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CellProthera Prepares For Phase 3 Push As Regenerative Cardiology Moves Closer To Clinical Reality

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Matthieu de Kalbermatten, CEO of CellProthera, discusses how new board appointments, manufacturing automation, and global clinical expertise are shaping the company's strategy to advance ProtheraCytesÂ® toward late stage development and future commercialisation.

Regenerative medicine is steadily redefining the future of cardiovascular care, with cell based therapies moving beyond experimental research into advanced clinical development. Among the companies leading this transition is CellProthera, which is preparing its stem cell therapy, ProtheraCytes®, for pivotal Phase 3 evaluation in patients following myocardial infarction.

Strengthened by strategic leadership appointments and a focus on scalable manufacturing, the company is positioning itself to address one of the largest unmet needs in cardiology: preventing the progression to heart failure by repairing damaged cardiac tissue. **In this Q&A with BioSpectrum Asia, Matthieu de Kalbermatten** shares insights on the company's next milestones, the evolving regulatory landscape, and the role of global expertise and investment in accelerating regenerative medicine programmes worldwide.

How do the appointments of Jérôme Hirtzlin and Anne de la Fortelle strengthen CellProthera's strategic direction ahead of Phase 3 development?

The appointments of Jérôme Hirtzlin and Anne de la Fortelle significantly reinforce CellProthera's strategic governance as the company approaches its pivotal Phase 3 trial. Their combined backgrounds bring complementary strengths in financing and entrepreneurship, directly supporting the transition from late-stage development toward commercialization.

Anne brings a wealth of international experience in successful biopharmaceutical companies that is aligned with Phase 3 large, multi-country clinical environments. She provides the company with strategic regulatory and strategic contracting expertise, all indispensable for the successful execution of a pivotal trial and future market entry.

Jérôme brings an original mix of industrial expertise, entrepreneurial agility, and financial vision, strengthening CellProthera's ability to scale, structure, and finance its operations for a successful Phase 3 and future commercialization.

What key milestones remain before ProtheraCytes® advances into late-stage clinical development?

The key step remains the preparation of Phase 3 operations, from GMP-compliant production to sites selection and operators' training.

How is CellProthera positioning itself within the broader regenerative cardiology and heart failure landscape?

CellProthera is emerging as a leading player in regenerative cardiology by advancing a therapy to a pivotal Phase 3 trial. While the field is mainly focusing on advanced chronic heart failure patients, CellProthera's investigational product, ProtheraCytes, addresses a less crowded but still underserved population of patients post-myocardial infarction. The therapy, which aims to repair cardiac tissue and acts early against heart failure progression, has the potential to be first-in-class in a field still dominated by pharmacological and device-based approaches that cannot restore lost myocardial function.

By focusing on this population, CellProthera situates itself at the intersection of high unmet need and regenerative innovation. Its approach is further differentiated by the integration of a proprietary transendocardial catheter, enabling precise delivery of CD34+ stem cells directly around the scar border zone. This device–therapy combination reinforces CellProthera's identity as an integrated procedural regenerative medicine company rather than a standalone cell manufacturer.

Operationally, CellProthera is positioning itself for future scalability and market readiness through process automation to enable parallelised, cost-efficient production. This strategy addresses one of the largest barriers in cell therapy — manufacturing scale-out — and aligns with the demands of treating high-prevalence cardiovascular conditions.

What regulatory and commercialisation challenges do you anticipate as cell therapies move deeper into cardiovascular applications?

Cell therapies entering cardiovascular indications face several challenges:

- Regulatory: potency assays and manufacturing consistency which can be tacked by automation
- Commercial: potential price pressure if large population which requires scalability and cost-efficient production

Companies must demonstrate not only scientific excellence but also operational reproducibility, economic viability, and clinical practicality.

How important is global clinical expertise and investment strategy in accelerating next generation regenerative medicine programmes?

Regenerative therapy success depends on its ability to harmonize standards across regions, training operators, and generating robust, internationally accepted evidence. Global trial designs, multi-regional regulatory alignment, and diverse clinical expertise is indispensable for proving efficacy and scalability.

At the same time, progress in this field is inseparable from large-scale, coordinated investment. Major industry players and governments are already investing heavily because industrial-scale manufacturing and global clinical readiness determine whether these therapies remain experimental or become widely accessible.

In essence, regenerative medicine advances fastest when international clinical capability and cross-border investment evolve together. Global clinical expertise ensures that therapies can be tested, validated, and adopted across health systems, while strategic investment builds the manufacturing and technological infrastructure needed to deliver them at scale. Together, they transform promising science into deployable treatments capable of reaching patients worldwide.