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BIONET Therapeutics Pioneers AI-Powered Exosomes for the Next Era of Precision Medicine

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Dr. Grace Lee, General Manager of BIONET Therapeutics, discusses how AI-driven discovery, industrial-scale manufacturing and Taiwanâ??s evolving regenerative medicine ecosystem are accelerating the shift towards cell-free therapeutics.

Exosomes are rapidly emerging as one of the most promising frontiers in regenerative medicine, offering the therapeutic potential of cellular signalling without many of the complexities associated with living cell therapies. From precision drug delivery and regenerative aesthetics to ophthalmology and pulmonary disease, their potential applications are expanding rapidly.

In an exclusive conversation with **BioSpectrum Asia, Dr. Grace Lee, General Manager of BIONET Therapeutics,** shares how the company is combining artificial intelligence, multi-omics and scalable manufacturing to advance exosome-based innovation. She also discusses BIONET's dual-track strategy of pursuing near-term commercial opportunities while building longer-term therapeutic pipelines, and why Taiwan could emerge as a pivotal global hub for the next generation of cell-free biologics.

What strategic opportunity do you see for exosomes in the future of regenerative medicine, drug delivery, and precision therapeutics?

Exosomes (extracellular vesicles, or EVs) represent a paradigm shift from living cell therapies to cell-free precision biologics. We view them as the ultimate convergent platform linking regenerative medicine and precision drug therapeutics. We identify our key strategic opportunities as follows:

- **Market Scale & Commercial Reach (Transforming Medical Aesthetics and Precision Cosmetics):** We are redefining the medical aesthetics and raw material supply markets by pioneering the fields of Precision Aesthetics and Functional Cosmetics. By leveraging AI to map the molecular fingerprints of specific stem-cell-derived exosomes, we can target precise skin microenvironments or cellular aging pathways with accuracy. Furthermore, BIONET Group is the first publicly listed group in Taiwan to secure official regulatory approval for human umbilical cord mesenchymal stem cell (UC-MSC) exosomes as a cosmetic ingredient, significantly strengthening our global commercial footprint.

- **The "Off-the-Shelf" Regenerative Revolution:** Traditional cell therapies face severe limitations in cell viability, immunogenicity, and complex cold-chain logistics. Exosomes bypass these hurdles. They preserve the potent paracrine signaling of parent stem cells (such as mesenchymal stem cells, or MSCs) but possess superior physicochemical stability. They can even be lyophilized into stable, ready-to-use powders, drastically reducing clinical handling barriers.

- **A Natural Nanocarrier for Targeted Drug Delivery (DDS):** Exosomes naturally cross biological barriers, including the blood-brain barrier (BBB) and the skin barrier. Through surface engineering or cargo loading, they can be customized to deliver specific payloads—such as mRNA, siRNA, small molecules, or functional proteins—directly to diseased tissues with high specificity.

What differentiates BIONET's exosome platform from other technologies currently being developed, particularly in terms of scalability, quality, and clinical translation?

As the core biopharmaceutical arm of BIONET Group, BIONET Therapeutics' competitive differentiation stands firmly on two pillars: our unparalleled biosource repository and our AI-driven development paradigm.

The World's Preeminent Repository: Our foundation is backed by the BIONET Group's Bone Marrow / Cord Blood Registry (BMDW), the largest ethnic Chinese repository and the 4th largest globally. This vast biological repository gives us an unrivaled advantage in sourcing diverse, high-quality stem cells for premium exosome and cell therapy development.

Unrivaled R&D Velocity via AI: Spearheaded by our AI and Data Application Center, our proprietary "DeepExoMir" AI prediction engine utilizes digital modeling to pre-identify experimental parameters in silico before wet-lab validation. By compressing exosome function prediction from several months to just a few hours, this breakthrough earned BIONET the top spot in the biomedical sector within *Business Weekly*'s prestigious "AI Innovation Top 100" Gold Award.

Integrated Multi-Omics & Batch Consistency: This computational power feeds directly into a fully integrated workflow that bridges biological complexity and industrial reproducibility. Going far beyond standard exosome metrics— such as size distribution, concentration, and surface markers— we perform comprehensive multi-omics characterization (proteomics, lipidomics, and miRNA microarray analysis) to map the molecular pathways across multiple disease indications. Crucially, exceptionally high proteomic correlation across production batches validates the robust consistency and scalability of our manufacturing platform.

Finally, our translational research is supported by peer-reviewed publications in international journals, including *the International Journal of Molecular Sciences*, spanning cell therapy, bioinformatics, and genomics.

Manufacturing remains one of the biggest challenges in exosome development. How is BIONET Therapeutics addressing issues such as production consistency, purification, and regulatory compliance?

Manufacturing is a defining challenge for the exosome industry, where commercial success demands a platform capable of producing high-quality exosomes at scale under strict regulatory standards. To ensure robust production consistency, BIONET Therapeutics has built a standardized process anchored in three core strategic pillars below:

- **We drive process optimization through advanced computational Intelligence and smart automation:**

By analyzing manufacturing data to identify critical process parameters (CPPs) and predict process outcomes, our AI platform significantly reduces batch-to-batch variability while optimizing cell banking and scalable bioreactor operations. Downstream, we overcome the limitations of traditional laboratory-scale purification through an AI-assisted, scalable

processing platform. This is embodied in our Exosome Foundry, where we have effectively solved the scalability and consistency puzzle by pioneering automated, intelligent production lines. Through this, BIONET Therapeutics has achieved an industrial-scale output of 10,000 bottles per day with strict batch-to-batch uniformity.

- **We demonstrate unmatched lot-to-lot consistency through rigorous validations:**

By leveraging quantitative Nanoparticle Tracking Analysis (NTA), flow cytometry for tetraspanins (CD9, CD63, and CD81), ELISA for specific functional biomarkers, and rigorous potency assays, we have demonstrated exceptional lot-to-lot consistency. These benchmark validation results have been peer-reviewed and published in *Extracellular Vesicles and Circulating Nucleic Acids*, a leading international journal dedicated to extracellular vesicle and exosome research.

- **We secure immediate commercial pathways through global regulatory alignment:**

For our therapeutic pipelines, we compile robust Chemistry, Manufacturing, and Controls (CMC) dossiers aligned with Taiwan FDA expectations. Concurrently, for our functional cosmetics branch, our diverse portfolio of exosome raw materials—including human-derived, animal-derived, and plant-derived extracellular vesicles—has successfully secured international INCI registration and is fully approved by the TFDA, clearing the path for immediate global commercial utilization.

Which therapeutic areas or disease indications do you believe will see the earliest commercial impact from exosome-based therapies, and where is BIONET Therapeutics focusing its development efforts?

We leverage a dual-track commercialization and R&D strategy designed to capture immediate, high-growth market opportunities while systematically building long-term, high-impact clinical pipelines.

Immediate commercial track focuses on the topical application of our premium exosomes in regenerative aesthetics. Our exosomes actively accelerate post-procedure healing, minimize downtime, and drive targeted skin barrier restoration and follicular regeneration for hair regrowth. This innovative modality continues to generate exceptional clinical interest and high commercial demand at premier global aesthetic forums, such as the Aesthetic Medicine World Congress (AMWC) Asia.

Long-term clinical track targets critical unmet needs through a specific development roadmap:

- **Ophthalmology**: ExoTear, our flagship exosome candidate for Dry Eye Disease (DED), has already been granted "Indicator Case Guidance" status by the Center for Drug Evaluation (CDE) in Taiwan. It shows profound potential for treating dry eye.
- **Pulmonology**: Utilizing umbilical cord mesenchymal stem cells (BU-01), we target Idiopathic Pulmonary Fibrosis (IPF) and Acute Respiratory Distress Syndrome (ARDS). IPF carries a 5-year survival rate lower than many cancers, with a global market projected to reach $11.7 billion by 2031.
- **Dermatology & Aesthetics**: Capitalizing on peer-reviewed clinical case studies published in *Cureus* and *Aesthetic Plastic Surgery*, BIONET Therapeutics is advancing exosome modalities for complex skin pathologies and regenerative aesthetics. These data demonstrate strong evidence of exosome-mediated tissue regeneration across deep second-degree scald burns, hypertrophic burn scars, and facial skin rejuvenation..

How do you see Taiwan's biopharmaceutical ecosystem supporting innovation in advanced modalities such as exosomes, and what collaborations are helping accelerate this field?

Taiwan is rapidly becoming a global exosome hub because it offers an ecosystem that fuses over 30 years of regenerative medicine R&D, world-class AI/tech infrastructure, and highly progressive legislation. The momentum is catalyzed by key domestic ecosystems:

The Regulatory Leap: The rollout of the "Regenerative Medicine Act" by the Ministry of Health and Welfare (MOHW), alongside the Regenerative Medicinal Products Act, provides the industry with extreme structural clarity. The "Conditional Approval" mechanism allows advanced therapeutics to seek conditional market access right after successfully completing Phase II clinical trials. These policies have fostered extensive clinical collaborations, creating an elite vanguard of clinicians that allows us to safely, ethically, and swiftly translate exosome therapeutics into clinical applications.

Cross-Domain Ecosystem Alliances: BIONET Therapeutics is a core contributor to the newly launched "Taiwan Exosome Industry Mapping Project" at Bio Asia-Taiwan 2026. This initiative connects over a thousand cosmetic factories, 1,500 aesthetic clinics, and over 25,000 pharmacies into a massive, highly resilient clinical-to-retail ecosystem.

Looking ahead, what are the key milestones BIONET Therapeutics hopes to achieve over the next three to five years, and how do you envision exosome technologies reshaping the future of biologics and precision medicine?

Over the next 3 to 5 years, BIONET Therapeutics is executing clear operational and global milestones:

- **Global Market Expansion:** Anchored on our 26+ years of clinical and cellular expertise, BIONET Therapeutics is aggressively driving overseas commercialization. We are actively entering international cosmetics, raw material, and clinical markets across Japan, Malaysia, Vietnam, Colombia, Australia, and Canada. In Japan specifically, we are actively positioning our high-specification exosomes directly into their advanced cosmetics and raw material supply chains.
- **Clinical Acceleration:** Advancing our core therapeutic pipelines (BU-01 and ExoTear) through accelerated clinical phases, utilizing Taiwan's Dual Acts on Regenerative Medicine framework to secure early-stage conditional approvals.
- **Continuous Platform Evolution:** Scaling our Exosome Foundry to accommodate a growing number of global B2B clients and medical centers, delivering bespoke, precision-engineered exosome formulations. We also leverage AI to significantly shorten exosome development timelines and accelerate the translation of research into commercial applications.

The Future Vision: Exosomes will entirely redefine the biologics industry by shifting the focus from living cell therapeutics to precision, cell-free nanomedicine. BIONET Therapeutics and BIONET Group are not merely participating in this shift; we are anchoring Taiwan as the indispensable, high-tech node in the global exosome supply chain.