Blue Cell Therapeutics

Allogeneic cell therapy for nerve regeneration and angiogenesis

April 2025

Clinic ready, scalable, safe and long-lasting allogeneic cell therapy for nerve regeneration and angiogenesis

- Blue Cell Therapeutics has developed a potentially curative solution for diseases where angiogenesis and nerve regeneration are beneficial.
- Lead product, BlueC-231, is in development for the treatment of severe Erectile Dysfunction (ED)
- Other indications under investigation, including Pulmonary Arterial Hypertension (PAH).
- Clinical proof of concept data with 72% full response in early clinical trial, and plan for two phase I/II trials with improved BlueC-231 cells in 2027. 1st arm in men with ED who have undergone prostatectomy and 2nd arm in men with diabetes mellitus
- Patented and scalable allogeneic manufacturing strategy for adipose derived stem cells with angiogenic and neuro-regeneration activity.
- 70,000 patients can be treated with material from a single donor.
- Looking for €39 MM Series A to reach clinical validation.

Blue Cell partners – academic, commercial, and hospitals

Experienced drug development team and 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

Ole Vahlgren
Chairman of the Board

Michael Ulveman
Board member

Anders Vadsholt
Board member

Anella S. Rogaczewski
Board member

Advisory board

Miguel Mulet
CEO Thytech, Tigenix. Alofisel on the market.

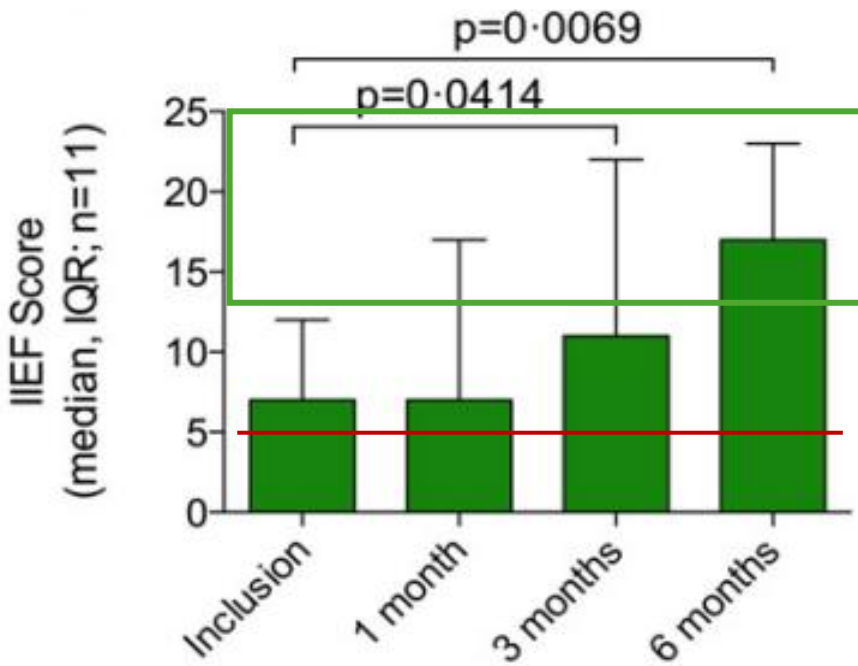
Ian Pearce
Prof. Urology, Manchester Royal Infirmary

Jakob Lerche Hansen
PhD, Novo Nordisk, Blue Cell Therapeutics

Early data show 72% of severe ED patients regained functional erection with autologous adipose-derived stem cells

- 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 year after prostatectomy
- 8 of 11 (72%) regained their ability to have an erection and perform sexually at 6 months.

Our clinical study



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

Confirmatory studies

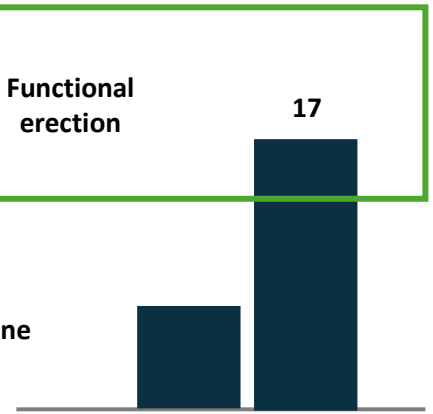


Illustration of effects of 6 academic stem cell studies*

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. Urologia Int. (2021). 105:935 and 4 other studies*

***Sansone et al., Sexual Medicine (2023). 11:204–21*

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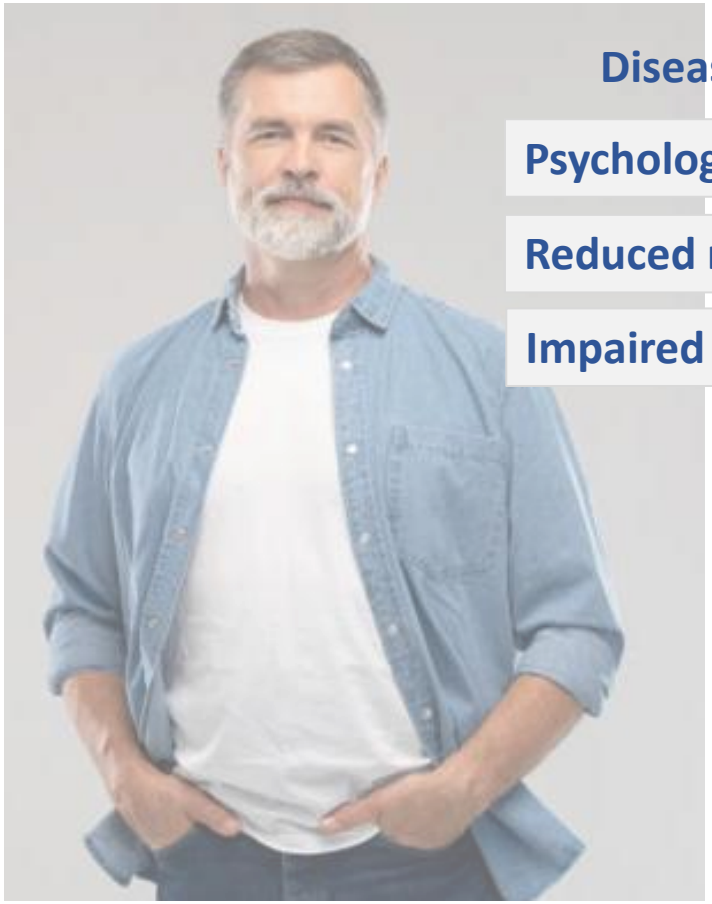
Cell therapy provides the first potentially curative treatment for Erectile Dysfunction by restoring vascular function



Disease mechanisms

- Psychological effects
- Reduced neuronal function
- Impaired vascular function

Entry market

Surgery related ED e.g.

Prostatectomy

Homogeneous patient population

Expansion market

Metabolic related ED e.g.

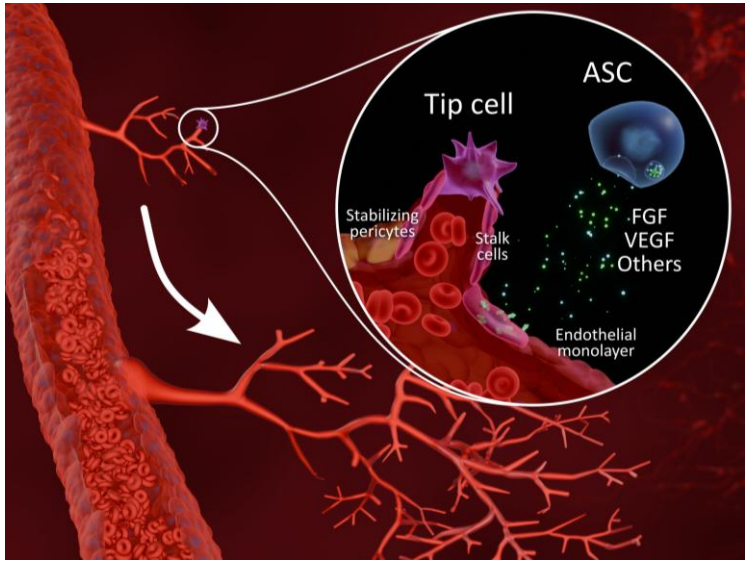
Diabetes, Vascular disease, Age

Heterogeneous patient population

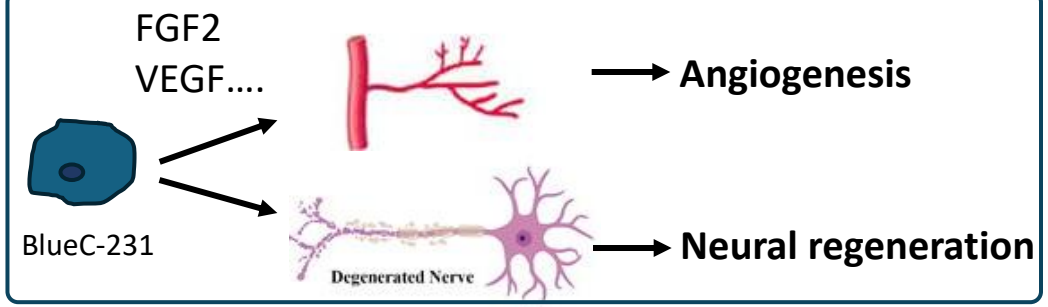
The causes of erectile dysfunction are diverse. The central cause is related to reduced blood supply to the penile tissue. This may be caused by surgery, metabolic or vascular diseases. Improving blood supply and nerve function are is the mechanisms of action believed to be able to cure erectile dysfunction

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

BlueC-231 (ASCs) stimulate angiogenesis…

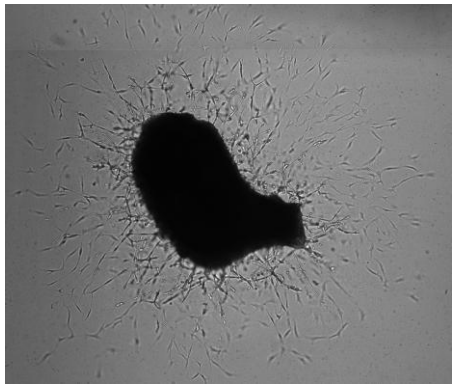


… and neuro-regeneration



BlueC-231 induce angiogenesis in Corpus Cavernosum slices – more efficiently than clinically tested SVF

A



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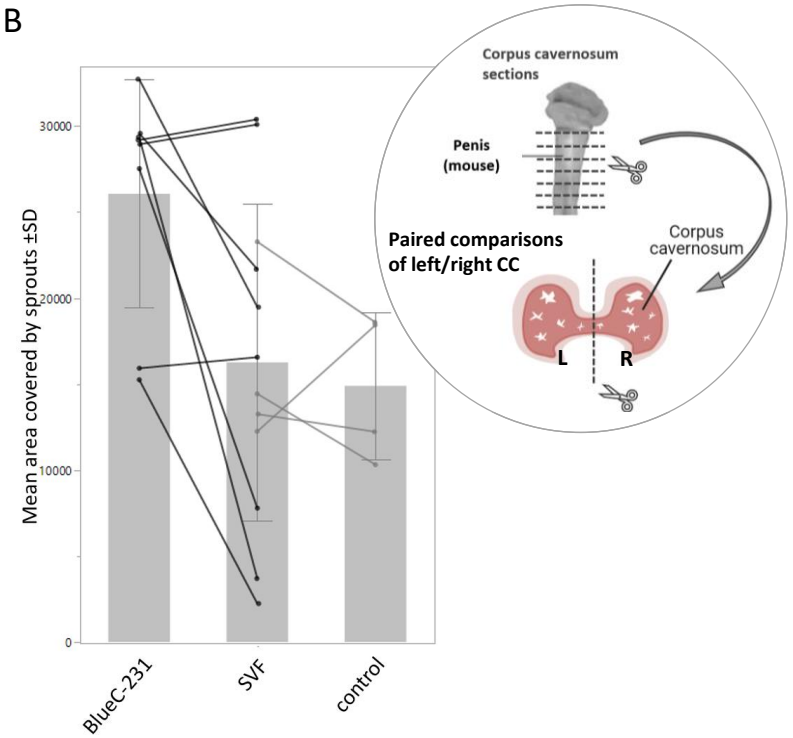

Increased outgrowth from Corpus Cavernosum slices co-cultured with BlueC-231.

A. Time-lapse video of sprouts from CC slice induced by BlueC-231
B. Paired comparison of sprouts from slices co-cultured 5 days with BlueC-231, SVF, or control.

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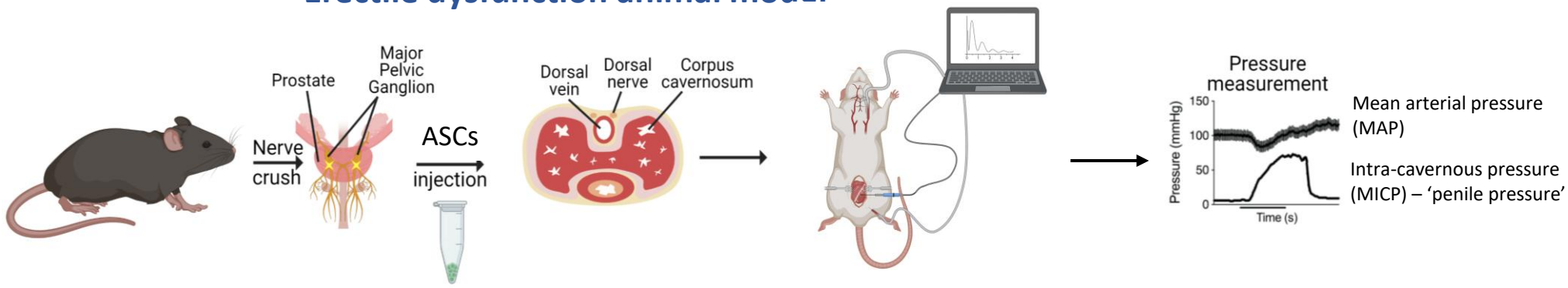
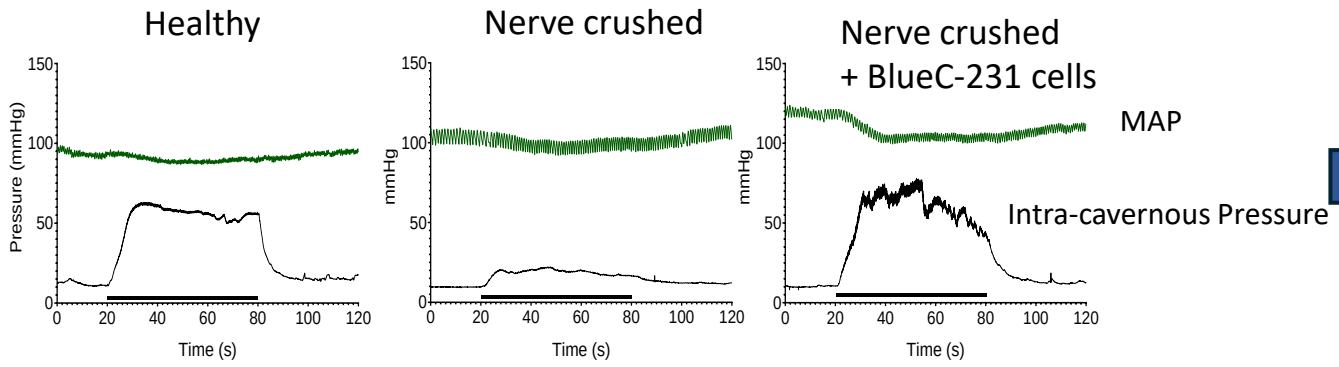
Note: SVF, Stromal Vascular Fraction is the same product that was dosed in our clinical study, see slide 4.

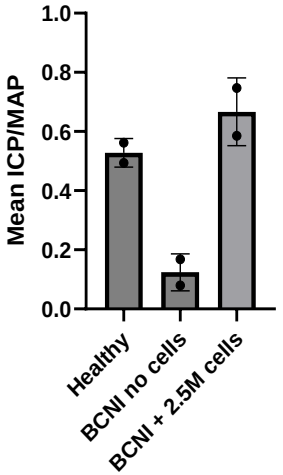
BlueC-231 human cells have robust effect in established preclinical POC model of erectile dysfunction

Erectile dysfunction animal model

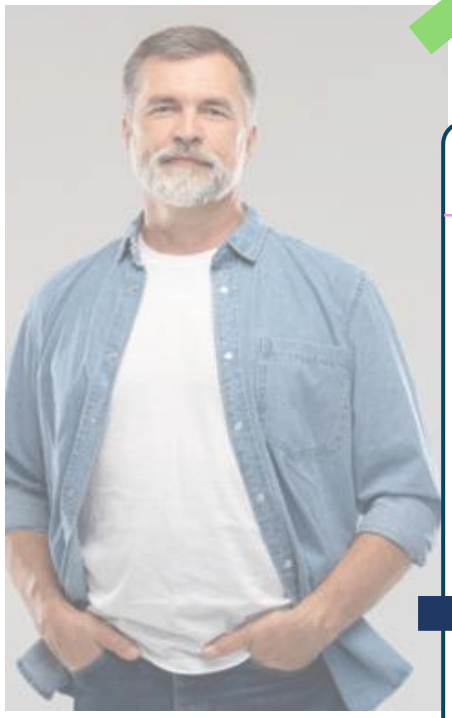


BlueC-231 cells rescue penile nerve damage





BlueCell will create a new market category with curative potential



NEW CATEGORY - Curative Cell Therapy

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1st line

Pharmacology

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

60-70% MS*

No spontaneity
Temporary effect
No effect in >30%

30%

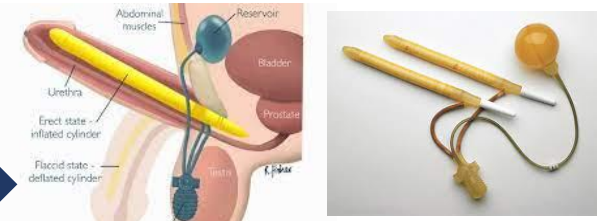
2nd and 3rd line

External medical devices

Tension rings,
Vacuum constriction devices

Uncomfortable
Temporary solution
~20% failure rate

Surgical medical devices

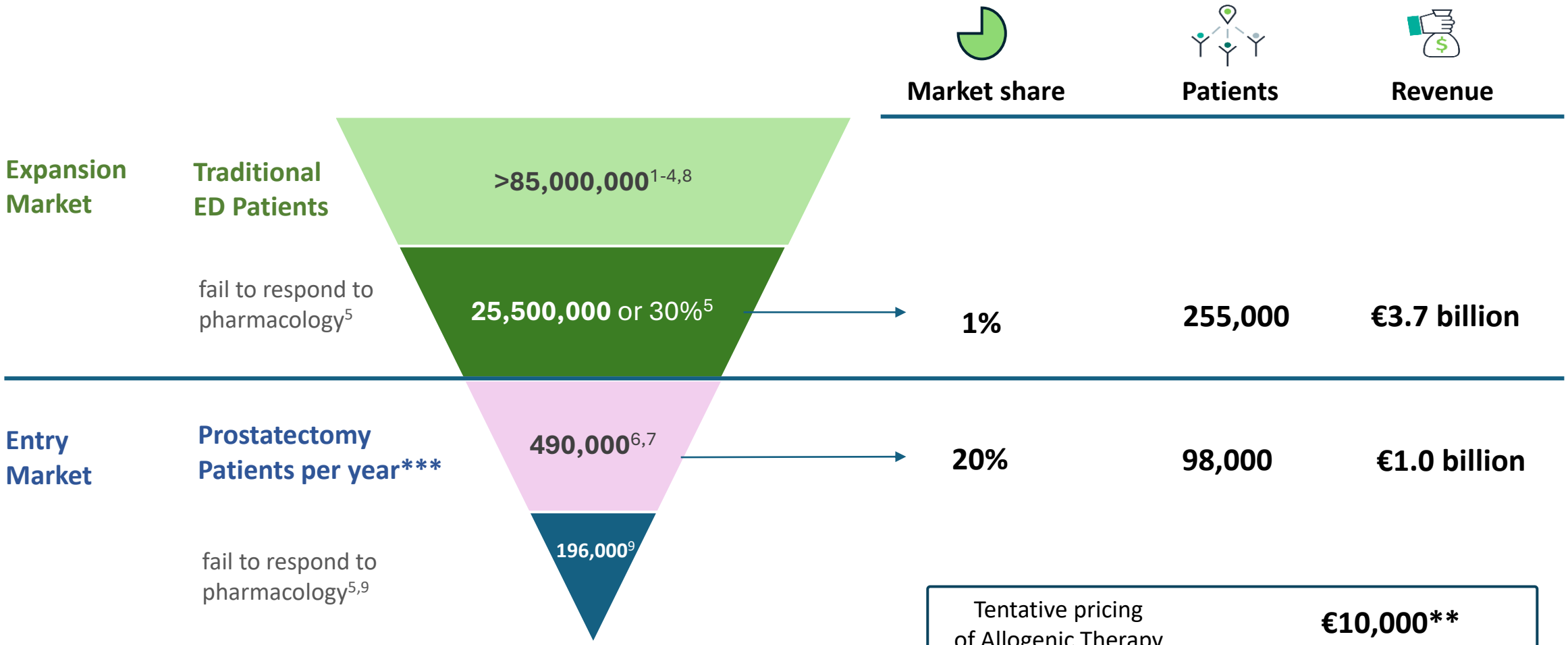


Penile prosthesis
Up to $30,000 pr. device/operation

Invasive
Infection, shortening of the penis
~30% dissatisfaction rate[1]

*Dark Horse Consulting

Large market potential 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)

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Scalable, with clear path to commercialization

Scalable for commercial success

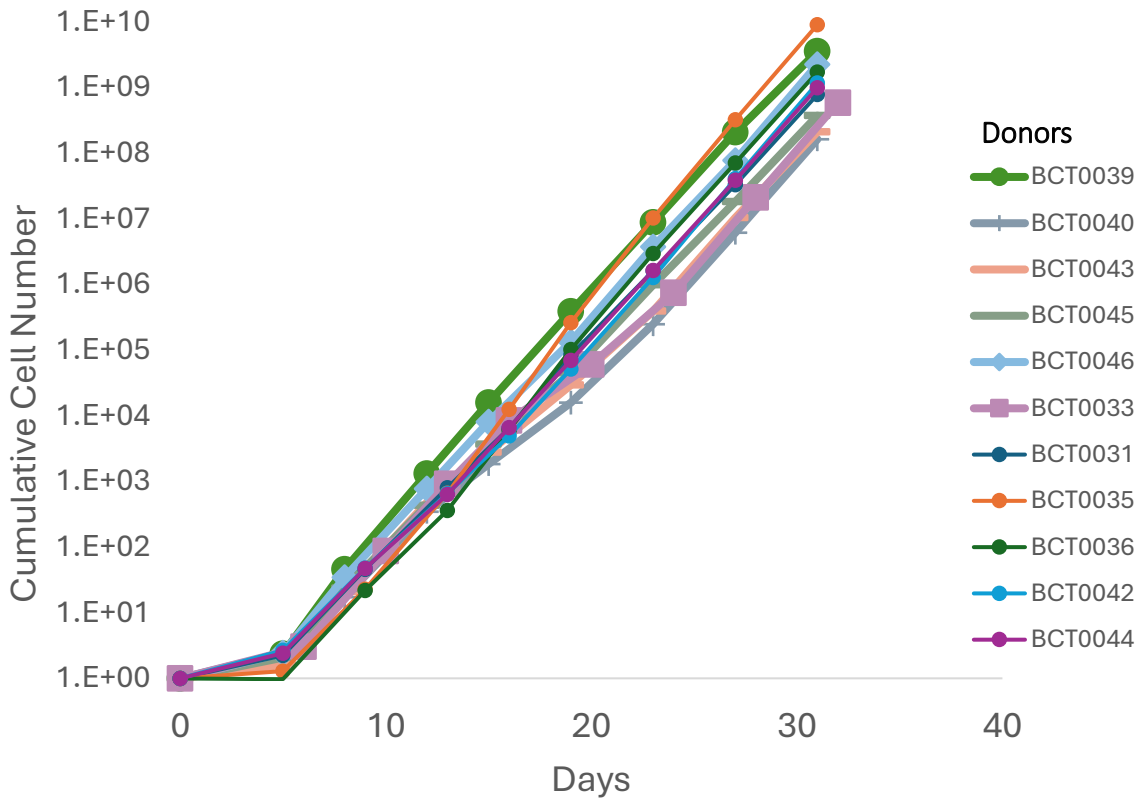
- Consistent and pure allogeneic cell product
- High proliferation of donor cells enable >70,000 patient treatments per donor
- Frozen for easy distribution and storage

✓ Off the shelf option for hospitals

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

✓ Commercial scalability

Robust proliferative ASC capacity across donors



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

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In a scientific advice meeting, HMRA has approved our pharmacology and toxicology program

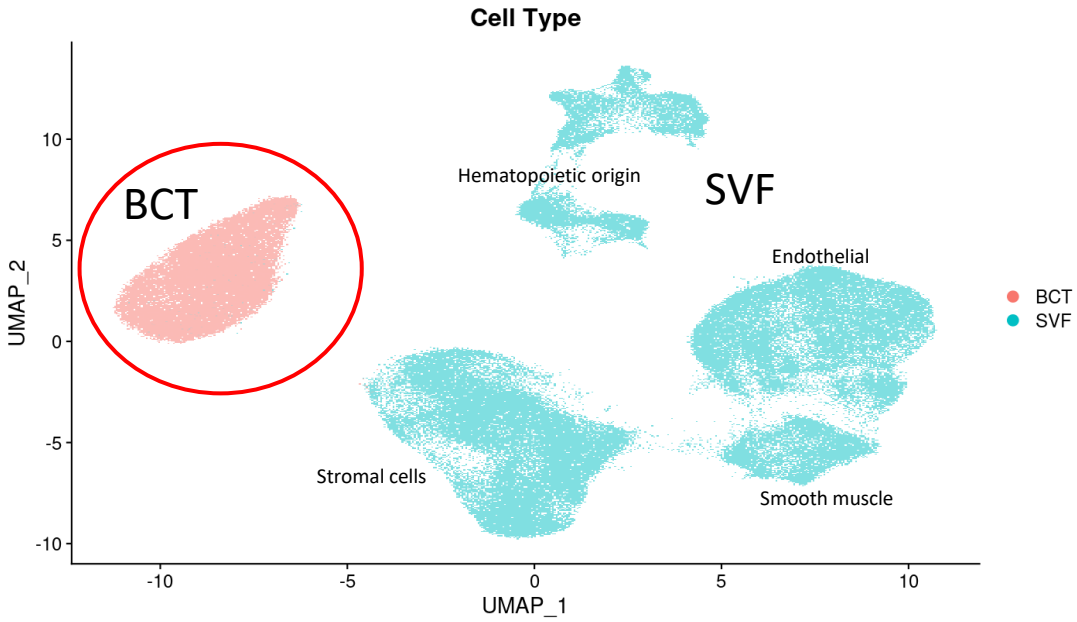
BCT-231 are non-natural, hence patentable in the USA.

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.

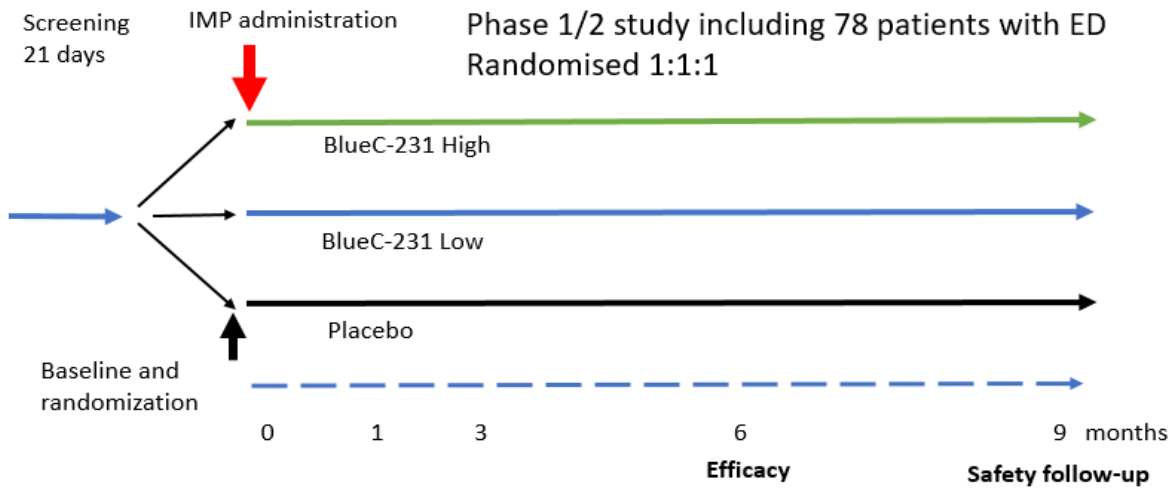
Clinical program executed by MAC Clinical Research

Collaboration with MAC Clinical Research

- Medicines and Healthcare Products Regulatory Agency (MHRA)-accredited clinical facility in Manchester
- Deep knowledge and experience with of ED trials
- MAC will invest £5M in the clinical trial

Clinical programs will comprise of two phase I/II studies in post-prostatectomy patients and diabetics followed by two confirmatory phase III studies

Treatment of ED in prostatectomized patients



One phase I/II study comparing two doses of BlueC-231 vs. placebo

Power of 90% to detect

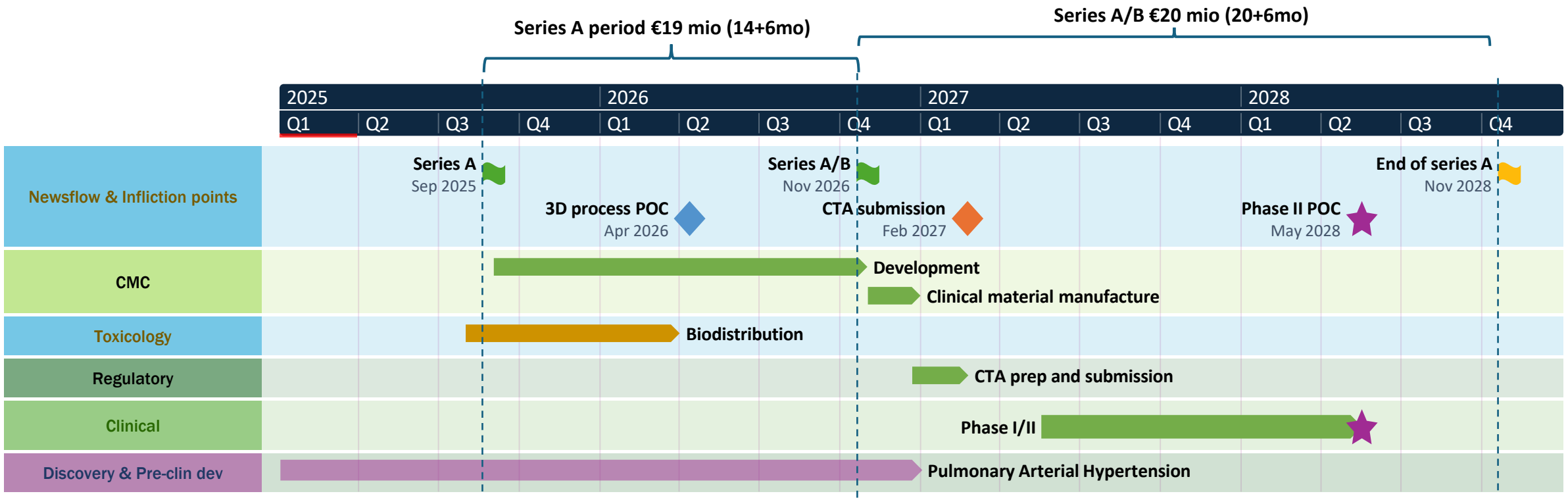
- mean increase in IIEF-5 of 5 points

Requires randomization of 78 patients

Inclusion criteria

- No nocturnal erection
- ED 6-12 months post prostatectomy
- Desire to be sexually active

Funding strategy for shortest overall timeline



Our Vision: A cell therapy that restores sexual function, spontaneity and sensitivity

Recent MSC Stem Cell Therapy breakthrough: Mesoblast got FDA approval for Ryoncil (Remestemcel-L-rk) to treat acute Graft versus Host disease (GVDH) in children

Industry worries

- Few stem cell therapies have been clinically proven
- High costs to produce cell therapies
- Challenges with developing scalable therapies
- Donor variation
- Unclear method of action
- Unproven stem cell therapies, targeting vulnerable consumers
- Market access built on ongoing pharmacotherapy, device, or surgical interventions

Our solution

- Autologous ASCs have been clinically proven in ED
- Cost-effective, scalable and reproduceable allogeneic therapies
- One donor treats 70,000 patients
- Low impact of donor variation
- BlueC-231 angiogenetic action corresponds to ED pathobiology
- Local administration
- Disruption of standard of care

Thank you

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