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Volume 1 Issue 2

BIOCONJUGATION INSIGHTS

SPOTLIGHT

Evolving ADCs: expanding horizons

BIOCONJUGATION INSIGHTS

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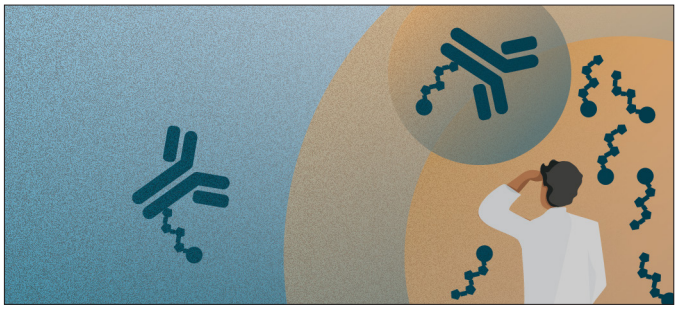
Evolving ADCs: expanding horizons



INDUSTRY INSIGHTS

SPOTLIGHT

Industry insights, June 2025

Esohe Idusogie

Bioconjugation Insights is delighted to bring you all the latest news in the bioconjugation space in this new Industry Insights article. Brought to you by one of our esteemed **Editorial Advisory Board** members, this article highlights the latest developments in collaborations, regulatory changes, marketing trends, and R&D in the field. Additionally, it provides insights into key clinical trials, innovations in tools and technology, and notable conferences and publications.

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COLLABORATIONS AND PARTNERSHIPS

Veraxa Biotech to go public in $1.64B merger to advance conjugate cancer therapies [1] and launch bispecific ADC program in partnership with OmniAb [2]

Swiss biotech Veraxa Biotech will go public in the US via a $1.64B merger with healthcare-focused special purpose acquisition company (SPAC) Voyager Acquisition, gaining access to capital for its next-generation ADC and bispecific T-cell engager programs. Veraxa's lead ADC, VX-A901, now in Phase I for leukemia, targets FLT3 with enhanced Fc potency. The company aims to have three conjugate-based candidates in clinical trials by 2029. Its proprietary BiTAC platform enables dual-targeting cytotoxicity with improved safety profiles, addressing dosing limitations of current therapies. The merger includes a $253M cash infusion, with listing expected on NASDAQ as 'VERX'.

Additionally, Veraxa has partnered with OmniAb to co-develop a novel bispecific ADC (bsADC) targeting solid tumors. The partnership leverages OmniAb's transgenic antibody discovery technologies with VERAXA's proprietary conjugation and linker platform to create next-generation therapeutics. VERAXA will lead development of a bsADC candidate by applying its in-house conjugation expertise to high-affinity human antibodies sourced via OmniAb's in vivo platforms. The resulting conjugate will address two cancer-relevant targets, with VERAXA handling preclinical validation.

The bsADC program will be jointly owned, with both companies sharing future revenues from development, licensing, or commercialization. This marks VERAXA's second major alliance in six months, reinforcing its strategy of growth through innovation-driven collaborations.

Araris strikes ADC partnership with Johnson & Johnson, extending conjugation platform reach [3]

Araris Biotech has signed a new ADC collaboration with Johnson & Johnson, marking its third major pharma partnership despite its recent acquisition by Taiho Pharmaceutical. Deal terms of this partnership remain undisclosed. The agreement centers on Araris' AraLinQ platform, a site-specific, one-step enzymatic conjugation technology that attaches payloads to off-the-shelf antibodies without prior modification. This method yields highly uniform and stable ADCs, aiming to lower production costs and shorten development timelines.

Astellas secures $1.3B deal with Evopoint for CLDN18.2-directed ADC [4]

Astellas has signed a licensing agreement with Evopoint Biosciences valued at up to $1.34B for global rights (excluding Greater China) to XNW27011, an investigational ADC targeting CLDN18.2. The deal includes a $130M upfront payment, up to $70M in near-term milestones, and further milestone payments plus royalties. The ADC leverages a topoisomerase I inhibitor payload and linker technology and is in Phase I/II clinical trials in China for solid tumors expressing CLDN18.2, including gastric, gastroesophageal, and pancreatic cancers. This acquisition complements Astellas' existing portfolio, which features Vyloy (zolbetuximab), the first approved CLDN18.2-targeted therapy.

REGULATORY CHANGES AND UPDATES

FDA grants accelerated approval to AbbVie's EMRELIS for advanced NSCLC with high c-Met overexpression [5]

The US FDA has granted accelerated approval to AbbVie's EMRELIS (telisotuzumab vedotin-tllv) for the treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) in adult patients with high c-Met protein overexpression who have previously received systemic therapy. EMRELIS is a c–Met–directed ADC designed to selectively deliver cytotoxic agents to tumor cells overexpressing c-Met, improving precision while limiting off-target effects. It is the first and only approved therapy for this specific biomarker-defined patient population, targeting tumors where ≥50% of cells show strong c-Met staining by FDA-approved immunohistochemistry testing. The approval is based on findings from the Phase II LUMINOSITY study, which enrolled 84 patients and showed an overall response rate (ORR) of 35% and a median duration of response of 7.2 months. Continued approval is conditional upon confirmation of clinical benefit in an ongoing Phase III confirmatory trial (TeliMET NSCLC-01).

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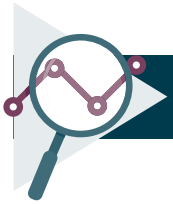
Daiichi Sankyo and Merck withdraw BLA for patritumab deruxtecan in previously treated EGFR-mutated NSCLC [6]

Daiichi Sankyo and Merck have voluntarily withdrawn their Biologics License Application (BLA) for patritumab deruxtecan, a HER3-DXd ADC, which was intended for accelerated approval in adult patients with previously treated, locally advanced or metastatic EGFR-mutated NSCLC. The drug, known as MSD outside the United States and Canada, is based on the HERTHENA-Lung01 Phase II trial. The decision to withdraw follows discussions with the FDA and the OS results for the confirmatory HERTHENA-Lung02 Phase III trial not meeting statistical significance. The withdrawl is separate from the FDA's June 2024 complete response, which addressed issues related to a third-party manufacturing facility.



MARKET TRENDS

Merck & Co. begins construction on $1B US hub for ADCs and biologics production [7]

Merck & Co. has broken ground on a $1B biologics facility in Wilmington, Delaware, and is set to become the US manufacturing base for Keytruda and next-generation biologics, including ADCs. The site will support launch and commercial-scale production, with lab operations expected by 2028 and clinical manufacturing by 2030. The center is projected to create over 500 full-time jobs initially, with potential for 1,500 more as operations expand. The move highlights Merck's push to strengthen US-based manufacturing amid evolving trade policies. CEO Robert Davis emphasized the facility's role in producing medicines "closer to patients" and its contribution to high-quality job creation. This investment positions Merck to scale ADC and biologics capabilities domestically, reinforcing its long-term manufacturing strategy for complex therapeutic platforms.

CLINICAL TRIALS AND RESEARCH

SystImmune's ADC first-line triple negative breast cancer trial expanded by Bristol Myers Squibb [8]

Bristol Myers Squibb (BMS) is advancing izalontamab brengitecan (BMS-986507/BL-B01D1), a bispecific ADC targeting EGFR and HER3, into a Phase II/III trial for first-line triple-negative breast cancer (TNBC). The conjugate links the antibody to a topoisomerase I inhibitor. This trial (IZABRIGHT-Breast01) will compare the ADC to standard chemotherapy in patients ineligible for PD-1-based therapy. BMS acquired ex-China rights from SystImmune in 2023 for $800M upfront, with milestone payments tied to clinical progress. This expansion highlights strong interest in ADCs and could trigger significant payouts

for SystImmune if first-line trials begin on schedule in 2025 and 2026.

RemeGen's ADC success in bladder cancer [9]

RemeGen's HER2-targeted ADC (disitamab vedotin), met primary endpoints for progression-free and overall survival (OS) in a Phase III bladder cancer trial, boosting prospects for Pfizer, which holds rights outside Asia. The 484-patient study in China tested the ADC with anti-PD-1 therapy Tuoyi (toripalimab), against standard chemotherapy, showing significant clinical benefit regardless of HER2 levels or cisplatin eligibility. The results support Pfizer's parallel global trial, expected to read out in about a year. Disitamab vedotin, marketed as Aidixi in China, is already approved for HER2-expressing bladder, gastric, and most recently, breast cancers. Despite the encouraging data, Pfizer earlier took a $200M impairment charge on the asset due to intensifying competition in the ADC space. Despite this, RemeGen's positive findings could shift momentum, particularly as combination strategies become a growing focus in ADC oncology pipelines.

Enhertu boosts response rates in early breast cancer, expanding ADC potential [10]

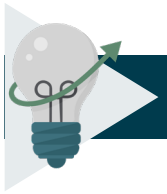
AstraZeneca and Daiichi Sankyo's HER2-targeting ADC Enhertu (trastuzumab deruxtecan) has achieved a new milestone, outperforming standard chemotherapy in the neoadjuvant setting for high-risk, early-stage HER2-positive breast cancer. In the Phase III DESTINY-Breast11 trial, Enhertu, followed by taxane-based THP therapy, significantly improved pathologic complete response rates versus the current standard regimen with ddAC-THP. Enhertu also showed a trend toward better event-free survival and had a more favorable tolerability profile with no new safety signals. Already approved for advanced HER2-positive, HER2-low, and HER2-ultralow breast cancers, Enhertu continues to expand its reach across disease stages and may now be poised to enter curative-intent settings.

Iksuda Therapeutics doses first patient in Phase I trial of CD19-targeting ADC [11]

Iksuda Therapeutics, based in Newcastle upon Tyne, UK, has successfully dosed the first patient in a Phase I, first-in-human trial evaluating IKS03, a CD19-targeting ADC, in advanced B cell non-Hodgkin lymphoma. IKS03 utilizes a clinically validated tumor-selective payload release format designed to enhance safety and efficacy. The trial will assess safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary anti-cancer activity across escalating doses to establish the recommended dose for expansion. Subsequent disease-specific cohorts will further evaluate efficacy. Patient enrollment is ongoing at sites across Italy, Spain, Australia, the US, and Canada, marking a significant step forward for Iksuda's novel ADC platform targeting hematologic malignancies.

David Simpson, CEO of Iksuda Therapeutics and Editorial Board Member of *Bioconjugation Insights*, stated:

> "With the first patient successfully completing the safety evaluation period with IKS03, Iksuda demonstrates its continued commitment to drive its differentiated ADCs through clinical proof of concept, further solidifying our position as a clinical-stage ADC-focused company. Although there have been advances in the treatment of non-Hodgkin lymphoma in recent years, there remains a significant unmet patient need, and we hope that IKS03 will be able to build on the potential benefit-risk profile suggested by the data generated in preclinical studies."



COMPANY START-UPS

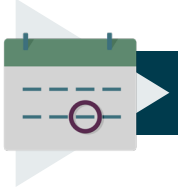
Synthetic Design Lab launches with $20M to redefine ADC payload precision [12]

Synthetic Design Lab has launched with $20M in seed funding to engineer ADCs that deliver cytotoxic payloads with up to 10-fold greater efficiency than current platforms. Its proprietary SYNTHBODY platform is designed to enhance ADC precision, safety, and adaptability through advanced conjugation control. Backed by Playground Global and Godfrey Capital, the biotech aims to enter the clinic in 2026, though pipeline details remain undisclosed. While others pursue broader approaches with dual-payload ADCs to address low antigen expression and resistance, Synthetic Design Lab focuses on pinpoint accuracy. Founder Daniel Chen, former VP of cancer immunotherapy at Genentech, leads the effort.

TOOLS AND TECHNOLOGIES

ProteinQure raises $11M to advance first AI-designed peptide-drug conjugate into the clinic [13]

ProteinQure has secured $11M in Series A funding to launch a first-in-human trial of PQ203, a potentially first-in-class peptide-drug conjugate (PDC) targeting the sortilin receptor in resistant tumors, including TNBC. Set to begin enrollment in Q3 2025, the US/Canada-based Phase I trial will test the AI-designed candidate in 70–100 patients. Unlike conventional ADCs, PDCs such as PQ203 may offer improved tumor penetration and safety due to their smaller size and lower immunogenicity. The candidate was designed using ProteinQure's ProteinStudio platform, which integrates AI models, molecular simulations, and wet lab validation to engineer novel peptides using non-canonical amino acids. With $16M in total funding and a proprietary machine learning model library, ProteinQure is positioning itself as a next-generation player in the targeted therapy landscape.



CONFERENCES, EVENTS, AND PUBLICATIONS

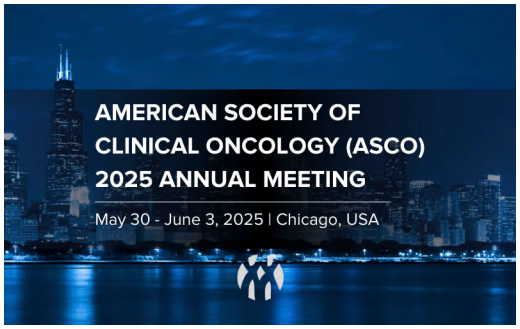
Heidelberg Pharma to share new clinical data on amanitin-based ADC HDP-101 at EHA 2025 [14]

Heidelberg Pharma will present new clinical results for its lead ADC HDP-101, at the 2025 European Hematology Association (EHA) Congress in Milan this June. The Amanitin-based ADC is being evaluated in a Phase I/IIa trial for relapsed or refractory

multiple myeloma. The candidate has shown promising early signals, including an ongoing complete response in a heavily pretreated patient treated continuously for over 19 months. Additional patients have demonstrated meaningful biological activity and clinical benefit. HDP-101 uses Heidelberg's proprietary antibody-targeted amanitin conjugate (ATAC) platform, which leverages the potent RNA polymerase II inhibitor Amanitin for targeted cytotoxic delivery. The study is currently enrolling cohort 8 at a dose level of 140 µg/kg. The data supports the potential of HDP-101 as a novel ADC approach in multiple myeloma, especially in treatment-resistant populations.

Genmab's FRα-targeting ADC, Rina-S, shows strong response in endometrial cancer at ASCO 2025 [15]

Genmab has reported encouraging data for rinatabart sesutecan (Rina-S), a folate receptor alpha-targeting (FRα-targeting) ADC, in heavily pretreated endometrial cancer, reinforcing the rationale behind its $1.8B acquisition of ProfoundBio in 2024. The presentation at American Society of Clinical Oncology (ASCO) 2025 showed Phase I/II data had objective response rates of 50% at 100 mg/m² and 45.5% at 120 mg/m², with durable responses ongoing in ~80% of responders in both cohorts. Two complete responses were observed at the lower dose. Disease control was achieved in all patients in the 100 mg/m² group. The most common treatment-emergent adverse events were neutropenia, anaemia, and gastrointestinal issues. Only 3.1% discontinued due to side effects. These results strengthen Genmab's strategic decision to advance Rina-S, now a core ADC asset in its oncology pipeline following a broader portfolio reprioritization.



Pfizer unveiled data on novel ADC-immunotherapy combinations at ASCO 2025 [16]

At the 2025 ASCO Annual Meeting, Pfizer spotlighted data from its expansive oncology pipeline, presenting data from over 60 abstracts, across major tumor areas, including breast, genitourinary, hematologic, and thoracic cancers, as well as colorectal cancer. Among these, they shared their strategy to explore novel vedotin ADCs in combination with immune-checkpoint inhibitors. This approach is aimed at amplifying anti-tumor immune responses. Notably, for the first time, Pfizer presented early-phase clinical data on two investigational ADCs in combination with pembrolizumab for thoracic cancers: sigvotatug vedotin (SV), an integrin beta-6 (IB6)-directed ADC being studied in lung and head and neck cancers, and PDL1V (PF-08046054): a PD-L1-targeted ADC being investigated in head and neck cancers. These Phase I findings highlight Pfizer's growing interest in rational combinations that leverage tumor-directed payload delivery with immune activation.

Promising CD123-targeted conjugate shows high response in newly diagnosed BPDCN [17]

Pivekimab sunirine, a novel ADC, demonstrated high response rates and manageable safety in newly diagnosed patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN), according to Phase I/II results from the CADENZA study presented at the 2025 ASCO Annual Meeting. As a CD123-targeting conjugate, pivekimab

delivers a cytotoxic payload directly to cancer cells, inducing cell death. Among 33 newly diagnosed patients, the ADC achieved an 85% ORR and 70% complete response rate, with a median OS rate of 16.6 months. Peripheral edema was the most common side effect, but it was reversible and manageable. Compared to existing therapies such as tagraxofusp-erzs, pivekimab sunirine represents a next-generation ADC approach with promising front-line potential. Researchers emphasized its role in advancing treatment for this rare and aggressive disease, with future studies potentially exploring combination regimens. The trial was funded by AbbVie.

SUMMARY

The ADC field has continued to expand with key clinical progress and strategic partnerships highlighting the growing momentum in conjugate-based oncology. Veraxa Biotech announced a $1.64B merger to advance it next-generation ADC and bispecific T cell engager pipeline, alongside a new bsADC collaboration with OmniAb targeting solid tumors. Araris Biotech also extended its AraLinQ conjugation platform through a new partnership with Johnson & Johnson, while Astellas secured a $1.3B global licensing deal for Evopoint's CLDN18.2-directed ADC.

Regulatory milestones included FDA's accelerated approval of AbbVie's c-Met–directed ADC EMRELIS for advanced NSCLC. Meanwhile, Merck began construction on a $1B US-based biologics and ADC facility to scale domestic production.

On the clinical front, pivekimab sunirine, a CD123-targeting ADC, demonstrated high response rates in newly diagnosed BPDCN, suggesting front-line potential. RemeGen's HER2-targeted disitamab vedotin met survival endpoints in a Phase III bladder cancer trial, and AstraZeneca/Daiichi Sankyo's Enhertu improved pathologic response rates in early HER2+ breast cancer, and BMS expanded trials for its bispecific ADC in first-line TNBC.

At the 2025 ASCO and EHA conferences, key data underscored the growing role of ADCs in oncology. Genmab reported robust response rates for its FRα-targeting ADC Rina-S in endometrial cancer, supporting its $1.8B acquisition of ProfoundBio. Heidelberg Pharma presented sustained clinical responses from its amanitin-based ADC HDP-101 in multiple myeloma. Pfizer also revealed early data on novel ADC-immunotherapy combinations, reinforcing the momentum behind rational conjugate-based combinations in solid tumors.

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EVENT PREVIEW

SPOTLIGHT

IMAPAC Biologics World Korea 2025

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Bioconjugation Insights **is delighted to share with you the first of a new content piece, the Event Preview. These concise articles will provide a summary of upcoming conferences, events, and summits, highlighting key presentations and speakers.**

As part of our ongoing coverage of key gatherings in the bioconjugation space, *Bioconjugation Insights* presents an event preview of the Biologics World Korea 2025. Taking place September 24–26, in Songdo Convensia, Incheon, South Korea, the event will showcase the latest advances, technologies, and collaborative opportunities in the fast-paced and ever-evolving biopharma world. This preview offers readers a glimpse into the sessions, speakers, and themes that will shape the discussions of ADCs, bioconjugates, and cell and gene therapy.

BIOLOGICS MANUFACTURING KOREA 2025

Biologics Manufacturing Korea 2025

Songdo Convensia, Incheon, South Korea

September 25–26, 2025

Biologics Manufacturing Korea 2025 returns for its 14th edition as the premier platform dedicated to advancing South Korea's biologics and biomanufacturing sector. The event begins on September 24 with two exclusive pre-conference activities: a site tour of

Prestige Biologics, offering an insider's look at a cutting-edge manufacturing facility, and a pre-conference workshop led by a world-leading manufacturing automation solutions partner, designed to provide actionable insights into the future of smart bioproduction. These sessions set the stage for two days of rich discussion and collaboration.

The main conference agenda spans a comprehensive range of topics including upstream and downstream processing, biosimilars development, bioprocess automation, analytics and quality, and supply chain optimization. A strong emphasis will be placed on the integration of predictive analytics and smart facility design to enhance efficiency, scalability, and regulatory compliance. Case studies from the FDA will offer valuable perspectives on process validation and quality control, while sessions on single-use technologies and advanced membrane filtration will showcase innovations in purification and yield improvement.

The event is expected to bring together key decision-makers and innovators shaping the future of biologics manufacturing in the region. Participating organizations include Samsung Biologics, Lotte Biologics, SK bioscience, GC Biopharma, Medytox, and solution providers such as MasterControl, alongside academic institutions like the International Vaccine Institute and Yonsei University. With forward-looking content and unparalleled networking opportunities, the 14th Biologics Manufacturing Korea 2025 conference serves as a central hub for industry professionals driving excellence in biologics production.

ADC & Bioconjugate East Asia 2025

Songdo Convensia, Incheon, South Korea

September 26, 2025

ADC & Bioconjugate East Asia 2025 will focus on the evolving landscape of ADCs in oncology and beyond. Held on September 26, the conference features a Leadership Panel Discussion on current market trends and future directions for ADCs, exploring applications beyond oncology, such as autoimmune and infectious diseases, investment trends, and regulatory pathways.

Through the conference, attendees can expect expert-led, highly interactive discussions focused on the South Korea, Japan, China, and Taiwan markets. Park Tae Kyo, Chief Executive Officer, Intocell, will present a session on advancing payloads and linker technologies for next-generation ADCs. In the same session, Doo Young Jung, CEO, PinotBio, will shed a new perspective on the development of novel dual payload ADCs, highlighting the Pinot-AD2C platform. Bryan Yeung, Vice President of Chemistry, Axcynsis Therapeutics, will introduce the preclinical development of AT2604, targeting ALPP/ALPPL2. Finally, in another notable session, Xueming Qian, CEO, Transcenta Holding, and Robert Chen, Director ADC, Innolake Biopharma, will discuss optimizing ADC target selection and engineering for maximum efficacy.

The conference delves into scaling up ADC production, advancements in bioconjugation technologies, and innovations in payloads and linker technologies, providing attendees with a comprehensive understanding of the latest developments in ADCs and bioconjugates.

Cell & Gene Therapy East Asia 2025

Songdo Convensia, Incheon, South Korea

September 25, 2025

Cell & Gene Therapy East Asia 2025 convenes experts from South Korea, Japan, China, and Taiwan to discuss breakthroughs in regenerative medicine over a full-day conference on September 25. The agenda features a Leadership Panel Discussion on the strategic overview of cell and gene therapy (CGT) in East Asia, with insights from Manh-Cuong Vo, General Manager, R&D Center, Vaxcell-Bio. Sessions cover scaling manufacturing processes, with KwangJun Yoon, CHA Biotech, discussing advancements in scalable CGT manufacturing. Lee Heon Ju, CEO, CarBio Therapeutics, presents the development of 5th-generation CAR-T cells targeting late-stage metastatic cancers. Seokjoong Kim, Chief Strategy Officer, GenEdit, explores innovations in polymer-based delivery systems for genomic medicine.

The conference also addresses regulatory landscapes across East Asia, CAR-T and CAR-NK therapies, and gene editing applications, providing a comprehensive view of the region's CGT advancements. Attendees gain valuable insights into the challenges and opportunities shaping the future of precision medicine in East Asia.

From biomanufacturing leaders to cell therapy pioneers, IMAPAC's Biologics World Korea 2025 is your gateway to cutting-edge biologics production, next-generation cell and gene therapies, and novel ADC innovations. Uniting three powerhouse conferences, this event equips you with the insights, tech, and partnerships to accelerate pipelines, scale manufacturing, and lead Asia's biopharma revolution.

As a reader of *Bioconjugation Insights*, you are entitled to a 15% discount on delegate tickets for the events! Just contact the team at **biologicsworld@imapac.com** specifying the event you are interested in attending and that you are a reader of the journal. You can find out more about the Biologics World Korea 2025 events **here**.

Additionally, to find out what other bioconjugate events are upcoming, you can find our online Events Calendar **here**.

Advancing ADC innovation through multidisciplinary integration

INTERVIEW

"...my multidisciplinary background has enabled the anticipation and resolution of challenges in process development and tech transfer for novel bioconjugates."

Lauren Coyle, Launch Commissioning Editor, *Bioconjugation Insights*, speaks with Nimish Gupta, Bioconjugation Process Development Lead, Regeneron, about the integration of his multidisciplinary expertise to advance ADC development. He discusses innovations in process design, analytical strategies, and technology transfer to accelerate clinical readiness and expand ADC applications beyond oncology.

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Q You have had over a decade of experience across multiple modalities, including process development, discovery sciences, and analytical development. How has this multidisciplinary background shaped your perspective on ADC innovation?

NG Throughout my career, I have had the opportunity to work across various facets of drug development, including a range of therapeutic modalities such as antibodies, small molecules, nanoparticles, and ADCs. These experiences

have significantly shaped my scientific outlook. Among these modalities, ADCs are particularly complex, as they combine biological molecules with synthetic organic compounds. This inherently interdisciplinary nature of ADCs necessitates a broad and integrated knowledge base.

My background has provided a comprehensive understanding of the components involved in ADCs. For instance, my experience with small molecules has proven instrumental in understanding the nuances of linker-payload properties and how these characteristics influence bioconjugation. Small molecule properties can impact the physical and chemical behavior of antibodies, thereby affecting conjugation conditions such as solubility and pH.

Similarly, my experience in antibody process development has been highly transferrable to bioconjugates. By recognizing the commonalities and distinctions between monoclonal antibodies and ADCs, it becomes possible to streamline ADC development by leveraging established knowledge from antibody therapeutics. For example, most antibody purification strategies can also be adapted to ADCs provided the key differences are understood. This approach facilitates more efficient drug development timelines.

In the analytical domain, a background in assay development for small molecules has enabled the rapid design of fit-for-purpose analytical methods tailored to ADCs. These methods are critical for monitoring in-process quality attributes, impurity profiles, and process clearance. During early-stage process development, the ability to implement scientifically robust and timely assays is essential to guide decision-making and support process optimization.

Additionally, my involvement in developing novel technologies and designing new ADCs has strengthened my foundation in ADC drug discovery. This experience allows for effective collaboration with discovery teams and ensures a smoother transition into process development. By facilitating cross-functional communication, mutual understanding is enhanced, and critical feedback can be exchanged in a timely manner. This alignment helps reduce risk and accelerate development timelines.

Overall, my multidisciplinary background has enabled the anticipation and resolution of challenges in process development and tech transfer for novel bioconjugates. This integrated perspective not only improves operational efficiency but also contributes to faster delivery of innovative therapies to patients.

Q Given your experiences with multiple modalities, how do you see ADCs evolving compared to other therapeutic platforms?

NG Each therapeutic modality possesses inherent advantages and limitations. No single platform currently offers a universal solution to all clinical needs. Thus, the continued development of various diverse modalities is essential to address the full spectrum of patient requirements. ADCs offer a distinct advantage here by enabling the targeted delivery of highly potent cytotoxic agents that would otherwise be unsuitable for systemic administration due to their toxicity. They effectively bridge the gap where conventional antibodies may lack sufficient potency.

This combination of high specificity and cytotoxic potential provides ADCs with a unique therapeutic profile, including the potential for improved safety through targeted action. The clinical success of several ADCs across a variety of indications has

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demonstrated the viability of this approach, and current developments suggest that the field is still in an early phase of expansion.

Recent advancements have significantly enhanced ADC design and performance. These include improvements in site-specific conjugation technologies, the development of more stable linker chemistries, and a refined understanding of antibody selection and target biology. These innovations are expected to contribute to broader therapeutic windows and improved clinical outcomes.

Although the full therapeutic promise of ADCs is still being realized, the ongoing evolution of the platform suggests continued and expanded relevance over the next five to ten years. Nevertheless, ADCs are not a universal solution. Their utility is likely to remain most impactful in specific indications, while parallel progress across other modalities remains necessary to address the heterogeneity of patient needs comprehensively.

Q ADCs have demonstrated significant therapeutic impact in oncology, with agents such as KADCYLA and ADCETRIS leading the field. What therapeutic areas beyond cancer appear most promising for future ADC expansion?

NG Bioconjugates have increasingly established themselves as a primary strategy for targeted drug delivery, and their potential applications are rapidly broadening. Wherever a synergistic combination between a targeting moiety and a therapeutic payload is feasible, the platform holds significant potential.

An emerging area of interest is the development of antibody-antibiotic conjugates. These represent a novel approach to addressing the growing challenge of antibiotic resistance, particularly in the context of multidrug-resistant bacterial strains. Given the limited discovery of new antibiotics in recent years, this application could have a considerable impact in the infectious disease domain.

Another promising direction is the use of antibody-oligonucleotide conjugates. While they retain relevance in oncology, they also present significant opportunities for treating genetic disorders, such as muscular dystrophies. This modality offers a means of targeted delivery of nucleic acid therapeutics, potentially enhancing efficacy and minimizing systemic toxicity.

Additionally, immune-modulating or immune-stimulatory conjugates are gaining traction as an innovative class of therapeutics. These conjugates aim to activate or direct the host immune response for therapeutic benefit and are being investigated for both autoimmune and infectious diseases. By leveraging immune mechanisms, these agents may offer more precise and durable interventions.

Beyond these examples, the scope of bioconjugation is expanding to include a diverse array of payloads, including steroids, antiviral agents, lipids, and metabolic modulators. The field is evolving rapidly, driven by both scientific creativity and unmet clinical needs. As a result, ADCs and other bioconjugates are increasingly being explored across

a wide spectrum of indications, making this a particularly transformative period for the platform.

Q What are the major scientific or technical hurdles in translating the success of ADCs from oncology to other therapeutic areas?

NG As the field explores the application of bioconjugates beyond oncology, several scientific and industrial challenges must be carefully addressed. To date, the majority of clinical and preclinical data for bioconjugates has been generated in the context of cytotoxic ADCs, primarily within oncology. These datasets provide the most robust evidence for efficacy and safety in human trials, serving as a foundational benchmark. However, directly extrapolating these insights to non-oncological indications may be inappropriate without a critical re-evaluation of underlying assumptions.

A key consideration is the differing safety and tolerability expectations in non-oncology populations. For example, whereas oncology patients may accept higher levels of toxicity due to the severity of the disease, non-cancer patient populations, potentially including healthy volunteers in early trials, may require significantly more stringent safety profiles. This shift necessitates lower impurity thresholds and greater consistency in manufacturing, which can place added pressure on process development and control strategies.

Further, expanding ADCs into new therapeutic areas will likely involve novel payload classes and innovative conjugation strategies. These innovations introduce additional complexity across CMC, including extended timelines for supply chain readiness and technology transfer. Planning for these challenges early in development is critical. Teams must be willing to take calculated risks and initiate activities proactively, even without precedent, to accelerate progression into clinical evaluation.

Establishing clinical proof-of-concept in non-oncology settings will be a crucial inflection point for the field. Once such data becomes publicly available, it will provide a foundation for further innovation and optimization. However, until that point, development teams must navigate a learning curve involving both unlearning certain oncology-specific paradigms and acquiring new knowledge specific to the underlying science and regulatory expectations of other indications.

Finally, the use of increasingly novel and potent payloads introduces additional safety and logistical considerations. These may include elongated linker-payload development timelines, specialized handling requirements, containment protocols, and the need for manufacturing partners with appropriate capabilities. Not all CDMOs are equipped to manage such materials, therefore, early engagement is essential to ensure compatibility between proposed designs and existing facility capabilities, minimizing the need for extensive retrofitting or delays.

Q From a tech transfer perspective, what are the biggest challenges in ensuring consistency and GMP production of bioconjugates?

NG The manufacturing of ADCs is heavily reliant on CDMOs, particularly for GMP production. One of the primary challenges in technology transfer to a

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CDMO is the disparity in equipment, scale, and operational capabilities between process development laboratories and GMP manufacturing facilities. These differences often necessitate modifications to the process, which can have unintended consequences on product quality.

Although the goal is to develop facility-agnostic processes that can be executed across various manufacturing sites, such flexibility is not always achievable, especially when the destination facility is unknown during early development. When the manufacturing site is identified early, process development can be more targeted, allowing for design choices that align with the specific constraints and capabilities of that facility. This alignment significantly facilitates a smoother transfer and more consistent production outcomes.

Another layer of complexity arises from the upstream linker-payload synthesis process. Impurities present in linker-payload batches can carry through to the final bioconjugate, potentially impacting quality attributes. Early-stage development often lacks a comprehensive understanding of how these raw material impurities influence bioconjugate quality, and variability between development-grade and GMP-grade linker-payload materials can introduce inconsistencies.

Building robust process knowledge early in development is essential. Identifying key process levers and their impact on product quality and process performance helps ensure smoother scale-up and transfer, minimizes variability, and reduces the risk of unforeseen issues during GMP production. This foundational understanding becomes particularly important for novel conjugates, where established platform knowledge may not be readily applicable. The rigor in knowledge building and the risk involved should be phase-appropriate—a speed-to-clinic approach for first-in-human processes versus well-established robustness for commercial processes.

Q Looking ahead, if a single key advancement could be implemented in ADC manufacturing or process development today, what would it be, and why?

NG Identifying a single transformative advancement is a challenging task, but one critical improvement in process development would be the implementation of automated, high-throughput scale-down methodologies for process parameter screening. This includes both conjugation reactions and chromatography steps, particularly from the perspective of novel ADCs, rather than well-established platform processes.

In the absence of standardized platform processes, it is essential to gather comprehensive process data efficiently, especially when operating under constraints of time and resources. High-throughput screening offers a robust solution to this challenge, enabling rapid and parallelized testing of multiple conditions.

When coupled with automated process analytics, this approach significantly reduces the time required to resolve development challenges. The data generated can then be

utilized to construct predictive models that inform optimal process set points. Further, this knowledge can be extrapolated to accelerate development for similar or future platform molecules.

An integrated approach to combine these methods has the potential to greatly enhance the efficiency and speed of ADC process development. Such advancements would also facilitate smoother technology transfer to manufacturing facilities, ultimately supporting faster and more reliable scale-up of novel therapeutics.

Q Finally, what would you say are your key priorities for the next year or two?

NG Over the next few years, a central focus will be on advancing Regeneron's diverse pipeline of ADCs, which spans multiple therapeutic areas and incorporates a range of modalities, linker chemistries, and payloads. This is an exciting and dynamic period for the field, offering significant opportunities for scientific innovation and learning.

A primary objective is to maintain a 'speed-to-clinic' mindset, with the overarching goal of progressing potential therapies to patients as efficiently as possible. Achieving this requires a highly collaborative, cross-functional approach, involving close coordination among internal teams and external partners, including CMOs, to ensure a clear and continuous path to GMP manufacturing readiness.

Our team has been actively employing design-of-experiments methodologies to generate a comprehensive knowledge base and establish platform processes that support accelerated development, particularly for novel conjugates. This effort will continue to be a priority, alongside a strong emphasis on innovation and creative problem-solving. By challenging conventional approaches and seeking more efficient strategies, we aim to reduce the timeline from lead selection to clinical evaluation.

At the same time, scientific curiosity drives us to deepen our understanding of the fundamental mechanisms underlying ADC design and production. Continuous technological advancement and process refinement remain key to improving long-term efficiency and productivity.

Equally important are our commitments to safety and environmental responsibility. Given the potent nature of the compounds involved, maintaining rigorous safety standards is non-negotiable. Finally, fostering a positive and motivating work environment is essential. Taking pride in the impact our work has on patients' lives serves as a powerful source of inspiration and purpose for the entire team.

The views and opinions expressed in this interview are those of Nimish Gupta and do not necessarily reflect the views of Regeneron Pharmaceuticals or its affiliates.

BIOGRAPHY

Nimish Gupta leads the Bioconjugation Process Development group at Regeneron Pharmaceuticals Inc., Tarrytown, NY. Nimish has over 16 years of industry experience spanning diverse areas from drug discovery to developing manufacturing processes. He has been

involved in advancing multiple molecules through the pipeline into the clinic across modalities such as small-molecules, nanoparticles, antibodies, and ADCs. This includes marketed products like Kevzara®, Praluent®, and several clinical candidates such as AT-1965, a novel liposomal oncology drug. Nimish has also developed two novel linker technologies for ADCs and has been passionately in the ADC field since 2012.

Nimish Gupta PhD, Group Lead, Bioconjugation Process Development, Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA

AUTHORSHIP & CONFLICT OF INTEREST

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BIOCONJUGATION INSIGHTS

EVENT SUMMARY

SPOTLIGHT

The 4th World ADC Asia 2025 Summit

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This event summary, brought to you by *Bioconjugation Insights* and the 4th World ADC Asia Summit, provides you with the key speakers and presentations from this year's event. Highlighting the latest in discovery, development, and manufacturing, this overview captures the most impactful sessions, innovations, and expert insights shaping the future of ADCs.

DISCOVERY, PRECLINICAL AND CLINICAL DEVELOPMENT, AND CMC

The 4th World ADC Asia 2025 Summit, held on June 10–12, 2025, featured three specialized content tracks, Discovery, Preclinical and Clinical Development, and CMC, tailored to professionals across the ADC development spectrum. The Development Track showcased novel targets and antibody engineering, such as Shu-Ichi Hashimoto's work on the ADLib KI-AMP system, and Heidi Wangs session on engineering bispecific ADCs with broader therapeutic indices. The Preclinical and Clinical Development Track highlighted translational models and clinical strategies, featuring insights from Nam-Gu Her on novel ADC preclinical efficacy and safety evaluation, as well as an update from Wenbin Lu on Dato-DXd's pivotal trial data. In the CMC Track, experts such as Alain Beck and Pooja Desai addressed manufacturing and optimizing strategies for speed, consistency, and regulatory compliance.

NOVEL TARGETS AND INNOVATIVE PAYLOADS

Innovations in targets and payloads took center stage, with speakers unveiling

next-generation ADCs. Zou Bin presented on AT03-65, a highly selective anti-CLDN6 ADC utilizing the proprietary AxcynDOT™ payload platform. Similarly, Dongzhou J Liu explored ROR-1 as an emerging target, and Soo Min Lee discussed immune-modulating and metabolism-targeting payloads. Additionally, Daniel Calarese presented dual-payload ADCs that simultaneously deliver two distinct drugs to improve efficacy in resistant tumors.

EMERGING BIOMARKER STRATEGIES AND CURRENT CLINICAL DATA

This year's summit also emphasized biomarker-driven development and clinical insights. Hadassah Sade introduced a TROP2 NMR biomarker for Dato-Dxd in NSCLC, developed using AI-based quantitative conscious scoring to improve outcome prediction. Martha Li presented a case study on Teliso-V, demonstrating how companion diagnostics can streamline regulatory approval. Clinical updates included Gilles Gallant presenting MYTX-011's Phase I cMET-targeting results, and Vivian Wang on VBC104's efficacy in lymphoma models resistant to existing therapies.

CASE STUDIES AND DISCOVERIES

Finally, the 4th World ADC Asia 2025 Summit highlighted pioneering case studies and first-in-class discoveries. Paul Song and Shih-Hsien Chuang presented on dual-payload ADCs that enhance therapeutic efficacy and combat secondary tumor resistance. Sang Hyun Lee introduced degrader-antibody conjugates, combining protein degradation with targeted delivery. Obinna Ubah discussed ELN28, an inflammatory disease soloMER-drug conjugate. Amy Que and Llorente Bonaga explored novel conjugation technologies and regulatory strategies for scalable, late-stage ADC manufacturing.

Whether you are driving early discovery, progressing clinical pipelines, or scaling up manufacturing, the 4th World ADC Asia 2025 Summit is the gateway to linker-payload design, bispecific ADC formats, biomarker integration, and dual-payload strategies.

You can find out more about the 4th World ADC Asia 2025 Summit **here**.

Additionally, to find out what other bioconjugate events are upcoming, you can find our online Events Calendar **here**.

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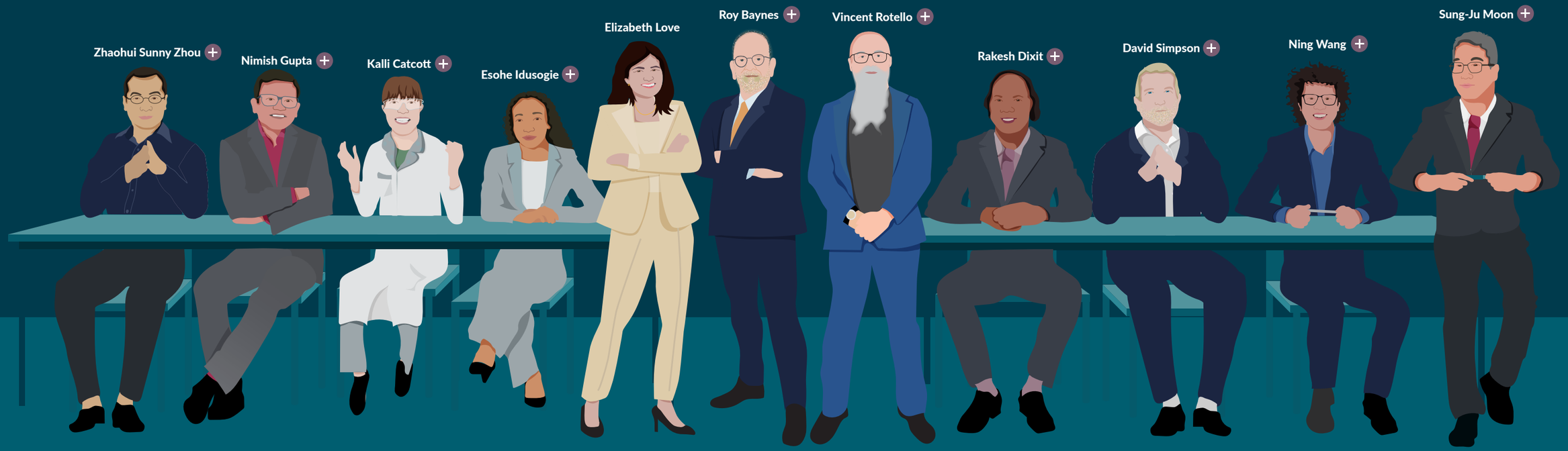
Meet the

BIOCONJUGATION INSIGHTS

Editorial Board

An integral part of the team behind *Bioconjugation Insights* is our fantastic **Editorial Advisory Board** (EAB). The members of our EAB played a crucial part in launching the journal and continue to be essential for its success. They generously contribute their time and expertise to help shape our content and ensure we highlight the topics and authors most relevant to our audience.

We surveyed a selection of our EAB members to learn more about their careers, interests, and their visions for the exciting future of both the journal and the fields it serves.



VIEW

the EdBoard in Numbers

Sung-Ju Moon

“Following the approvals of Trodelvy and Enhertu, the focus in ADC development has shifted from solely emphasizing efficacy to enhancing the therapeutic index. This transition aims to maximize anti-cancer activity while minimizing off-target toxicities, thereby improving patient outcomes .”


HOW MANY YEARS HAVE YOU WORKED IN BIOCONJUGATES?
WHAT TYPE OF ORGANIZATION DO YOU WORK FOR?
WHAT'S YOUR FAVORITE SNACK?
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WHAT'S YOUR FAVOURITE SONG OR ALBUM OF 2024?

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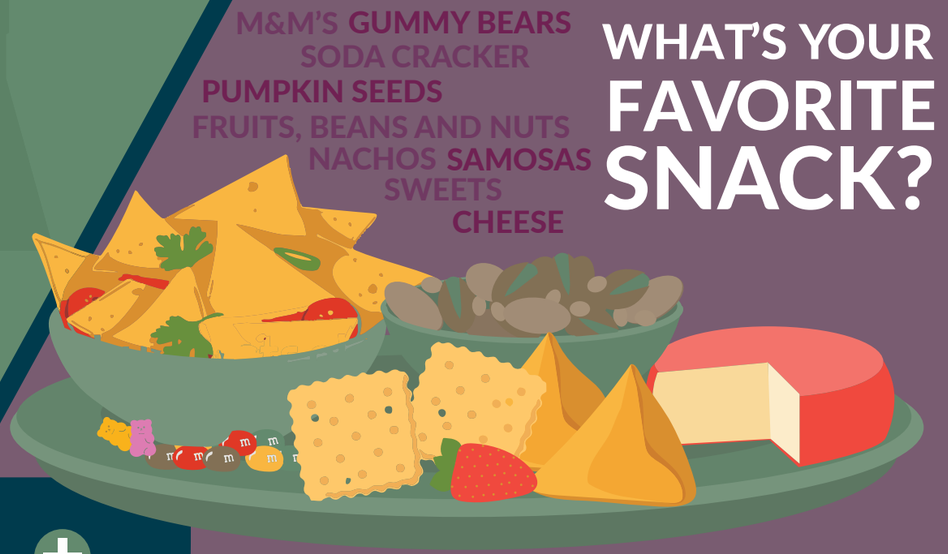

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