

# Dr. Shiran Shapira: Nano24



### **Could you introduce yourself and Nano24, and share how the development of EXO-CD24 is pioneering a brand-new class of targeted exosome therapeutics?**

I am Dr. Shiran Shapira, Co-Founder and CSO/CTO of Nano24. The concept behind EXO-CD24 emerged directly from my long-standing collaboration with Prof. Nadir Arber, a physician-scientist and a leader in translational medicine who has explored CD24 biology for many years. Our collaborative work on CD24-driven immune regulation and exosome biology made us ask a simple but powerful question: could we harness the natural immune-regulatory properties of CD24 and present them on a natural biological carrier directly at the site of inflammation? Can we create a new, physiologically inspired approach to immune modulation with therapeutic potential?

Therefore, we founded Nano24 with the goal of translating exosome biology into clinically meaningful therapeutics. Our lead candidate, EXO-CD24, is based on human exosomes engineered to display CD24, a natural regulator of innate immune responses, on their surface. What makes the approach particularly exciting is that we are not simply using exosomes as passive delivery vehicles. We combine the biological activity of CD24 with the natural membrane architecture and delivery properties of exosomes, creating a multivalent, membrane-presented immunomodulatory therapeutic.

Rather than broadly suppressing immunity or targeting a single downstream cytokine, EXO-CD24 is designed to intervene upstream in the inflammatory cascade by modulating DAMP-driven immune activation. We believe this represents an opportunity to establish a new class of exosome-based immunomodulatory therapeutics.

Importantly, what we have built extends beyond a single therapeutic candidate. EXO-CD24 is the lead product emerging from a broader exosome-engineering platform that we believe can be adapted to display different therapeutic molecules on the exosomal surface and potentially incorporate therapeutic cargo within the vesicle. In that sense, EXO-CD24 is both a drug candidate and the first clinical validation of a broader technology platform.

Our ambition is therefore not simply to develop one drug for one indication, but to establish a new therapeutic modality that can generate multiple products across inflammatory and other diseases.



### **Moving from promising preclinical biology into active clinical trials is notoriously challenging for EV platforms. What were the most significant operational or CMC hurdles Nano24 had to solve to successfully advance EXO-CD24 into the clinic?**

One of the major challenges in developing any EV therapeutic is transforming a compelling biological concept into a reproducible, well-characterized and scalable pharmaceutical product.

For EXO-CD24, this required establishing a controlled producer-cell system, developing a robust purification process, defining relevant critical quality attributes, and implementing analytical methods capable of characterizing both the exosome and its functional CD24 component. Maintaining consistency in particle characteristics and CD24 presentation while scaling the manufacturing process has been particularly important.

Another key challenge was ensuring that the product remained compatible with its intended route of administration. Because EXO-CD24 is delivered by inhalation, we also needed to demonstrate that nebulization preserves the key characteristics of the exosomes and CD24 presentation. Moving into the clinic therefore required us to think beyond “producing exosomes” and instead develop EXO-CD24 as a defined and controlled biological drug product. That transition has been one of the most important lessons of our development program.

**Your presentation highlights being “Targeted by Nature, Powered by Innovation.” How does utilizing natural exosome homing and biology provide distinct safety and biodistribution advantages compared to synthetic nanoparticles or conventional biologics?**

Exosomes offer something fundamentally different from an artificial delivery particle: they are naturally evolved biological communication systems.

Their membrane composition, nanoscale architecture and ability to interact with recipient cells provide an attractive biological framework for therapeutic delivery. In EXO-CD24, we leverage this natural architecture while displaying CD24 in a membrane-associated, multivalent configuration rather than administering it simply as a soluble molecule.

For our pulmonary strategy, we combine these properties with local inhaled administration, allowing us to deliver the therapeutic directly to the organ where the inflammatory process is occurring while seeking to limit unnecessary systemic exposure.

Importantly, these advantages must ultimately be demonstrated empirically rather than assumed simply because a product is exosome-based. For us, therefore, the combination of exosome biology, local delivery and the clinical safety experience accumulated with EXO-CD24 is particularly important.

**Without giving too much away, what is the central clinical insight, translational milestone, or data takeaway you hope the audience takes from your session in Berlin?**

The central message I hope the audience takes away is that exosome therapeutics can move beyond technological promise and become real clinical-stage medicines.

With EXO-CD24, we have progressed from a mechanistic hypothesis, through preclinical proof-of-concept and manufacturing development, into multiple clinical studies with more than 260 treated patients.

Most importantly, our recent randomized, placebo-controlled Phase IIb study in ARDS provides an opportunity to connect the underlying biology with meaningful clinical outcomes. I will share how the clinical efficacy data, findings and safety experience collectively support EXO-CD24's biological activity and its continued development.

What is particularly important to us is that our clinical experience is no longer limited to observing an immediate treatment effect. We now have long-term follow-up extending beyond five years in patients from our early clinical program. This provides a unique opportunity to examine not only the acute response to treatment, but also the durability of the clinical outcome and long-term safety. The long-term follow-up has been particularly encouraging, with the survival benefit observed during the acute period remaining evident years after treatment. For a therapy administered for only a few days, observing a sustained long-term clinical signal is especially compelling and raises important questions about the potential consequences of controlling the initial inflammatory injury.



For me, the translational milestone is therefore not simply that we succeeded in administering an exosome product to patients. It is that we are beginning to see how rationally engineered exosome biology can translate into clinically meaningful and potentially sustained therapeutic effects.

**With Exosomes Europe co-located alongside Cell & Gene Therapy International and LNPs Europe, what cross-industry discussions or clinical collaborations are you most looking forward to this November?**

I am particularly interested in discussions that bridge EV biology, advanced manufacturing, drug delivery and clinical translation.

The field is reaching a stage where the most important questions are no longer only whether we can engineer an extracellular vesicle, but how we can manufacture it reproducibly at scale, characterize it appropriately, select the right therapeutic payload or surface molecule, and demonstrate meaningful advantages in patients.

I am also very interested in the convergence between exosomes, cell and gene therapy, and other nanoparticle delivery technologies. Each field has developed different solutions to challenges such as targeting, cargo delivery, manufacturing and regulatory characterization, and there is a great deal we can learn from one another.

From Nano24's perspective, we are always interested in scientific, clinical and strategic collaborations that can help us expand both EXO-CD24 and the broader potential of our exosome platform.

I look forward to joining everyone in Berlin!

**Shiran & Nano24 will be joining us at Exosomes Europe this November in Berlin.**

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