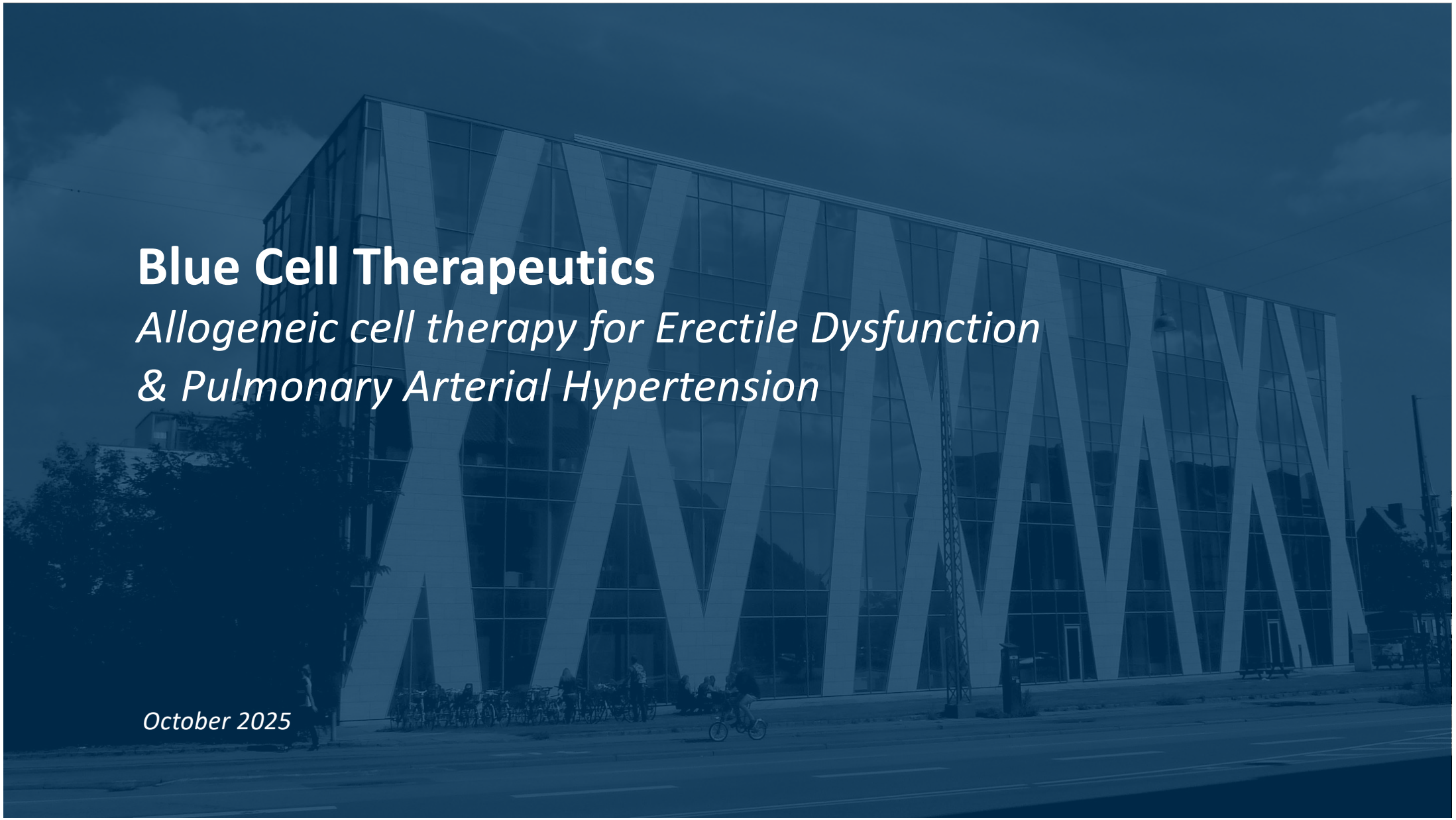


Blue Cell Therapeutics

Allogeneic cell therapy for Erectile Dysfunction & Pulmonary Arterial Hypertension

October 2025

Our Vision: An innovative and scalable cell therapy platform to cure severe Erectile Dysfunction (ED) and Pulmonary Arterial Hypertension (PAH)

- Blue Cell Therapeutics, the biotech developing cell therapies for severe erectile dysfunction and Pulmonary Arterial Hypertension where angiogenesis and nerve regeneration are beneficial
- Established in 2020 by Dr. Søren P. Sheikh based on 10 years of medical research at Odense University Hospital. Raised more than 12 MM € from investors and grants; founders and business angels.
- Developed a lead cell product BlueC231 with robust IP position and scalable allogeneic manufacturing strategy for adipose derived stem cells with angiogenic activity. 70.000 patients can be treated with material from one single donor
- Clinical proof of concept data with 72% full response in early clinical trial, and plan for a phase I/II trial with improved BlueC-231 cells in 2026 in ED after prostatectomy and in ED due diabetes mellitus
- We are raising a Series A round of 31 MM € for cell product development and to complete one clinical phase I/II trial. BCT is seeking investors for a consortium by Q4 2025

Blue Cell partners – academic, commercial, and hospitals

Experienced drug development team and strong Board of directors

Management

Søren P Sheikh MD, PhD, HD
Chief Executive/Medical Officer

Rigsh · SDU · OUH

Thomas Sandal, MSc, EBA
Chief Development/Technology Officer

gsk · Crescendo biologics · AGC Biologics · pokeAcell · BIORIGIN

Blue Cell team

Benjamin Class, PhD
Senior Scientist

Maja L. Nybo, PhD
Senior Scientist

Reza Yarani, PhD
Senior Scientist

Jone Kvam, MSc
Scientist

Mingshu M Eriksen, BSc
Senior Lab Technician

Mette Søgaard Hansen, BSc
Senior Lab Technician

Board of Directors

Olav Hellebo
Chairman of the board

Ole Vahlgren
Board member

Anella S. Rogaczewski
Board member

Michael Ulveman
Board member

Scientific Advisory board

Peter Andersen
Chief R&D Officer, Treefrog Therapeutics.

Ian Pearce
Prof. Urology, Manchester Royal Infirmary

Jakob Lerche Hansen
PhD, Novo Nordisk, Blue Cell Therapeutics

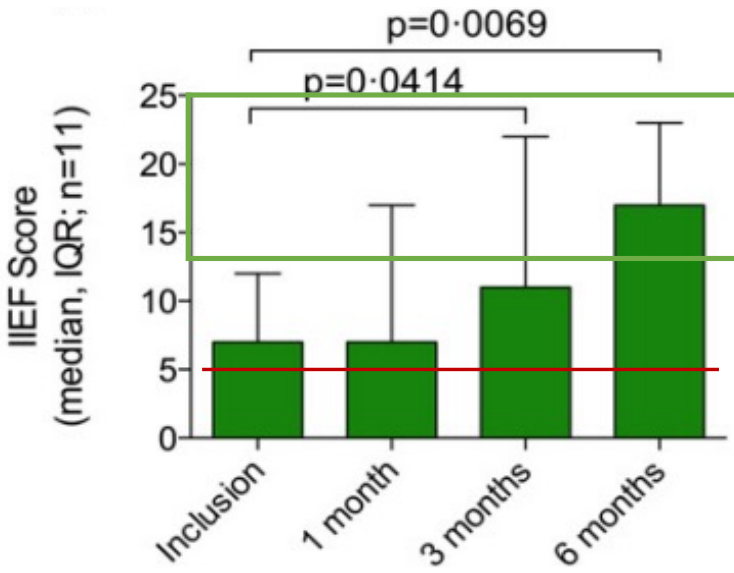
Clinical Proof of Concept

Clinical study by Sheikh group show 72% of severe ED patients regain functional erection with autologous Adipose-derived Stem Cells

Our clinical study: design and results

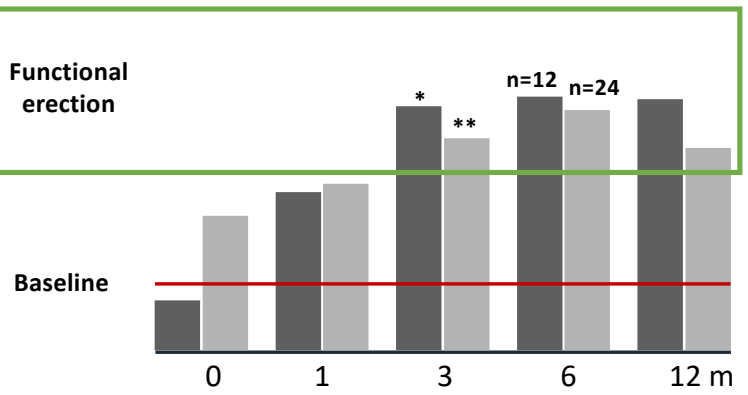
- 11 patients with severe ED and unresponsive to pharmaceuticals enrolled in clinical trial at Odense University Hospital
- Treated with BlueCell autologous Adipose-derived Stem Cell therapy 1 years after prostatectomy
- 72% achieve good effect 6 months after treatment

Our clinical study



Haahr and Sheikh et al., EBioMedicine (2016). 5:204–210

Academic Studies, *Yiou et al.; **Al Demour et al



Yiou trial was in prostatectomized patients while Al Demour worked with diabetic ED patients

International Index of Erectile Function questionnaire (IIEF) scores for each patient at inclusion, 1, 3 and 6 months after a single intra-cavernous bolus of autologous ASCs.

** Yiou et al. Eur Urol Focus (2017), 3:643. **Al Demour et al. Basic and Clinical Andrology (2024). **34**:13*

In Vitro and In Vivo POC - Mode of Action

Cell therapy provides the first potentially curative treatment for Erectile Dysfunction by restoring vascular function

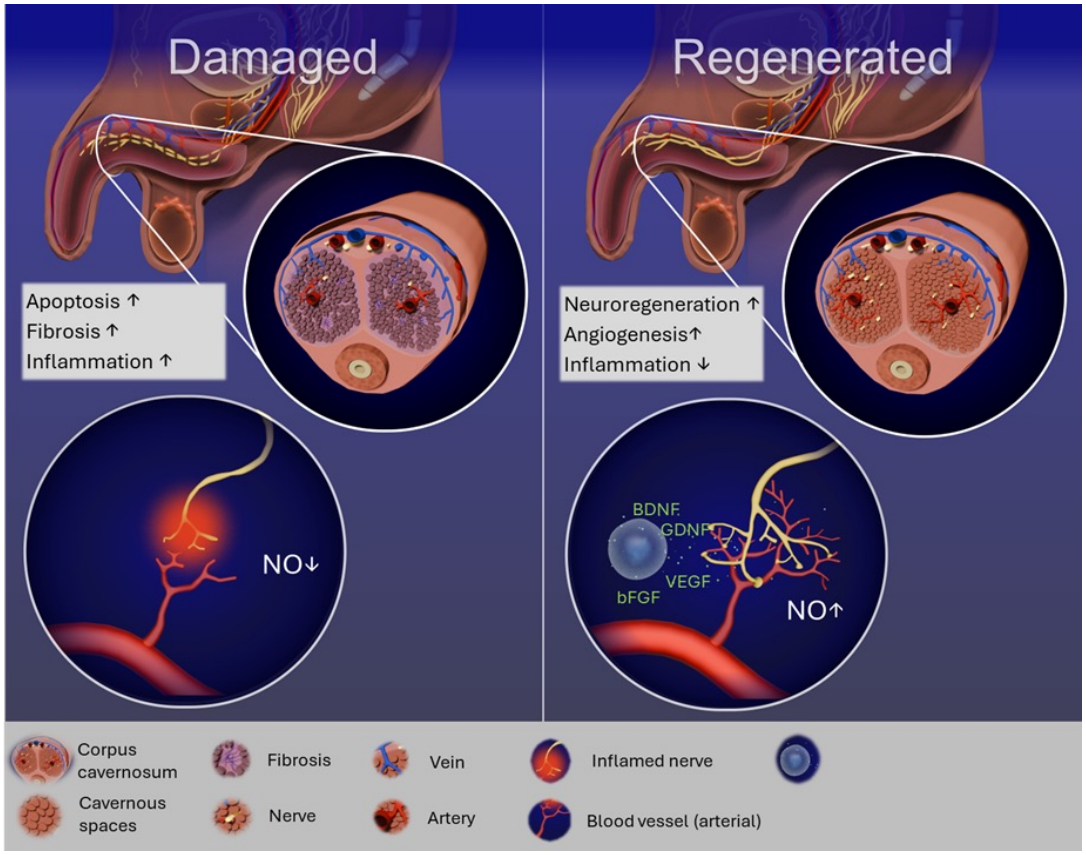
Disease mechanisms

- Reduced neuronal function
- Impaired vascular function

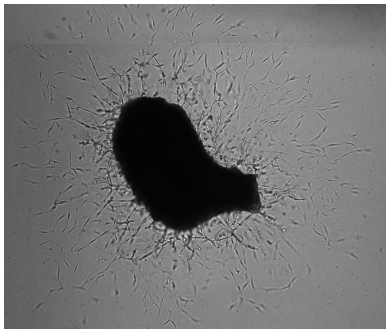
Entry market	Expansion market
Surgery related ED e.g. Prostatectomy	Metabolic related ED e.g. Diabetes, Vascular disease, Age
Homogeneous patient population	Heterogeneous patient population

The causes of erectile dysfunction are diverse. The central cause is related to reduced blood supply to the penile tissue. This may be caused by surgery, metabolic or vascular diseases. Improving blood supply is the mechanism of action believed to be able to cure erectile dysfunction

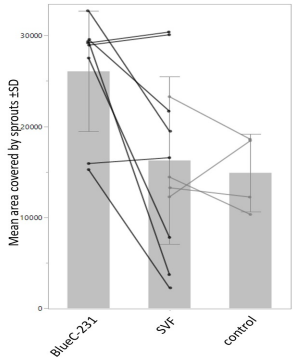
BlueC231 can recreate blood vessels, restore damaged nerves, and alleviate and cure erectile dysfunction



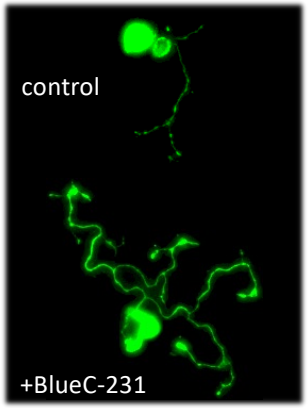
BlueC-231 induce angiogenesis



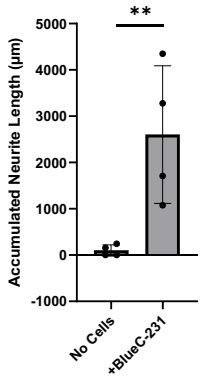
Time-lapse video of sprouts from rat Corpus Cavernosum slice



BlueC-231 induce neurogenesis

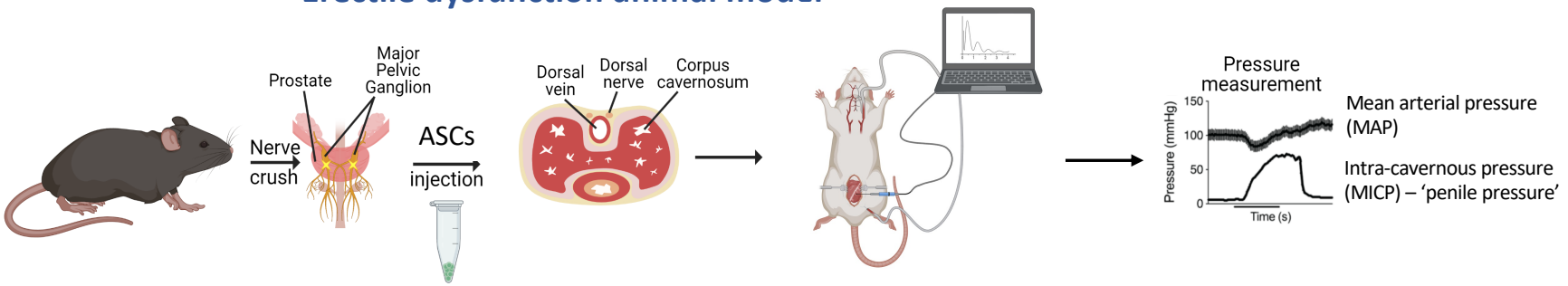


Neurite outgrowth from mouse Dorsal Root Ganglia's

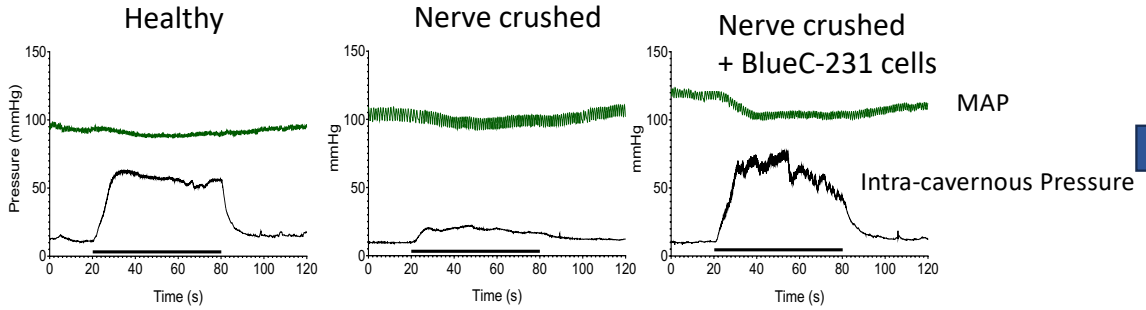


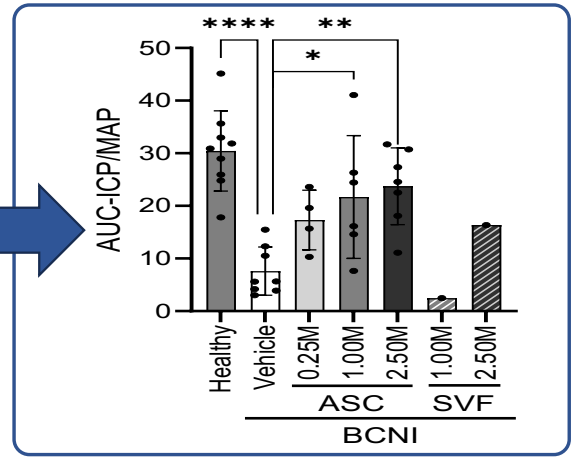
BlueC-231 human cells have robust effect in established preclinical POC model of erectile dysfunction

Erectile dysfunction animal model



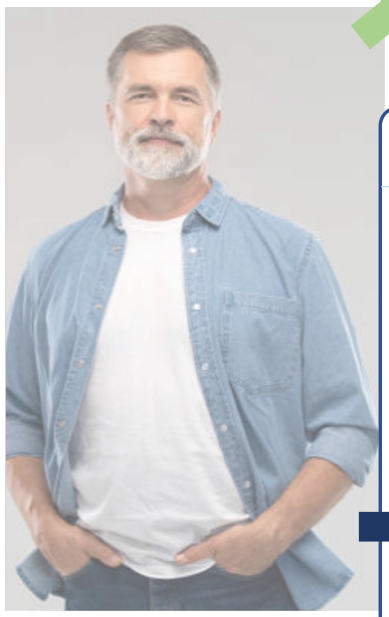
BlueC-231 cells rescue penile nerve damage





Detailed Market Potential

BlueCell will create a new market category with curative potential



NEW CATEGORY - Curative Cell Therapy

bluecell therapeutics

1st line

Pharmacology

Viagra, Cialis, Levitra, etc.
MUCE (ointment)

60-70% MS*

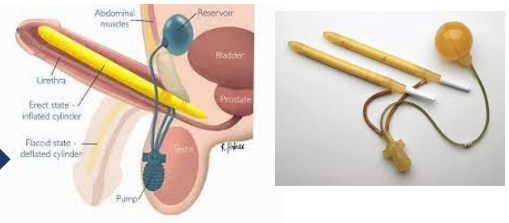
30%

2nd and 3rd line

External medical devices

Tension rings,
Vacuum constriction devices

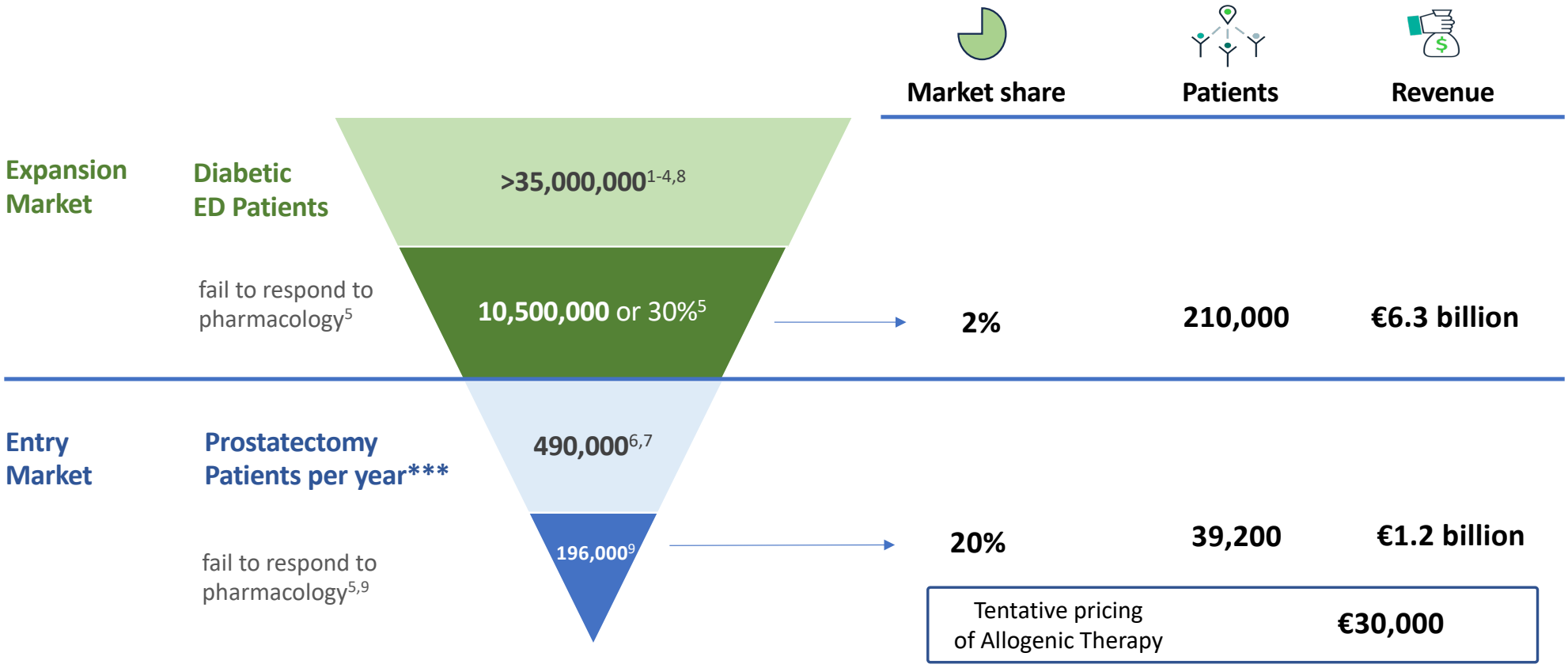
Surgical medical devices



Penile prosthesis

*Dark Horse Consulting

Market potential is large with a commercially scalable solution*



*Dark Horse Consulting

***Inventory patients as well as China and India not included, only Europe, US and Australia

Sources: 1) Current Opinion in Supportive and Palliative Care (2016), 2 Johns Hopkins, 3 American Cancer Society (2023), 4 Sexual Medicine Reviews (2020), 5 Journal of Clinical Urology (2023), 6 GlobalData.com 7 Journal of Clinical Urology (2023)8 American Cancer Society, European Cancer Information System, Prostate Cancer UK, 9 Dovepress

**Alofisel, the only ASC product on the market carries a price tag of €40,000 (fistula treatment)

Competition within ED cell therapy market and our allogeneic advantage

Key Attributes	**Pharmicel**	**Blue Cell Therapeutics**
	Autologous therapy	Allogeneic therapy
Cell Origin	Cultured from bone marrow	Cultured donor stromal cells from Adipose tissue
Pricing	Unknown	$30.000 per allogenic therapy
IP Rights	Culture condition patents filed	Patent on both cell type and culture conditions filed
Clinically Tested	Phase I/II [1]	Preclinical ready for clinical trial
Investment Backing	Unknown	Raised $12 million via investors and public grants

bluecell therapeutics

(1) Cytotherapy 2021,

Improved Product Characteristics

BlueC213 has a achieved a scalable allogenic and reproducible product across donors

Scalable for commercial success

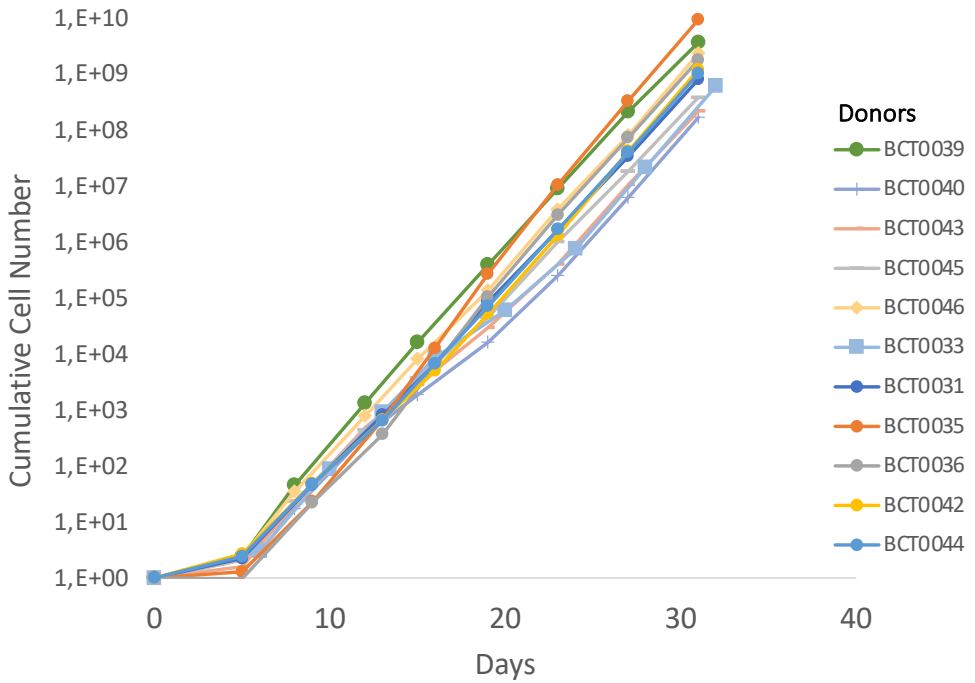
- Consistent and pure allogeneic cell product
- High proliferation of donor cells enable >70,000 patient treatments per donor
- Frozen for easy distribution and storage

✓ Off the shelf option for hospitals

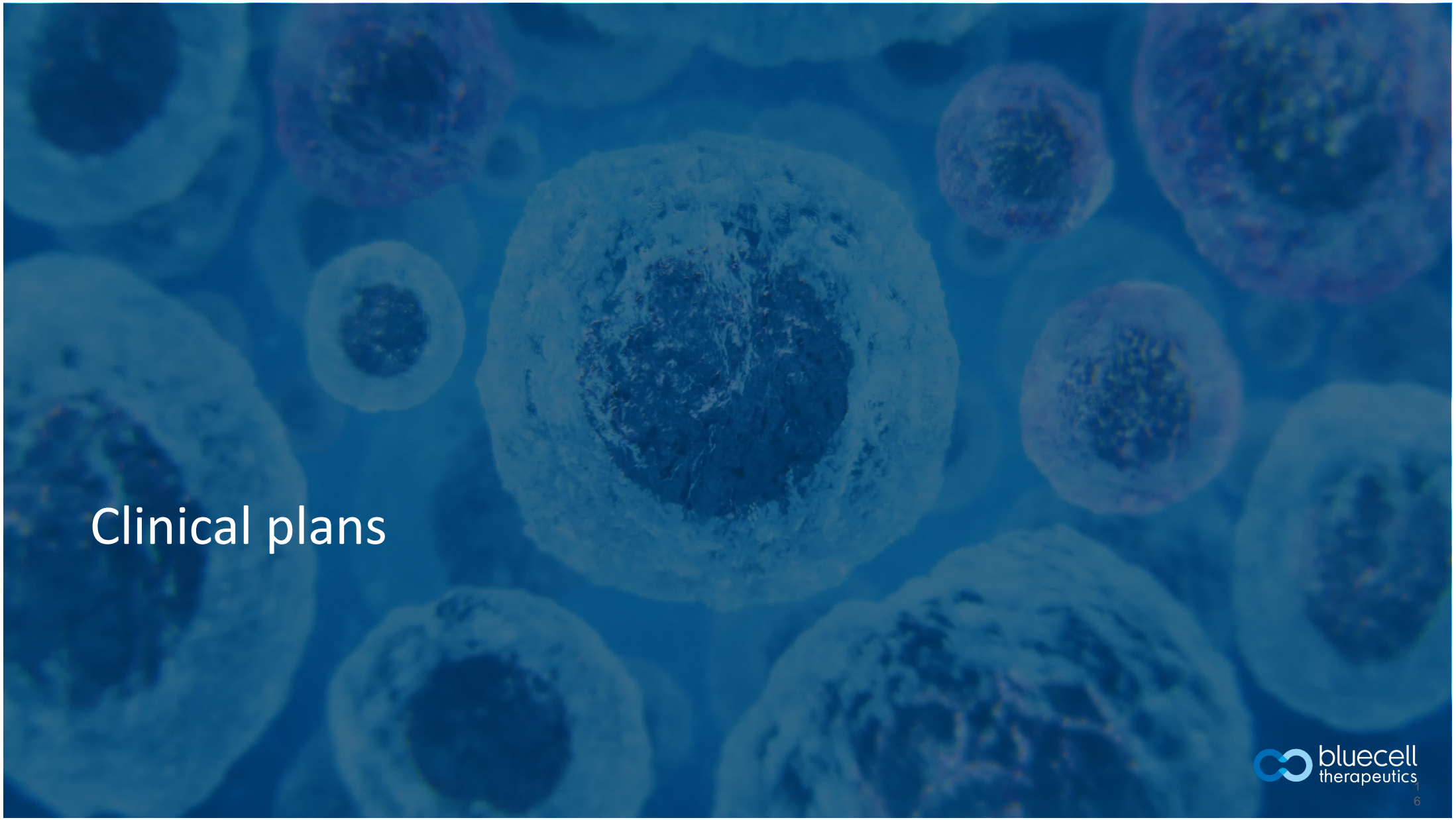
✓ Good manufacturing economics at <1,000€/patient

✓ Commercial scalability

Robust proliferative stem cell capacity across donors



Stromal Vascular Fraction (SVF) from 11 individual donors expanded for 8 passages in BCT media



Clinical plans

Clinical program executed by MAC Clinical Research

Collaboration with MAC Clinical Research

- MAC operates a Medicines and Healthcare Products Regulatory Agency (MHRA)-accredited clinical facility in Manchester
- MAC previously ran the clinical trials for ED for the company Initiator, and therefore has deep knowledge regarding ED
- The clinical program will comprise one phase 1/2 study in post-prostatectomy patients and type 2 diabetics followed by a confirmatory phase 3 studies

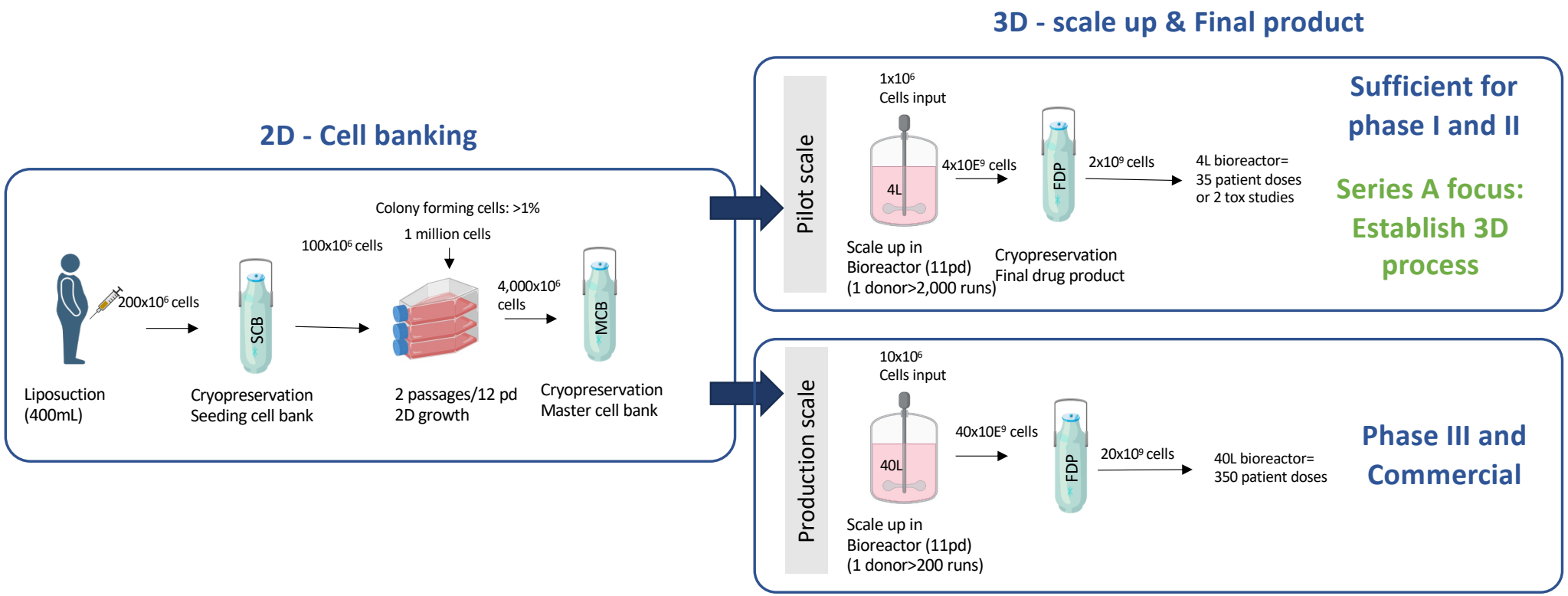
Target Product Profile for BlueC-231 Drug Product for Erectile Dysfunction (ED)

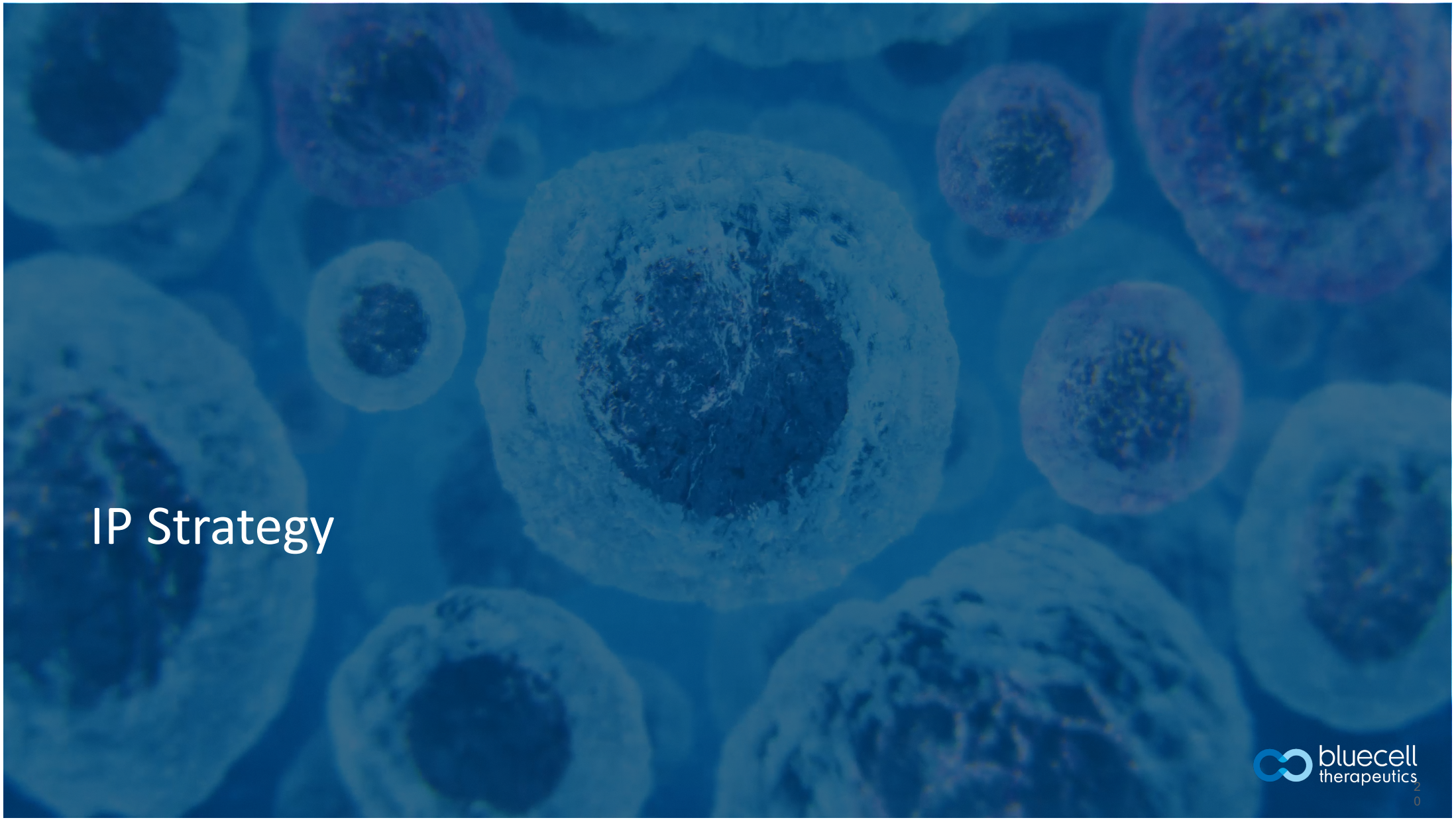
	PRIMARY	EXTENDED
Indication	ED treatment following radical prostatectomy for prostate cancer	Treatment of ED in patients with diabetes
Target population	Patients with ED following radical prostatectomy (RP) • Sexually active before RP • Urinary continent • IIEF-5 score below 15	Patients with diabetes and ED • Sexually active within last 3 years • IIEF-5 score below 15
Efficacy	Increase in IIEF-5 score of 5 points or more in at least 50% of treated patients	Increase in IIEF-5 score of 5 points or more in at least 50% of treated patients
Safety key AEs	Systemic AEs in less than 5% Immunologic AEs in less than 2% Local reactions in less than 5%	Systemic AEs in less than 5% Immunologic AEs in less than 2% Local reactions in less than 5%
Dosing/administration	One single intra-cavernous injection of BlueC-231	One single intra-cavernous injection of BlueC-231

Manufacturing Process

bluecell therapeutics

Cell 3D production – simplicity is beautiful





IP Strategy

bluecell therapeutics

Patent Strategy

We are using Goodwin Procter LLP, San Francisco as advisors

IP Portfolio

Patent applications planned and filed for media composition, scale up manufacturing processes, cell product and indications

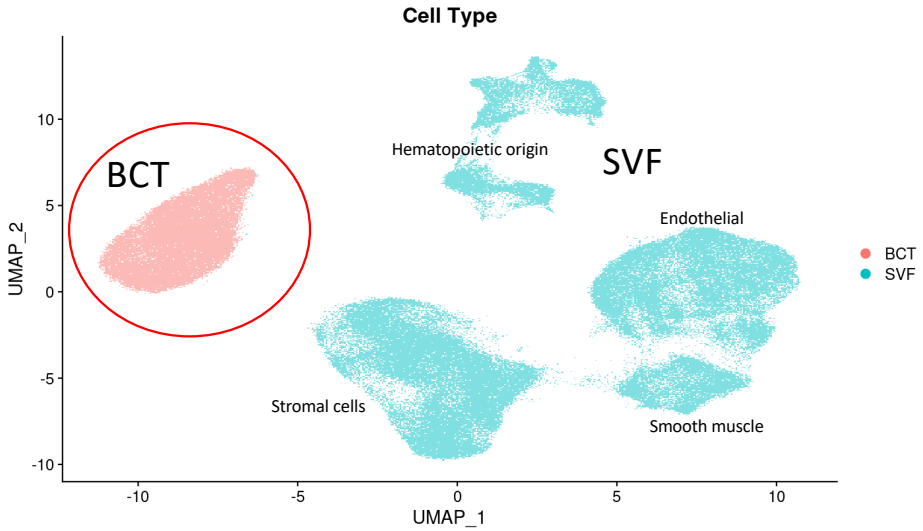
BCT-231 are non-natural, hence patentable in the USA.

Based on RNA content, BCT cells do not cluster with any SVF cells

BCT

We compare the similarity of BCT cells to the SVF dataset

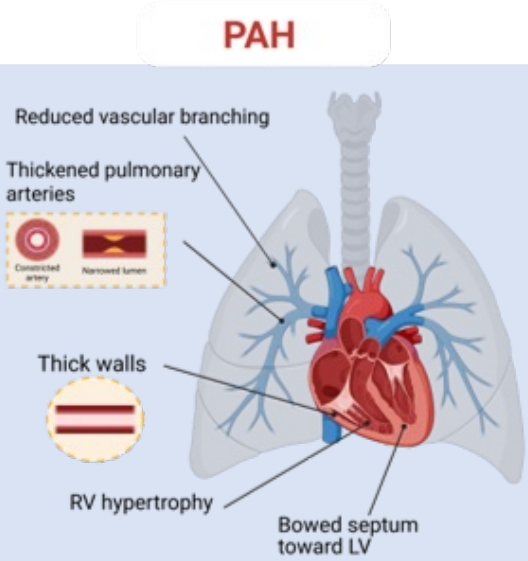
Donor	% Cells with anchors	Could MAP?	Mean Mapping Score
BCT0032	0.27	FALSE	-
BCT0035	0.32	FALSE	-
BCT0036	0.19	FALSE	-



Conclusion

There was less than 1% of cells with Anchors so the datasets couldn't be mapped to the SVF dataset. This indicates that BCT cell types differ from the cell types in the SVF dataset.

PAH is an orphan disease with a high unmet need and serious adverse progression



- Disease progress due to increased arterial and ventricular pressure via wall thickening
- Current treatments are symptomatic without solving underlying pathology
- Blue Cell therapy goal to alleviate arterial constriction by stimulating NO induced vasodilatation
- Clear regulatory advantages, straight 'go to market' strategy and good reimbursement precedence

Global Incidence & Mortality

Orphan disease with **550,000 prevalence cases and 41.600 new cases yearly** with a 5% CAGR

Women Health issue with **4:1 female to male ratio**

5-year mortality over 50%

The Blue Cell Therapy Solution

Blue Cell angiogenic and neurogenic effects including NO upregulation could solve the underlying pathology and prevent disease progression

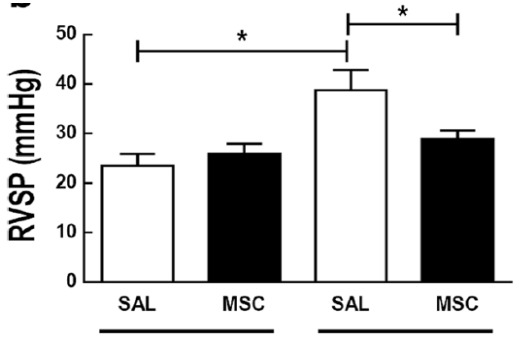
Strong In-Vivo results with a scalable allogenic solution

Sources: Boucly, A., Weatherald, J., Savale, L., Jais, X., Cottin, V., Prevot, G., et al. (2021). External validation of a refined four-stratum risk assessment score from the French pulmonary hypertension registry. European Respiratory Journal, 57(2), 2002468. D'Alonzo, G. E., Barst, R. J., Ayres, S. M., Bergofsky, E. H., Brundage, B. H., Detre, K. M., et al. (1991). Survival in patients with primary pulmonary hypertension: Results from a national prospective registry. Annals of Internal Medicine, 115(5), 343-349. GBD 2021 Pulmonary Hypertension Collaborators. (2024). Global, regional, and national burden of pulmonary hypertension, 1990–2021: A systematic analysis for the Global Burden of Disease Study 2021. The Lancet Respiratory Medicine. Hoeper, M. M., Simon, R. G. J., & Gibbs, J. S. R. (2013). Pulmonary arterial hypertension: Diagnosis and management. BMJ, 345, e7367. Humbert, M., Sitbon, O., Chaouat, A., Bertocchi, M., Habib, G., Gressin, V., et al. (2010). Pulmonary arterial hypertension in France: Results from a national registry. American Journal of Respiratory and Critical Care Medicine, 173(9), 1023-1030.

PAH – the next indication

Why PAH?

Stem cells (MSC) reduce rat Cardiac pressure *

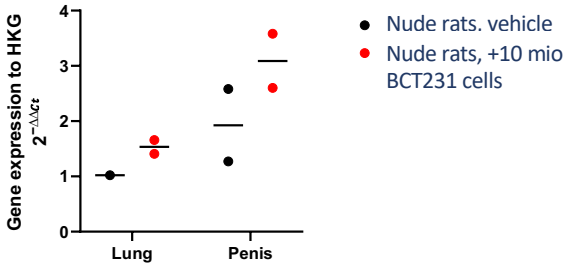


Shared signaling pathophysiology

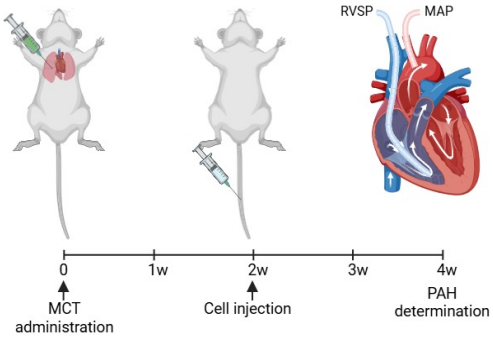
Mechanism	ED Pathophysiology	PAH Pathophysiology
Endothelial Damage	Impaired NO synthesis → reduced vasodilation	Loss of NO bioavailability → vasoconstriction
Vascular Dysfunction	Cavernosal artery fibrosis	Pulmonary artery intimal hyperplasia
Nerve Damage	Post-prostatectomy autonomic nerve injury	Pulmonary vascular denervation

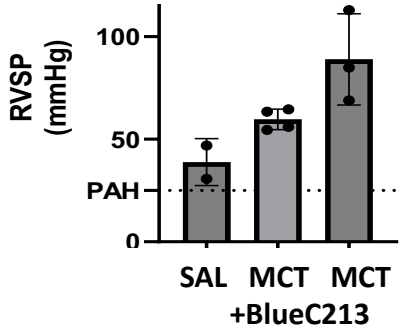
BlueC213 reduce rat Cardiac pressure and upregulate NO synthesis

eNOS is upregulated (mRNA)



PAH induced by MCT (monocrotaline)



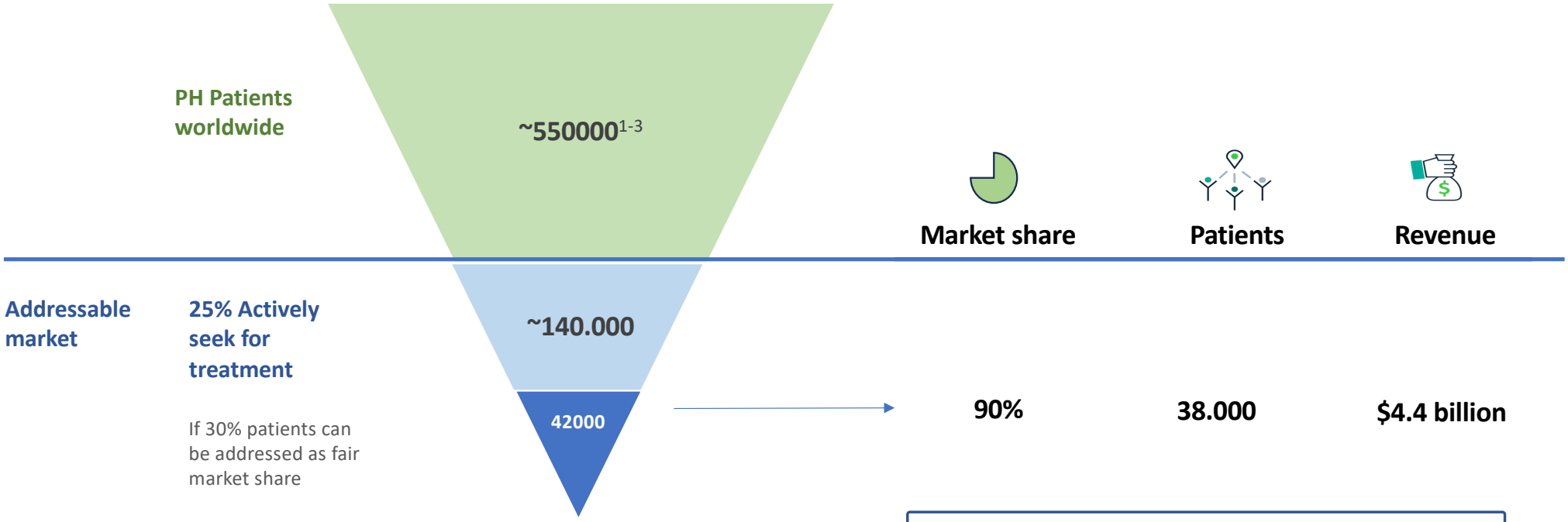


*de Mendonça et al. Stem Cell Research & Therapy (2017) 8:220 DOI 10.1186/s13287-017-0669-0

Competitors mainly symptomatic - target's one or two signaling pathways only

	Molecule	MoA	Orphan drug designation	Clinical Status
MERCK WINREVAIR (sotatercept-csrk)	**Sotatercept**, Biologic (First in class)	**Restores BMPR2 signaling** via ActRIIA-Fc ligand trap, balances pro/anti-proliferative signaling in vasculature	✓	Launched
ZyMEDi	**ZMA001**, Biologic anti-KARS1 mAb (First in class)	**Targets KARS1-mediated inflammation** (macrophages infiltration), involved in endothelial dysfunction & pulmonary vascular remodeling	✓	Running Phase I
Cereno Scientific	**CS1**, Small molecule histone deacetylase inhibitor	**Epigenetic modulation** to reduce vascular proliferation and fibrosis, promote vascular homeostasis	✓	Running Phase II
ATXA Therapeutics Limited	**NTP42**, Small molecule + 2 more molecules for PAH in their pipeline	**Blocks thromboxane receptor**, preventing platelet aggregation and inflammation, potentially reduces vascular remodeling	✓	Phase I completed

Blue Cell's potential PAH market reaches several billion with a commercially scalable solution

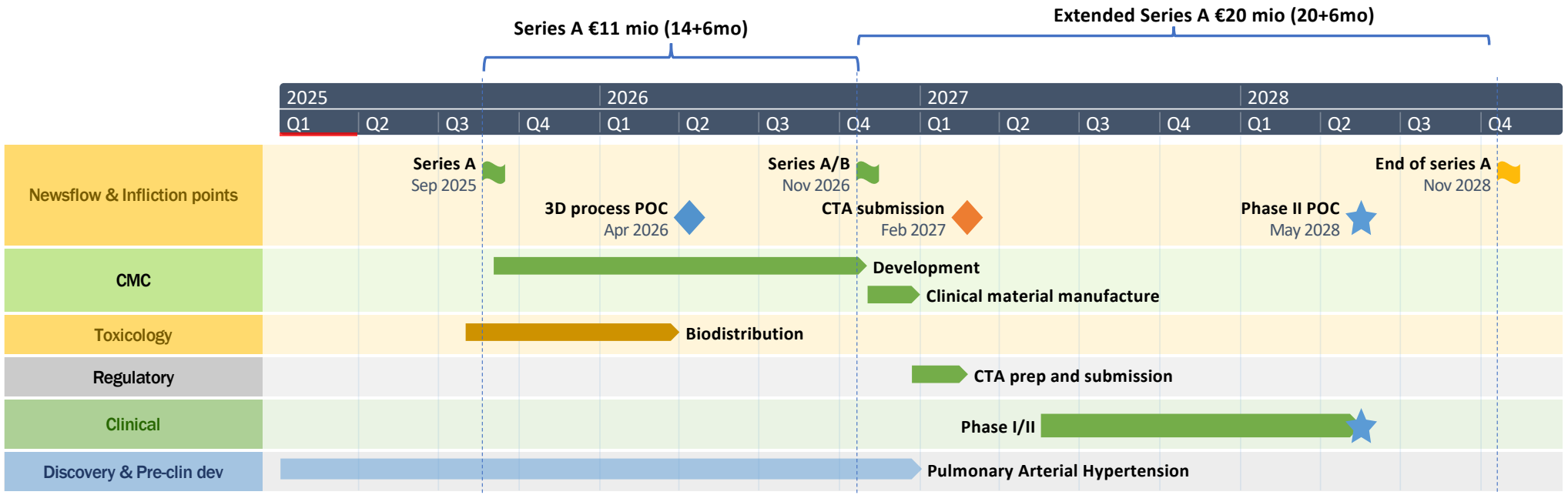


Sources: 1) Watzker, A., et al. (2024). Economic burden of pulmonary arterial hypertension in the U.S. PharmacoEconomics, 42(5), 587–597. 2) Leber, L., et al. (2021). Epidemiology of PAH and CTEPH: A systematic review. Pulmonary Circulation, 11(1), 1–12. 3) Maron, B. A., et al. (2021). Pulmonary arterial hypertension: Diagnosis and treatment updates. Am J Respir Crit Care Med, 203(12), 1472–1487.

*Winrevair from Merck, the first in class product on the market for PAH carries a price tag of ~$230,000

Funding Scenarios and Timelines

Funding strategy for shortest overall timeline



Thank you

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E-mail sheikh@blue-cell.com