT05009966](#)) to evaluate safety, tolerability, pharmacokinetics, immunogenicity, and initial efficacy of SYSA1801 in the treatment of CLDN 18.2

positive advanced malignant solid tumors. Sponsored by CSPC Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd., the study will enroll an estimated 272 patients. The estimated start and primary completion dates are in October 2021 and December 2023, respectively.

- SYSA1801 is an anti-Claudin-18.2 human monoclonal antibody-conjugated to the drug MMAE drug.

On August 19, 2021, details were posted on clinicaltrials.gov for a Phase 1/1b open-label, first-in-human, single agent, dose escalation and expansion study ([NCT05013554](https://clinicaltrials.gov/ct2/show/study/NCT05013554)) for the evaluation of safety, pharmacokinetics, pharmacodynamics, and anti-tumor activity of SAR443216 in participants with relapsed/refractory HER2-expressing solid tumors. Sponsored by Sanofi, the study will enroll an estimated 184 patients. Although the estimated start date is August 18, the study is listed as not yet recruiting. The primary completion date of the study is October 2023.

- SAR443216 a trispecific antibody with binding sites for HER2, CD3 and CD28, and containing a mutated IgG4-Fc that lacks effector functions.

On August 27, 2021, details were posted on clinicaltrials.gov for a Phase 1 study ([NCT05025085](https://clinicaltrials.gov/ct2/show/study/NCT05025085)) investigating AGEN1777 as a single-agent and in combination with a PD-1 inhibitor in patients with advanced solid tumors. Sponsored by Agenus Inc. with collaborator Bristol-Myers Squibb, the study will enroll an estimated 75 patients. The study's estimated start and primary completion dates are in September 2021 and September 2023, respectively.

- AGEN1777 is an Fc-engineered, IgG1 bispecific antibody that targets TIGIT and another inhibitor receptor not yet disclosed, but also expressed on T-cells and NK cells.

On September 1, 2021, details were posted on clinicaltrials.gov for a Phase 1 study ([NCT05029882](https://clinicaltrials.gov/ct2/show/study/NCT05029882)) to assess adverse events and change in disease activity in adult participants with non-small cell lung cancer receiving intravenous ABBV-

400. Sponsored by AbbVie, an estimated 100 patients will be enrolled. The study's estimated start and primary completion dates are in September 2021 and June 2025, respectively.

- ABBV-400 is an anti-c-Met antibody-drug conjugate that utilizes a topoisomerase inhibitor payload.

First patients dosed with new investigational antibody therapeutics

On August 18, 2021, a Phase 1 study ([NCT05007782](#)) to evaluate the safety and tolerability of GS-1811 as monotherapy and in combination with pembrolizumab in adults with advanced solid tumors was started. Sponsored by Gilead Sciences, the study will enroll an estimated 62 patients, and the primary completion date is in May 2024. Gilead Sciences, Inc. licensed the JTX-1811 program, renamed GS-1811, from Jounce Therapeutics, Inc.

- GS-1811 is an afucosylated antibody targeting of CCR8, a chemokine receptor enriched on tumor-infiltrating T regulatory (T_{REG}) cells. The antibody is designed to selectively deplete immunosuppressive T_{REG} cells.

On August 17, 2021, [Citryll BV announced that the first healthy volunteer has been enrolled and dosed](#) in a Phase 1 clinical trial to evaluate the safety, tolerability, and pharmacokinetics of CIT-013. CIT-013 is being developed for autoimmune and chronic inflammatory diseases and other indications where Neutrophil Extracellular Traps (NETs) play an important role in pathogenesis.

- CIT-013 is a humanized therapeutic antibody that [binds to citrullinated Histones H2A and H4 and inhibits NET formation](#), promotes tissue NET clearance, and hence blocks the proinflammatory and toxic activities of NETs.

Marketing applications filed for tebentafusp

On August 24, 2021, Immunocore Holdings Plc announced that [regulators in the United States and European Union \(EU\) have each accepted applications](#)

for the approval of tebentafusp (IMCgp100) for the treatment of HLA-A*02:01-positive adult patients with metastatic uveal melanoma. FDA's expected target action date is February 23, 2022. EMA has agreed to the company's request for accelerated assessment of their marketing application. Tebentafusp has been granted Priority Review; Real Time Oncology Review; Breakthrough Therapy designation; Fast Track designation; and orphan drug designation by the FDA in the United States; orphan drug status in the EU; and Promising Innovative Medicine (PIM) designation under the UK Early Access to Medicines Scheme for metastatic uveal melanoma.

- Tebentafusp is a soluble protein composed of a high-affinity T cell receptor specific to a peptide sequence from the gp100 antigen, which is presented on melanoma tumor cells by HLA-A2, fused to an anti-CD3 single-chain antibody fragment.

Bimekizumab and Tafasitamab approved in the EU

On August 20, 2021, the **European Commission authorized marketing of Bimzelx (bimekizumab) in the EU** for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Bimekizumab is approved at a recommended dose of 320 mg, administered by two subcutaneous injections every four weeks to week 16 and every eight weeks thereafter.

- Bimekizumab is a humanized IgG1 kappa antibody that selectively inhibits IL-17A and IL-17F by binding regions that are common to these pro-inflammatory cytokines, which share ~50% sequence identity and are expressed as homodimers and IL-17A/F heterodimers.

On August 26, 2021, MorphoSys AG and Incyte announced that the **European Commission granted conditional marketing authorization for Minjuvi (tafasitamab)** in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma who are not eligible for autologous stem cell transplant.

Incyte and MorphoSys share global development rights to tafasitamab; Incyte has exclusive commercialization rights to tafasitamab outside the United States.

Tafasitamab's brand name is Monjuvi in the U.S., and Minjuvi in the EU.

- Tafasitamab is a humanized Fc-modified cytolytic anti-CD19 monoclonal antibody.

Zimberelimab granted first approval in China

On August 30, 2021, Ligand Pharmaceuticals Incorporated announced that its partner [Gloria Biosciences received approval from China's National Medical Products Administration for zimberelimab](#), an OmniAb-derived antibody for the treatment of recurrent or refractory classical Hodgkin's lymphoma. Gloria Biosciences has development and commercialization rights in China with respect to zimberelimab through a sublicense agreement with Ligand's licensee Wuxi Biologics Ireland Limited.

- Zimberelimab is a human monoclonal antibody that targets PD-1.

Sesen Bio withdraws MAA in Europe

On August 20, 2021, [Sesen Bio, Inc. withdrew its marketing authorization application to the EMA for oportuzumab monatox](#) (Vysyrium™) for the treatment of BCG-unresponsive non-muscle invasive bladder cancer. The company is pausing its plans to pursue regulatory approval of Vysyrium in Europe until there is more clarity from the FDA on the next steps regarding their BLA. If an additional clinical trial is required, the company anticipates re-submission in 2023.

- Oportuzumab monatox (Vysyrium™, Vicineum®, VB4-845) is a humanized single-chain variable fragment targeting epithelial cell adhesion molecule fused to Pseudomonas aeruginosa exotoxin A (ETA(252-608)).

Antibody News You Should Know

September 1 - 15, 2021

Want your news faster? Follow us on [LinkedIn!](#)

[COVID-19 intervention news](#)

New anti-SARS-CoV-2 antibody revealed

On September 8, 2021, [SpikImm and Institut Pasteur reported that SPKM001](#) potentially neutralizes the original SARS-CoV-2 strain and its variants of concern, including the Alpha, Beta, Gamma, Delta and Delta Plus variants. SpikImm expects to start clinical trials in 2022 in Europe, North America or Brazil.

- SPKM001 is a high affinity human monoclonal antibody targeting the receptor-binding domain on the SARS-CoV-2 Spike protein.

FDA declines request for lenzilumab's emergency use authorization

On September 8, 2021, [Humanigen, Inc. was informed](#) that its request for emergency use authorization for lenzilumab for the treatment of patients newly hospitalized with COVID-19 had been declined by FDA. In declining the request, FDA stated that it was unable to conclude that the known and potential benefits of lenzilumab outweigh the known and potential risks of its use as a treatment for COVID-19. The company indicated that NIH's ACTIV-5/BET-B study ([NCT04583969](#)) is expected to provide further data that may support a new EUA request.

- Lenzilumab is a human IgG1 kappa antibody targeting GM-CSF.

Updates on non-COVID-19 interventions

New antibody therapeutics queued to enter clinic

On September 10, 2021, details were posted on clinicaltrials.gov for a Phase 1 dose escalation study ([NCT05040932](https://clinicaltrials.gov/ct2/show/study/NCT05040932)) to evaluate the safety, tolerability and pharmacokinetics of YH004 as a single agent and combination with anti-PD-1 toripalimab in subjects with advanced solid tumors and relapsed or refractory non-Hodgkin's lymphoma. Sponsored by Eucure (Beijing) Biopharma Co., Ltd, the study will enroll an estimated 80 patients. The estimated start and primary completion dates are in September 2021 and January 2024, respectively.

- YH004 is a 4-1BB agonist antibody.

On September 10, 2021, Elpiscience Biopharmaceuticals, Inc. announced its [investigational new drug \(IND\) application for ES002 was cleared by the FDA](#). A first-in-human clinical trial will be initiated in the U.S. to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary clinical activity of ES002 in patients with advanced solid tumors.

- ES002 is a humanized anti-CD39 antibody.

On September 13, 2021, Hummingbird Bioscience, announced that the [FDA has allowed the initiation of a first-in-human study of HMBD-002](#). The Phase 1, multi-center, open-label trial will evaluate HMBD-002, as a monotherapy and in combination with pembrolizumab in patients with advanced solid malignancies.

- HMBD-002 is an IgG4 anti-VISTA antibody.

On September 14, 2021, details were posted on clinicaltrials.gov for a Phase 1 study ([NCT05043987](https://clinicaltrials.gov/ct2/show/study/NCT05043987)) to evaluate safety of CPO102, an anti-Claudin 18.2

antibody-MMAE drug conjugate administered intravenously in patients with advanced pancreatic and gastric cancers. Sponsored by Conjupro Biotherapeutics, Inc., the study will enroll an estimated 72 patients. The estimated start and primary completion dates are in February 2022 and February 2025, respectively.

- CPO102 is an anti-Claudin 18.2 antibody-MMAE drug conjugate.

On September 15, 2021, CStone Pharmaceuticals announced that the **IND application of multi-specific antibody CS2006/NM21-1480 has been approved by China's** National Medical Products Administration. The upcoming clinical study will evaluate the safety, pharmacokinetics, and anti-tumor efficacy of CS2006/NM21-1480 in Chinese patients with advanced solid tumors.

- CS2006/NM21-1480, a monovalent, tri-specific antibody-based molecule targeting PD-L1, 4-1BB, and human serum albumin, was discovered and engineered by Numab Therapeutics.

GNC-035 in first clinical study

On September 10, 2021, details were posted on clinicaltrials.gov for a Phase 1 study (**NCT05039931**) to evaluate GNC-035, a tetra-specific antibody, in participants with locally advanced or metastatic solid tumors. Sponsored by Sichuan Baili Pharmaceutical Co., Ltd., the study will enroll an estimated 29 patients. Initiated in June 201, the study's primary completion date is in June 2023.

- GNC-035, a "guidance, navigation and control" antibody derived from Systimmune's platform, targets PD-L1, 4-1BB, CD3, and ROR1.

Navicixizumab queued for Phase 3 clinical study

On September 14, 2021, details were posted on clinicaltrials.gov for a Phase 3 study (**NCT05043402**) of navicixizumab plus paclitaxel and navicixizumab monotherapy in comparison to paclitaxel monotherapy in patients with platinum-

resistant epithelial ovarian, primary peritoneal, or fallopian tube cancer.

Sponsored by OncXerna Therapeutics, Inc., the study will enroll an estimated 400 patients. The estimated start and primary completion dates are in November 2021 and November 2023, respectively.

- Navicixizumab is a bispecific antibody targeting DLL4 and VEGF.

BLA for tislelizumab accepted for review by FDA

On September 13, 2021, BeiGene, Ltd. announced that [FDA accepted for review a Biologics License Application for tislelizumab](#) as a treatment for patients with unresectable recurrent locally advanced or metastatic esophageal squamous cell carcinoma after prior systemic therapy. The BLA, filed in collaboration with Novartis, is supported by the positive global Phase 3 RATIONALE 302 trial (NCT03430843). FDA target date for a first action on the BLA is July 12, 2022.

- Tislelizumab is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages.

Attending a virtual meeting soon?

The Antibody Society members save up to 20% on
registration fees to attend:

[World Bispecific](#), September 29 - October 1, 2021

Antibody News You Should Know

September 15 - October 1, 2021



The Antibody Society members **save 10%** on the fee for this course:

Student Discount: AB5fksb6YY2q (\$315)

Non-Student Discount: AB5gh6iOAS37 (\$427.50)

[View details here](#)

[COVID-19 intervention news](#)

New anti-SARS-CoV-2 antibody revealed

On September 23, 2021, [Twist Bioscience Corporation](#) reported that its internally-discovered antibody candidate TB202-3 (CoVIC-094) demonstrated potent binding to diverse SARS-CoV-2 variant mutations, including strains with the E484K, N501Y, D614G, Y453F and K417N mutations in pseudovirus assays, indicating this therapeutic antibody may be effective in treating many strains of COVID-19. The Coronavirus Immunotherapy Consortium (CoVIC), which was formed to analyze candidate antibody therapeutics side-by-side in standardized assays and now includes over 350 monoclonal antibodies directed against the SARS-CoV-2 Spike protein, [published the results in Science](#).

- TB202-3 is a single domain VHH nanobody targeting the SARS-CoV-2 spike protein.

Phase 2 study results for Toll-like receptor 4 inhibitor EB05

On September 20, 2021, [Edesa Biotech, Inc. announced](#) positive results from the Phase 2 part of an ongoing Phase 2/3 clinical study evaluating EB05 as a single-dose treatment for hospitalized COVID-19 patients. Among the findings, the study's Data and Safety Monitoring Board reported a 28-day death rate of 14.3% (2/14) in the EB05 arm versus 36.8% (7/19) in the placebo arm in critically severe patients on extracorporeal membrane oxygenation therapy. Patients treated with EB05 plus standard of care had a 68.5% reduction in the risk of dying when compared to placebo plus standard of care at 28 days (HR: 3.17 placebo vs. EB05; 95% CI: 0.66-15.35; p=0.15).

- EB05 is a humanized IgG1 antibody targeting Toll-like receptor 4.

Process for MAA submission for lenzilumab moves forward in EU

[Humanigen, Inc. announced](#) the European Medicines Agency has appointed a rapporteur and a co-rapporteur as part of the pre-submission process related to their plan to submit a Marketing Authorization Application (MAA) for the use of lenzilumab to treat patients hospitalized with COVID-19. The company will seek a Conditional Marketing Authorization, which allows approval of a medicine that addresses unmet medical needs of patients on the basis of less comprehensive data than normally required.

- Lenzilumab is a human anti-GM-CSF IgG1 monoclonal antibody.

Data supporting BLA for REGEN-COV™ published

On September 29, 2021, [Regeneron Pharmaceuticals, Inc. announced](#) that the New England Journal of Medicine published positive results from a Phase 3 trial (NCT04425629) that assessed the ability of REGEN-COV™ (casirivimab and imdevimab) to treat COVID-19 in infected high-risk non-hospitalized patients (outpatients). The trial met its primary and all secondary endpoints and showed treatment with REGEN-COV significantly reduced the risk of hospitalization or death, with a safety profile consistent with previously reported data. In August, Regeneron submitted the first of two Biologics License Applications (BLAs) for

REGEN-COV. The initial submission included data on the efficacy and safety of REGEN-COV to treat and prevent SARS-CoV-2 infection in non-hospitalized people. The second BLA submission will focus on those hospitalized because of COVID-19, and is expected to be completed later this year.

- REGEN-COV™ is a mixture of two human anti-SARS-CoV-2 antibodies, casirivimab and imdevimab.

Celltrion's regdanvimab granted approval in Korea

On September 18, 2021, [Celltrion Group announced](#) that the Korean Ministry of Food and Drug Safety (MFDS) approved regdanvimab for extended use in elderly patients aged 50 years and over, or with at least one underlying medical condition, with mild symptoms of COVID-19, and adult patients with moderate symptoms of COVID-19. Previously granted Conditional Marketing Authorisation for emergency use, regdanvimab's full approval is the first granted by the Korean MFDS for a monoclonal antibody treatment for COVID-19.

- Regdanvimab is a human IgG1 monoclonal antibody that targets the SARS-CoV-2 spike protein.

[Updates on non-COVID-19 interventions](#)

New antibody therapeutics queued to enter clinic

On September 17, 2021, [InnoCare Pharma and Keymed Biosciences jointly announced](#) that the IND of CM355, which was developed by a joint venture between the two companies called Tiannuojiancheng Pharma, has been cleared by the China's National Medical Products Administration. CM355 will be evaluated as a treatment for B-cell malignancies, including non-Hodgkin lymphoma.

- CM355 is a bispecific antibody that targets CD20 and CD3.

On September 23, 2021, details were posted on clinicaltrials.gov for a Phase 1, open-label, multicenter, dose-escalation study ([NCT05054348](https://clinicaltrials.gov/ct2/show/study/NCT05054348)) of IO-108 as monotherapy and in combination with pembrolizumab in adult subjects with advanced relapsed or refractory solid tumors. Sponsored by Immune-Onc Therapeutics Inc., the study has an estimated enrollment of 36 patients and an estimated start date of September 25, 2021, although it was listed as not yet recruiting when accessed on October 1.

- IO-108 is a human anti-LILRB2 IgG4 antibody with a S228P mutation in the hinge region to prevent Fab-arm exchange.

On September 29, 2021, details were posted on clinicaltrials.gov for a Phase 1B, dose-escalation study ([NCT05060276](https://clinicaltrials.gov/ct2/show/study/NCT05060276)) of the safety and preliminary efficacy of an STI-3258 in patients with relapsed or refractory solid tumors. Sponsored by Sorrento Therapeutics, Inc., the study has an estimated enrollment of 30 patients and an estimated start date in December 2021.

- STI-3258 is an anti-Trop2-SN38 antibody-drug conjugate.

On October 1, 2021, details were posted on clinicaltrials.gov for a Phase Ia, randomized, double-blind, placebo-controlled, single dose-escalation study ([NCT05064345](https://clinicaltrials.gov/ct2/show/study/NCT05064345)) to evaluate the safety, tolerability and pharmacokinetics of HB0034 in adult healthy subjects. Sponsored by Shanghai Huaota Biopharmaceutical Co., Ltd., the study is due to start in December 2021.

- HB0034 is a recombinant humanized anti-IL-36R monoclonal antibody.

First clinical studies started for XTX101, BI 765049, and Invetx's fully canine mAb (IVX-01)

On September 16, 2021, [Xilio Therapeutics, Inc.](https://www.xiliotherapeutics.com) **announced** that the first patient has been dosed in the company's Phase 1/2 clinical trial evaluating

XTX101 for the treatment of solid tumors. NCT04896697 is a first-in-human, multicenter Phase 1/2 study of XTX101 in patients with advanced solid tumors.

- XTX101 is an Fc engineered anti-CTLA-4 monoclonal antibody.

On September 20, 2021, [Oxford BioTherapeutics announced](#) that it received a milestone payment from Boehringer Ingelheim for the progress of an oncology drug candidate (BI 765049) into the clinic. NCT04752215 Phase 1 is a dose escalation trial of BI 765049 and BI 765049 + anti-PD-1 BI 754091 administered by repeated intravenous infusions in patients with malignant solid tumors expressing B7-H6.

- BI 765049 is a bispecific antibody that targets B7-H6 and CD3.

On September 20, 2021, [Invetx announced](#) that it has initiated a clinical field study in dogs targeting an undisclosed chronic indication with IVX-01, its proprietary, novel, fully canine, high-affinity and half-life extended monoclonal antibody. In related news, on September 27, 2021, [Invetx and Boehringer Ingelheim announced](#) they entered into a collaboration agreement to develop novel, species-specific monoclonal antibody biotherapeutics targeting a wide range of diseases in the veterinary species, initially focused on dogs and cats.

Phase 3 trials of Mim8 and a combination of favezelimab/pembrolizumab due to start soon

On September 22, 2021, details were posted on clinicaltrials.gov for Phase 3 study ([NCT05053139](#)) to investigate efficacy and safety of NNC0365-3769 (Mim8) in adults and adolescents with hemophilia A with or without inhibitors. Sponsored by Novo Nordisk A/S, the study has an estimated enrollment of 230 patients and an estimated start date in December 2021.

- Mim8 is a human bispecific antibody bridging FIXa and FX on platelets, enhancing FX activation and thereby coagulation.

On October 1, 2021, details were posted on clinicaltrials.gov for Phase 3 study ([NCT05064059](#)) of MK-4280A (coformulated favezelimab [MK-4280] plus pembrolizumab) versus standard of care in previously treated metastatic PD-L1 positive colorectal cancer. Sponsored by Merck Sharp & Dohme Corp., the study has an estimated enrollment of 432 patients and an estimated start date in November 2021.

- Favezelimab is a humanized IgG4 monoclonal antibody that targets LAG3.

BLA for fixed-dose combination of relatlimab and Opdivo® submitted to FDA

On September 20, 2021, [Bristol Myers Squibb announced](#) that the FDA accepted for priority review the Biologics License Application (BLA) for the fixed-dose combination of relatlimab and Opdivo® (nivolumab), administered as a single infusion, for the treatment of adult and pediatric patients (12 years and older and weighing at least 40 kg) with unresectable or metastatic melanoma. The FDA assigned a Prescription Drug User Fee Act (PDUFA) goal date of March 19, 2022.

- Relatlimab is a human anti-LAG-3 IgG4 monoclonal antibody.

BLA for lecanemab submitted to FDA

On September 28, 2021, [Eisai Co., Ltd. and Biogen Inc. announced](#) that Eisai initiated a rolling submission to the FDA of a BLA for lecanemab for the treatment of early Alzheimer's disease. The BLA is being submitted under the accelerated approval pathway. A PDUFA date has not yet been set.

- Lecanemab is a humanized IgG1 antibody that targets amyloid beta protofibrils

Tisotumab vedotin (TIVDAK) approved by FDA for treatment of cervical cancer

On September 20, 2021, [Genmab A/S and Seagen Inc. announced](#) that the

FDA granted accelerated approval to TIVDAK (tisotumab vedotin-tftv) for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. TIVDAK is approved under the FDA's Accelerated Approval Program based on tumor response and the durability of the response.

- Tisotumab vedotin is an antibody-drug conjugate composed of a human IgG1 antibody targeting tissue factor conjugated to the microtubule-disrupting agent monomethyl auristatin E via a protease-cleavable linker.

Attending a virtual meeting soon?

The Antibody Society members save up to 20% on registration fees to attend:

World ADC, October 11-14, 2021

- Use code TABS10 for a 10% discount

PEGS Europe, November 2-4, 2021

- Use code TAS20 for a 20% discount

Festival of Biologics, November 9-11, 2021

- Use code ASociety20 for a 20% discount