

CYP-006TK Demonstrates Safety and Efficacy in DFU Clinical Trial

Melbourne, Australia; 5 December 2024: Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, has successfully completed its Phase 1 clinical trial of CYP-006TK in diabetic foot ulcers (DFU).

Key Highlights

- The trial met its primary objective, with CYP-006TK found to be safe and well-tolerated – no participants withdrew from the trial due to adverse events, and no suspected serious adverse reactions were reported.
- Importantly, the trial also generated positive efficacy data, indicating improved wound healing for CYP-006TK compared to the standard of care control group.
- The mean¹ change from baseline in wound surface area was:
 - After 12 weeks, a decrease (improvement) of 181 mm² in the CYP-006TK group, and an increase (deterioration) of 355 mm² in the standard of care control group.
 - After 24 weeks (end of study), a decrease (improvement) of 261 mm² in the CYP-006TK group, and an increase (deterioration) of 62 mm² in the standard of care control group.
- The mean change from baseline in wound surface area expressed as a percentage was:
 - After 12 weeks, a decrease (improvement) of 64.6% in the CYP-006TK group compared to a decrease of 22.0% in the standard of care control group.
 - After 24 weeks, a decrease (improvement) of 83.6% in the CYP-006TK group compared to a decrease of 47.8% in the standard of care control group.²
- The study also indicates that larger wounds in particular healed to a greater extent in the CYP-006TK group compared to the standard of care control group.

Dr Jolanta Airey MD, Cynata’s Chief Medical Officer said:

“Diabetic foot ulcers represent a substantial unmet medical need; they are a very prevalent and challenging complication of diabetes worldwide due to high morbidity, high risks of lower extremity amputation and associated mortality. Patients have a high rate of recurrent hospitalisations with consequent cost to the healthcare system. There is a desperate need for more effective interventions to improve wound healing and thus reduce the risk of severe infection and amputation. The results from this clinical trial of Cynata’s topical MSC product are very promising. If subsequent trials confirm similar effects, then we might be on the path to a therapy that promotes successful wound healing in this challenging condition. We look forward to working with Cynata to continue development of this innovative product.”

Dr Kilian Kelly, Cynata’s Chief Executive Officer and Managing Director, said:

“We are very pleased and encouraged by these results. First and foremost, the trial achieved its primary objective of safety. Furthermore, whilst the trial was not powered to show statistically significant efficacy, we believe there is a clear signal indicating improved wound healing compared to standard of care treatments in this trial. We will now turn our attention to the next steps for this exciting program, including our strategy for further clinical development, engagement with regulatory agencies (including the FDA)

and engagement with potential commercial partners. Finally, today's results further exemplify the commercial attractiveness of the broader Cymerus™ platform, with the Company now having two distinct product candidates that have generated positive clinical data – CYP006-TK in DFU, and CYP-001 in graft versus host disease, which also previously demonstrated very encouraging safety and efficacy data.^{3,4} The Company eagerly awaits further results from three more clinical trials over the next ~18 months which could also further add to the commercial attractiveness of the Cymerus™ platform.”

About the Clinical Trial

CYP-006TK is Cynata's Cymerus™ iPSC⁵-derived MSC⁶ topical wound dressing product candidate, which comprises MSCs seeded onto a novel silicone dressing.

Due to reduced blood flow, patients with diabetes are at risk of developing non-healing wounds on the feet/lower limbs, which are also known as DFU. In addition to causing severe pain and discomfort, DFU pose a significant risk of infection, and if treatment is unsuccessful, amputation may be necessary – an outcome that occurs in ~20% of patients who develop DFU.⁷ An estimated 38 million Americans have diabetes,⁸ up to 34% of whom will develop DFU.⁹ The annual costs to US public and private payers to treat DFU are estimated to be US\$9-13 billion per year.¹⁰

In this Phase 1 trial, which took place at a number of clinical centres around Australia, a total of 30 patients with DFU were randomised to receive either:

- (i) CYP 006TK treatment for four weeks, followed by standard of care treatment for the rest of the study; or
- (ii) standard of care treatment throughout the study.

Follow-up visits in this trial continued until 24 weeks after the initiation of study treatment. At each follow-up visit, three-dimensional images of the study ulcer were taken using specialised camera equipment. Images were then analysed by a technician independent of the clinical centre and blind to treatment allocation. This facilitated calculation of the wound surface area, and consequently the change in size of the wound over time.

Results of the Clinical Trial

The primary objective of the trial was to assess the safety and tolerability of CYP-006TK. There were no suspected serious adverse reactions¹¹ reported, and no participants withdrew from the trial due to adverse events. The only adverse events considered to be at least possibly related to CYP-006TK treatment were non-serious, mild to moderate local administration site reactions, which occurred in seven participants.

Change in wound surface area from baseline was assessed using the mixed-effects model for repeated measures, which is a standard statistical approach used to assess this type of outcome measure.

The mean change from baseline in wound surface area expressed in terms of mm² was:

- After 12 weeks, a decrease (improvement) of 181 mm² in the CYP-006TK group, and an increase (deterioration) of 355 mm² in the standard of care control group.
- After 24 weeks (end of study), a decrease (improvement) of 261 mm² in the CYP-006TK group, and an increase (deterioration) of 62 mm² in the standard of care control group.

The mean change from baseline in wound surface area expressed as a percentage was:

- After 12 weeks, a decrease (improvement) of 64.6% in the CYP-006TK group compared to a decrease of 22.0% in the standard of care control group.

- After 24 weeks, a decrease (improvement) of 83.6% in the CYP-006TK group compared to a decrease of 47.8% in the standard of care control group.²

Analysis of Larger Wounds (wounds measuring >200 mm²)

The Company also conducted an analysis that segmented participants by wound size at baseline. This analysis indicates that CYP-006TK had a particularly pronounced benefit in larger wounds.

A total of eleven participants had wounds measuring <200 mm² at baseline (six in the CYP-006TK group; five in the control group). If wounds <200 mm² are excluded, and the remaining larger wounds (>200 mm²) are analysed separately,¹² there are even greater differences in outcomes between groups:

- The mean change from baseline in wound surface area for larger wounds was:
 - After 12 weeks, a decrease (improvement) of 262 mm² in the CYP-006TK group, and an increase (deterioration) of 540 mm² in the standard of care control group.
 - After 24 weeks (end of study), a decrease (improvement) of 354 mm² in the CYP-006TK group, and an increase of 135 mm² in the standard of care control group.
- The mean change from baseline in wound surface area for larger wounds, expressed as a percentage was:
 - After 12 weeks, a decrease (improvement) of 68.4% in the CYP-006TK group compared to an increase of 3.9% in the standard of care control group.
 - After 24 weeks, a decrease (improvement) of 84.2% in the CYP-006TK group compared to a decrease of 32.2% in the standard of care control group.²

This indicates that the potential wound healing benefit of CYP-006TK is even greater in larger wounds. This is especially encouraging as patients with larger wounds are more likely to experience an amputation.¹³

Conclusion

The trial met its primary objective of demonstrating safety and tolerability of CYP-006TK in participants with DFU. Importantly, the trial also generated positive efficacy data, indicating improved wound healing in the CYP-006TK group compared to the standard of care control group. It is also encouraging that this study indicates that larger wounds healed to a greater extent in the CYP-006TK group compared to the standard of care control group.

Continued Trading Halt

The Company will remain in trading halt pending an announcement of a potential capital raising, which is expected no later than opening of trading on Friday, 6 December 2024. The Company is not aware of any reason why the halt should not continue, nor any other information necessary to inform the market about the trading halt.

-ENDS-

Authorised for release by Dr Kilian Kelly, CEO & Managing Director

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About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical-stage stem cell and regenerative medicine company focused on the development of therapies based on Cymerus™, a proprietary therapeutic stem cell platform technology. Cymerus™ overcomes the challenges of other production methods by using induced pluripotent stem cells (iPSCs) and a precursor cell known as mesenchymoangioblast (MCA) to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale without the limitation of multiple donors.

Cynata has demonstrated positive safety and efficacy data for its Cymerus™ product candidates CYP-001 and CYP-006TK, in Phase 1 clinical trials in steroid-resistant acute graft versus host disease (GvHD), and diabetic foot ulcers (DFU), respectively. Further clinical trials are now ongoing: a Phase 2 trial of CYP-001 in GvHD under a cleared US FDA IND; a Phase 1/2 trial of CYP-001 in patients undergoing kidney transplant; and a Phase 3 trial of CYP-004 in osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus™ technology in preclinical models of numerous other diseases, including critical limb ischaemia, idiopathic pulmonary fibrosis, asthma, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

Cynata Therapeutics encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group.

¹ Mean calculated using the mixed-effects model for repeated measures; differences were not statistically significant, as expected given that the study was not powered to show efficacy.

² For clarity, the Company confirms that the change from baseline in the control group at both 12 and 24 weeks was an increase when calculated as mean change in mm², but a decrease when calculated as a percentage. While this may seem like a discrepancy, it is correct – it is a consequence of wound size at baseline varying between patients. For example, if there were two wounds, one measuring 100 mm², and the second measuring 1,000 mm² at baseline, and:

- The surface area of the first wound reduced from 100 mm² to 0 mm² (i.e. reduction of 100 mm² or 100%)

- The surface area of the second wound increased from 1,000 mm² to 1,500 mm² (i.e. increase of 500 mm² or 50%).

- In this example the mean change from baseline in wound surface area is an increase of 200 mm² (-100mm² + 500mm² / 2) but the mean percentage change from baseline is a decrease of 25% (-100% + 50% / 2).

This demonstrates that when smaller wounds improve but larger wounds deteriorate, there can be an overall reduction in mean wound surface area when expressed as a percentage, despite the mean wound surface area increasing when expressed in mm².

³ Bloor AJC, et al. Nat Med. 2020;26:1720–1725.

⁴ Kelly K, et al. Nat Med. 2024;30(6):1556-1558.

⁵ iPSC = induced pluripotent stem cell.

⁶ MSC = mesenchymal stem (or stromal) cell.

⁷ McDermott et al. Diabetes Care. 46:209–221 (2023).

⁸ American Diabetes Association: <https://diabetes.org/about-diabetes/statistics/about-diabetes>

⁹ McDermott et al. Diabetes Care. 46:209–221 (2023).

¹⁰ Raghav et al. Ther Adv Endocrinol Metab. 9(1) 29-31 (2018).

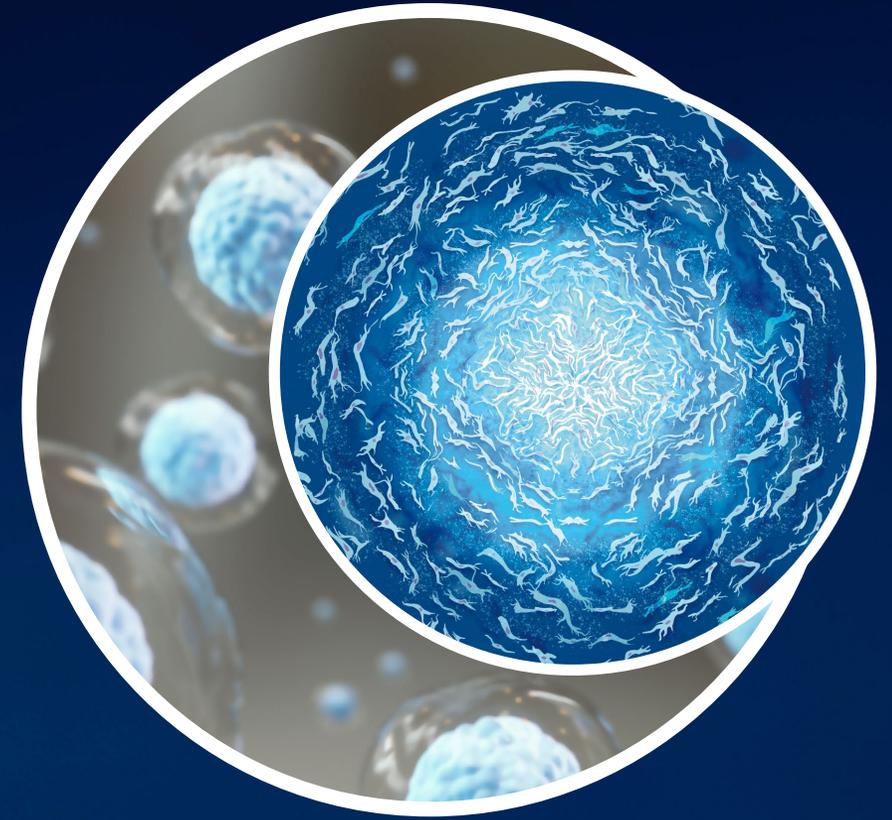
¹¹ A suspected adverse reaction is when a causal relationship between the investigational product and an adverse event is at least a reasonable possibility.

¹² Post-hoc analysis.

¹³ Pickwell K, et al. Diabetes Care. 2015;38(5):852-7.



Clinical Trial Results: Phase 1 Trial of CYP-006TK in Diabetic Foot Ulcers



A Clinical Stage Company Pioneering the Next Generation
of Cellular Therapies
5 December 2024

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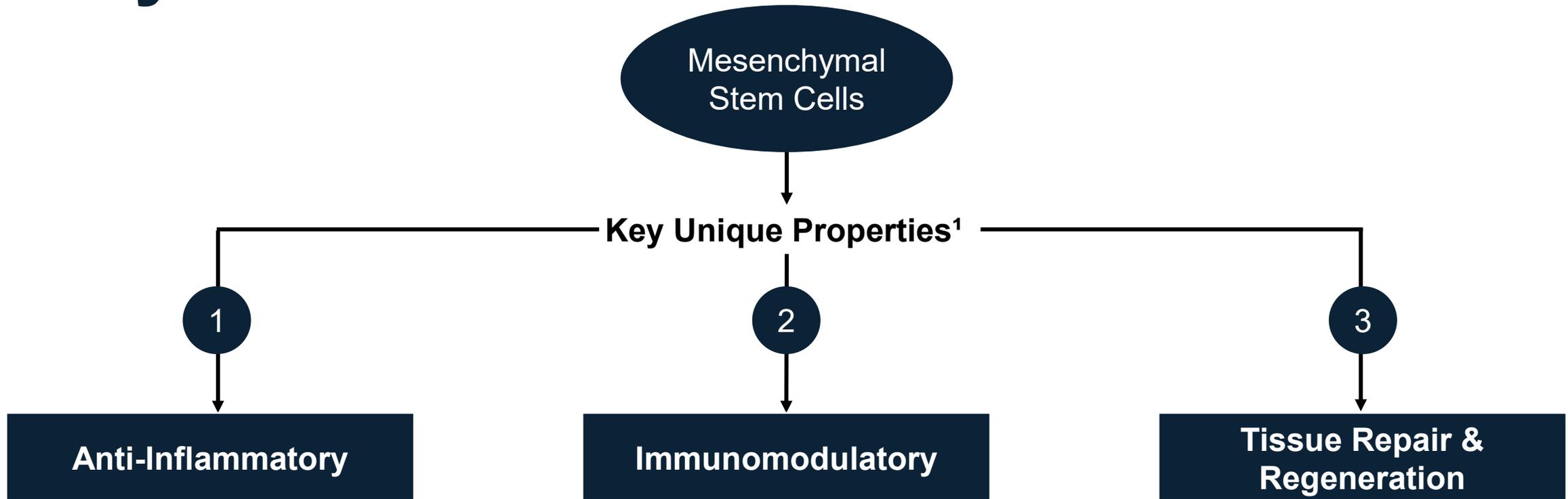
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Target indications

Indication		Trial phase	Upcoming catalysts*	Market opportunity
 Acute Graft vs Host Disease (aGvHD) FDA Orphan Designation	Cynata Funded & Managed	Phase 2 ongoing	Enrolment completion – H1 2025 Results – H2 2025	US\$600m ¹
 Diabetic Foot Ulcers (DFU)		Phase 1 complete	Results released Dec 2024	US\$9.6bn ²
 Osteoarthritis (OA) <i>(managed by USYD, funded by NHMRC)</i>	Partner Funded & Managed	Phase 3 ongoing <i>(enrolment complete)</i>	Results – H1 2026	US\$11.6bn ³
 Kidney Transplantation <i>(managed and funded by LUMC)</i>		Phase 1/2 ongoing	Results (Cohort 1) – H1 2025	US\$5.9bn ⁴

Note: Cynata retains commercial rights for both of the partner funded & managed programs

Why MSCs?



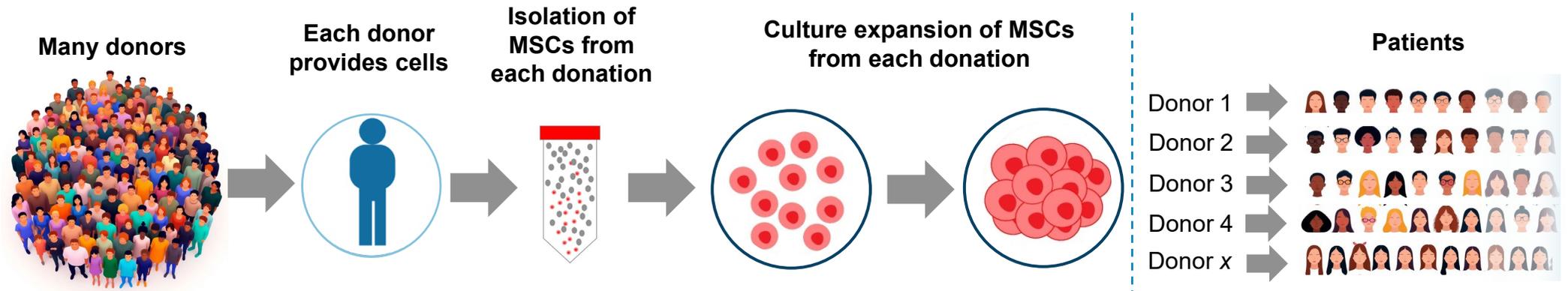
Importance:

Inflammation and inappropriate immune responses contribute to many diseases/medical disorders, and often lead to tissue damage. Consequently, the anti-inflammatory and immunomodulatory properties of MSCs, as well their ability to promote tissue repair and regeneration, can play an important role in treating many diseases.

Unlike many other cell therapies where patients have to be matched to donors, MSCs can be used without matching donors to recipients

Conventional MSC manufacturing process

Standard Process¹



New donors must be identified on regular basis; donors must consent to **surgical extraction**

MSCs must be **isolated** from **mixture of cells** from **each** donation – producing only **small number** of MSCs per donation

Extensive culture expansion required (growing cells) – **large number** of MSCs required

Different batches of MSCs come from **different donors**

Major Challenges

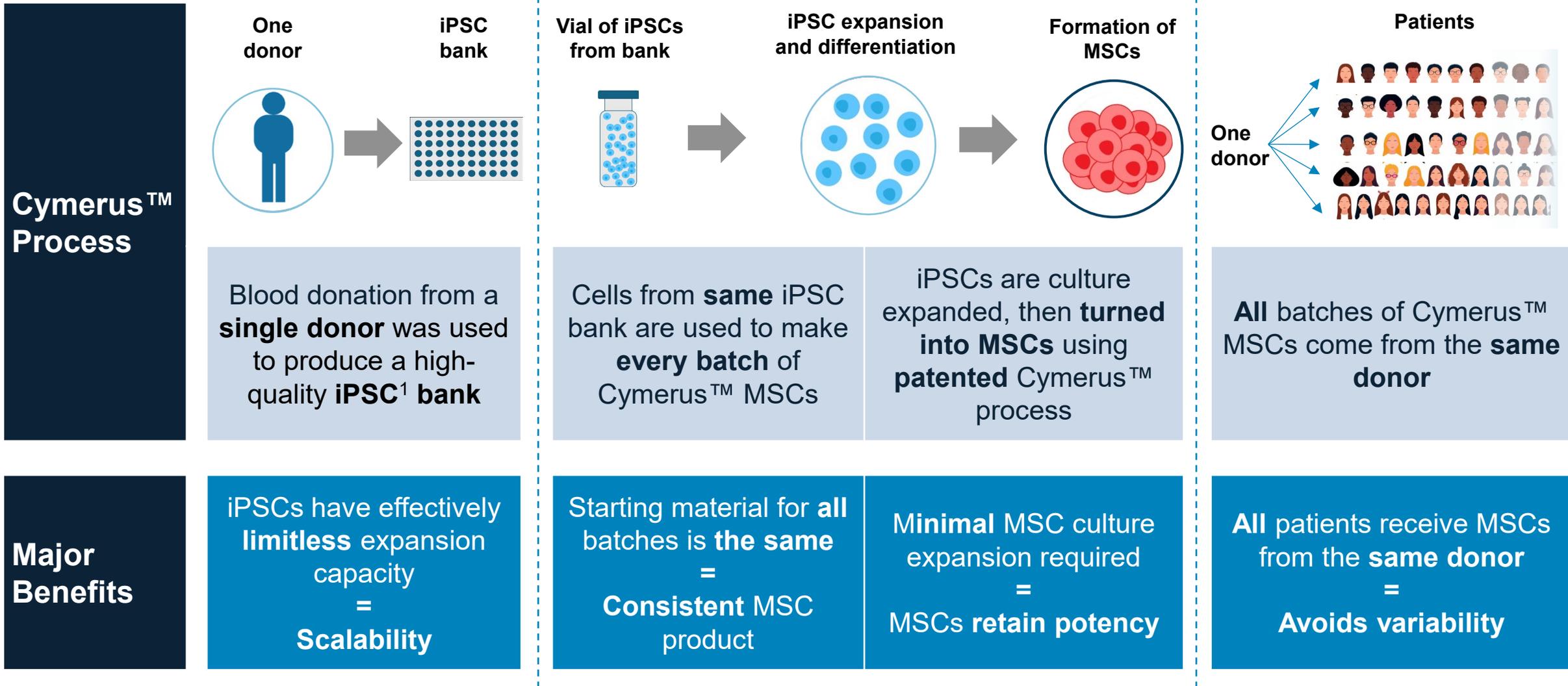
Different donors
= Variable starting material
= **Inconsistent product**

Small number of MSCs retrieved per donation
= **Extensive** MSC culture expansion required

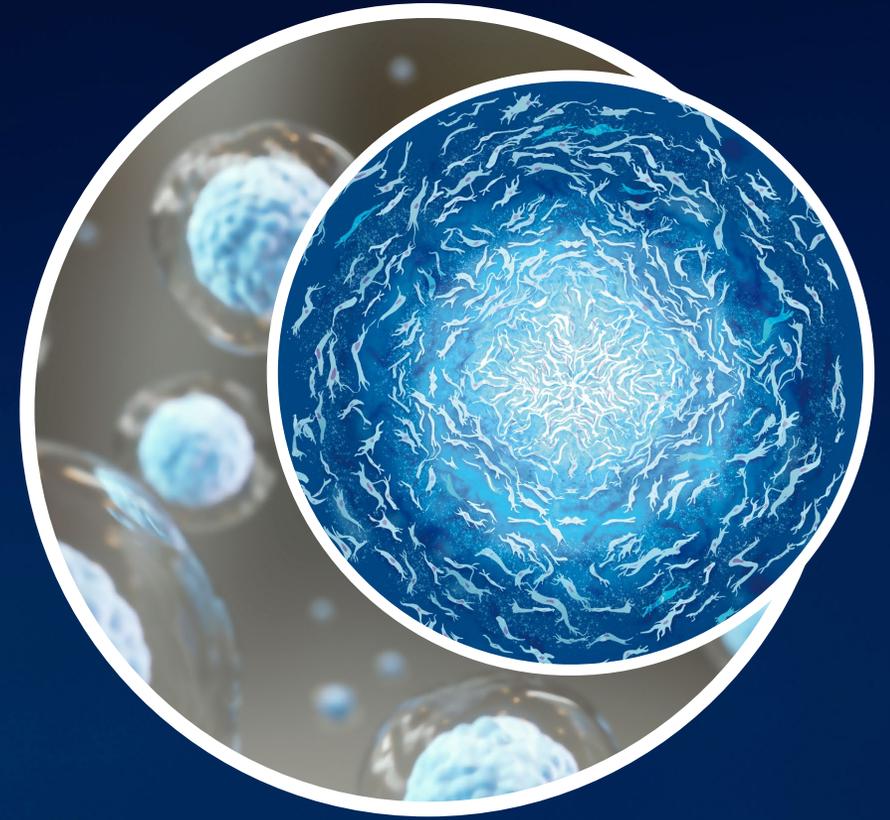
Extensive MSC culture expansion
= **Functional changes**
= **Loss of potency**

MSCs from **different donors** are administered to **different patients**
= **Inconsistent results**

The solution: the Cymerus™ process

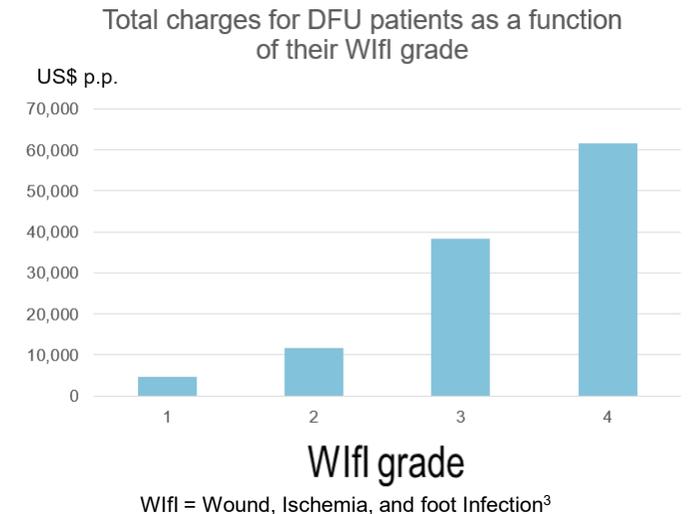


CYP-006TK for Diabetic Foot Ulcers



Diabetic foot ulcers (DFU)

- Open sore or wound that develops in patients with diabetes
- Very difficult to heal, which can lead to serious complications such as serious infection
- 20% of patients who develop DFU will require an amputation¹
- Multi-disciplinary team can be required to treat: GP, endocrinologist, podiatrist, wound care nurse, vascular surgeon and infectious disease specialist
- Cost to treat DFU in the US can exceed US\$60,000 per patient (depending on severity)²
- Annual costs to US public and private payers estimated to be US\$9 – 13 billion per year²



Diabetes is the **fastest growing** public health concern worldwide⁴

~38 million Americans have diabetes⁵

Up to 34% of those with diabetes will develop a foot ulcer¹

20% of patients with DFU will require **amputation** of the foot or limb¹

150,000+ amputations **per year** in the US due to **DFU**⁶

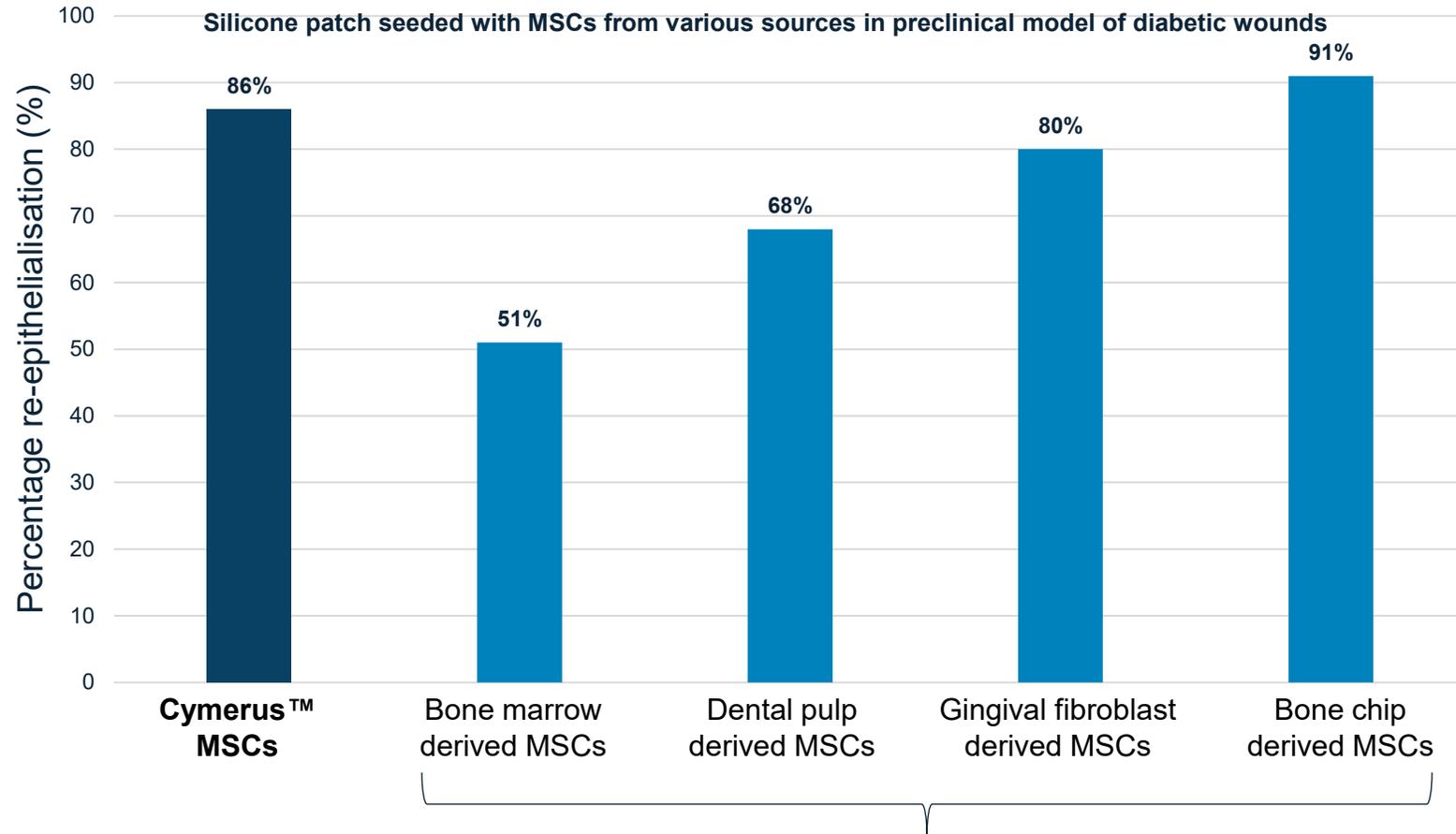
Estimated costs to US public and private payers **US\$9–13 billion** per year²

Diabetic foot ulcer examples



MSCs in DFU

MSCs have demonstrated strong success in pre-clinical DFU models



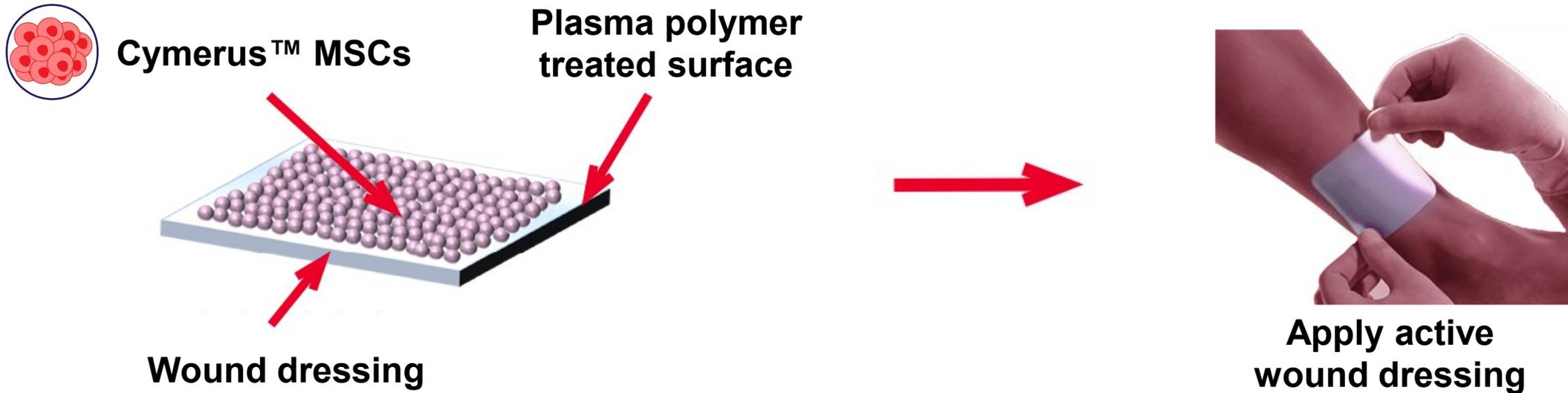
Major Challenges with manufacturing these MSCs consistently at scale

Key findings

- Primary outcome measured was extent of wound surface re-epithelialisation (healing) after 3 days
- Cynata's Cymerus™ MSCs resulted in significantly greater re-epithelialisation (86%) compared to bone marrow MSCs (51%)
- Cynata's Cymerus™ MSCs are the only MSCs capable of being produced consistently at scale

Cynata's MSC product for DFU

- Cynata has developed a proprietary wound dressing using MSCs ("CYP-006TK")
- CYP-006TK utilises a proprietary surface-coating, optimised for the delivery of MSCs directly to the wound



DFU | Phase 1 clinical trial

Indication

Non-healing diabetic foot ulcers (DFU)

Product

CYP-006TK (Novel silicone dressing seeded with Cymerus™ iPSC-derived MSCs)

Study Design

- Randomised controlled trial in ~30 adults
- Patients randomised to receive either standard of care (SOC) or CYP-006TK for 4 weeks, followed by SOC
- Primary objective is safety; efficacy measures include wound healing, pain and quality of life

Study Conduct

- Clinical sites in Australia (Adelaide and Perth)
- Patient enrolment complete (April 2024)
- All patient visits complete (September 2024)

Results

- **Final results released in December 2024**

DFU | Phase 1 clinical trial – key results

Primary Objective

CYP-006TK **successfully achieves** its primary objective:

- safe and well-tolerated (primary objective)
- no participants withdrew from the trial due to adverse events
- no suspected serious adverse reactions were reported

Mean change in wound surface area from baseline (mm²)*

Time	CYP-006TK	Standard of Care
12 weeks	Decreased by 181 mm ²	Increased by 355 mm ²
24 weeks	Decreased by 261 mm ²	Increased by 62 mm ²

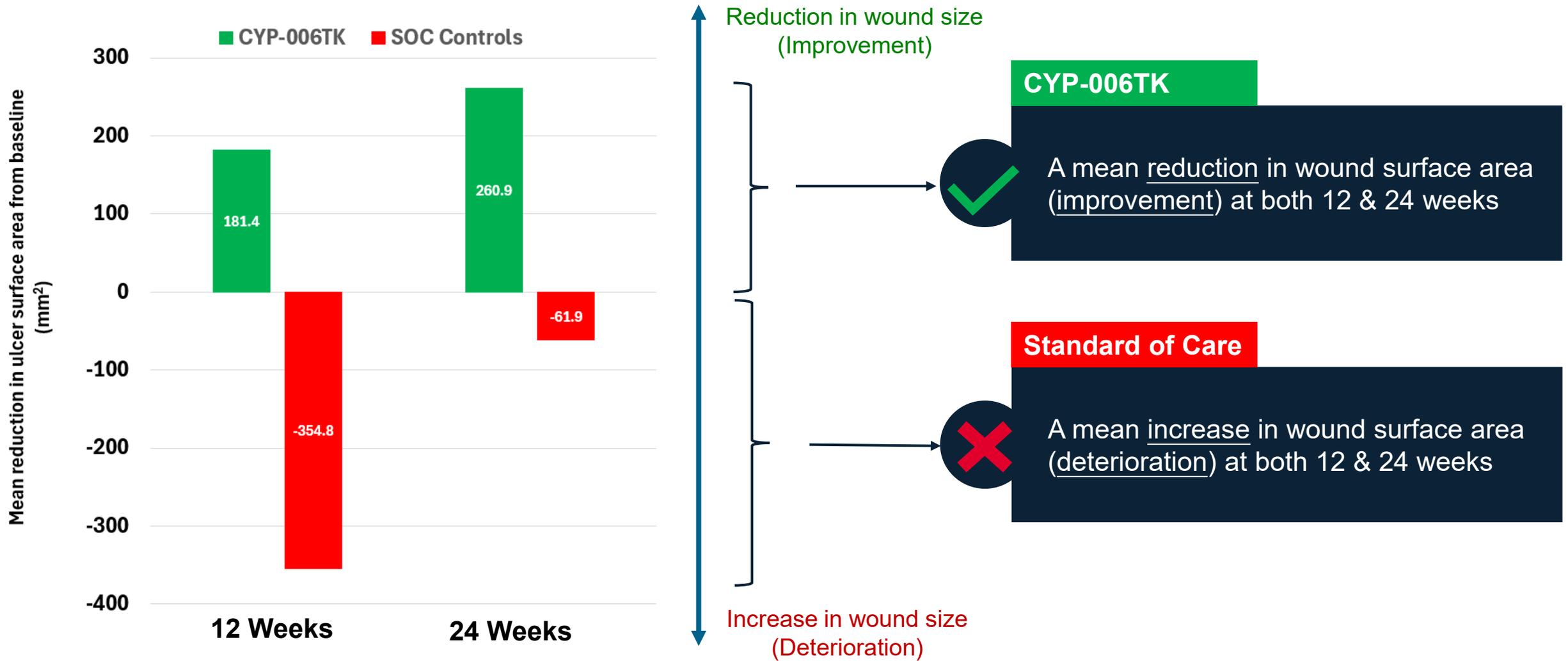
Mean change in wound surface area from baseline (%)

12 weeks	Decreased by 64.6%	Decreased by 22.0%
24 weeks	Decreased by 83.6%	Decreased By 47.8%

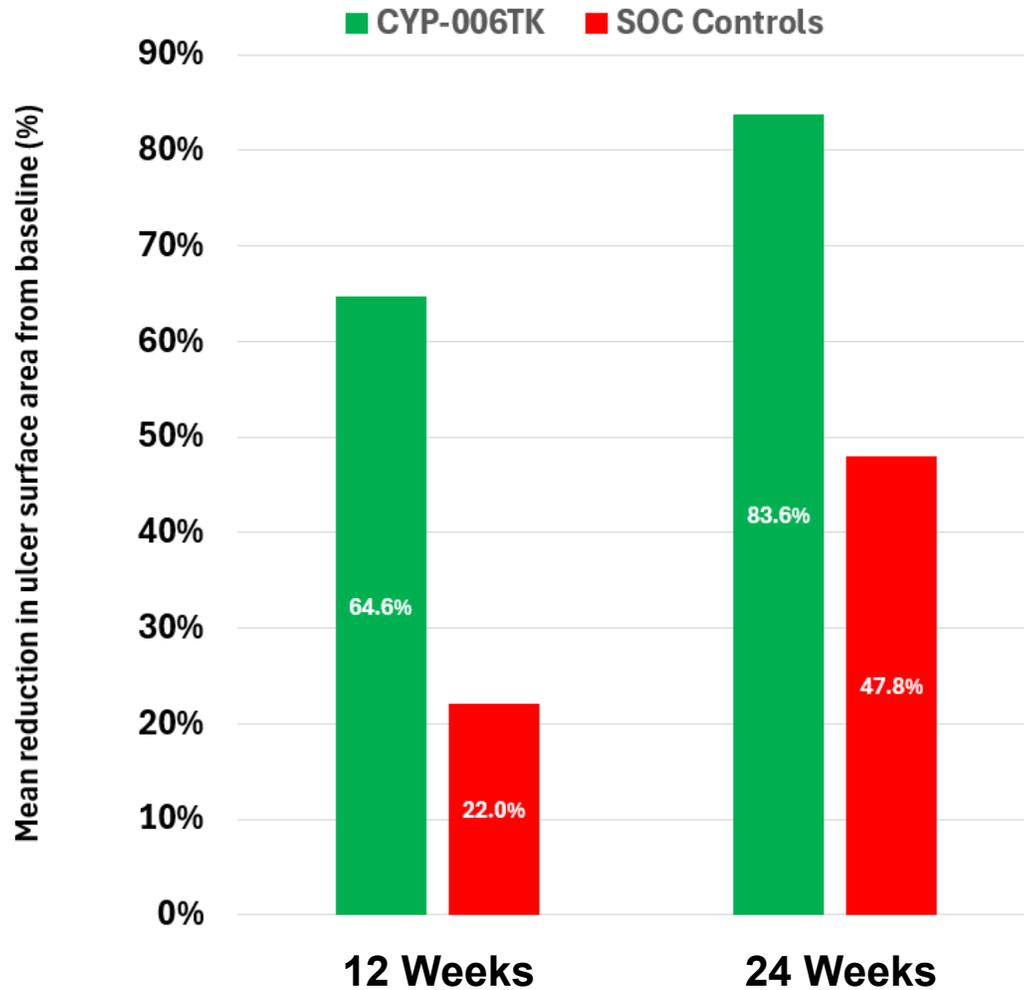
N=15

N=15

Mean change in wound surface area (mm²)



Mean change in wound surface area (%)



CYP-006TK

- Markedly greater mean reduction (improvement) by percentage than in the standard of care control group, at both 12 & 24 weeks
- Large percentage reduction in ulcer surface area from baseline in CYP-006TK group is consistent with change in mm²

Standard of Care

Increase in ulcer surface area from baseline in mm² combined with a reduction in percentage terms indicates that **larger** wounds were **less likely** to heal

Question: How can the wound surface area in the standard of care control group increase (i.e. deteriorate), but at the same time reduce (improve) when expressed as a percentage?

Answer: The fact that mean wound surface area in mm² in the standard of care control group increased (worsened), while the change in percentage terms decreased (improved), indicates that larger wounds healed to a lesser extent than smaller wounds in that group.

For example, if there were two wounds, one measuring 100 mm², and one measuring 1,000 mm² at baseline, and:

- The surface area of Wound 1 reduced from 100 mm² to 0 mm² (i.e. reduction of 100 mm² or 100%)
- The surface area of Wound 2 increased from 1,000 mm² to 1,500 mm² (i.e. increase of 500 mm² or 50%)
- In this example the mean change from baseline in wound surface area is an increase of 200 mm², but the mean percentage change from baseline is a decrease of 25%

This demonstrates that when smaller wounds improve but larger wounds deteriorate, there can be an overall reduction in mean wound surface area when expressed as a percentage, despite the mean wound surface area increasing when expressed in mm²

	Baseline	End of Study	Reduction (mm ²)	Reduction (%)
Wound 1	100	0	100	100%
Wound 2	1,000	1,500	-500	-50%
	Mean Reduction		-200 mm ²	+25%

Segmenting the data – larger wounds¹

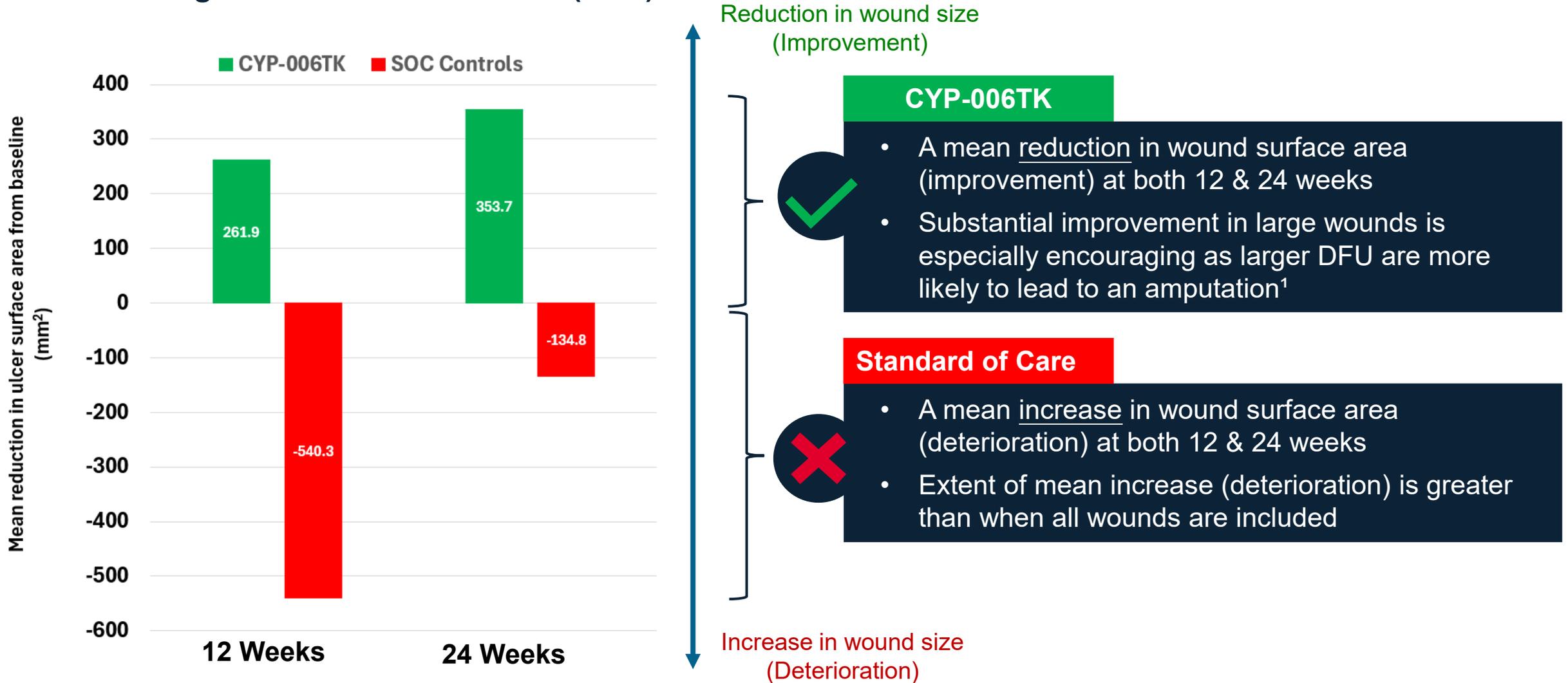
A total of eleven participants had wounds measuring <200 mm² at baseline (six in the CYP-006TK group; five in the control group).

If smaller wounds <200 mm² are excluded and the remaining larger wounds (>200 mm²) are analysed separately, there are even greater differences in outcomes between groups:

	Time	CYP-006TK	Standard of Care
Mean change in wound surface area from baseline (mm²)*	12 weeks	Decreased by 262 mm ²	Increased by 540 mm ²
	24 weeks	Decreased by 354 mm ²	Increased by 135 mm ²
Mean change in wound surface area from baseline (%)	12 weeks	Decreased by 68.6%	Increased by 3.9%
	24 weeks	Decreased by 84.2%	Decreased by 32.2%
		N=9	N=10

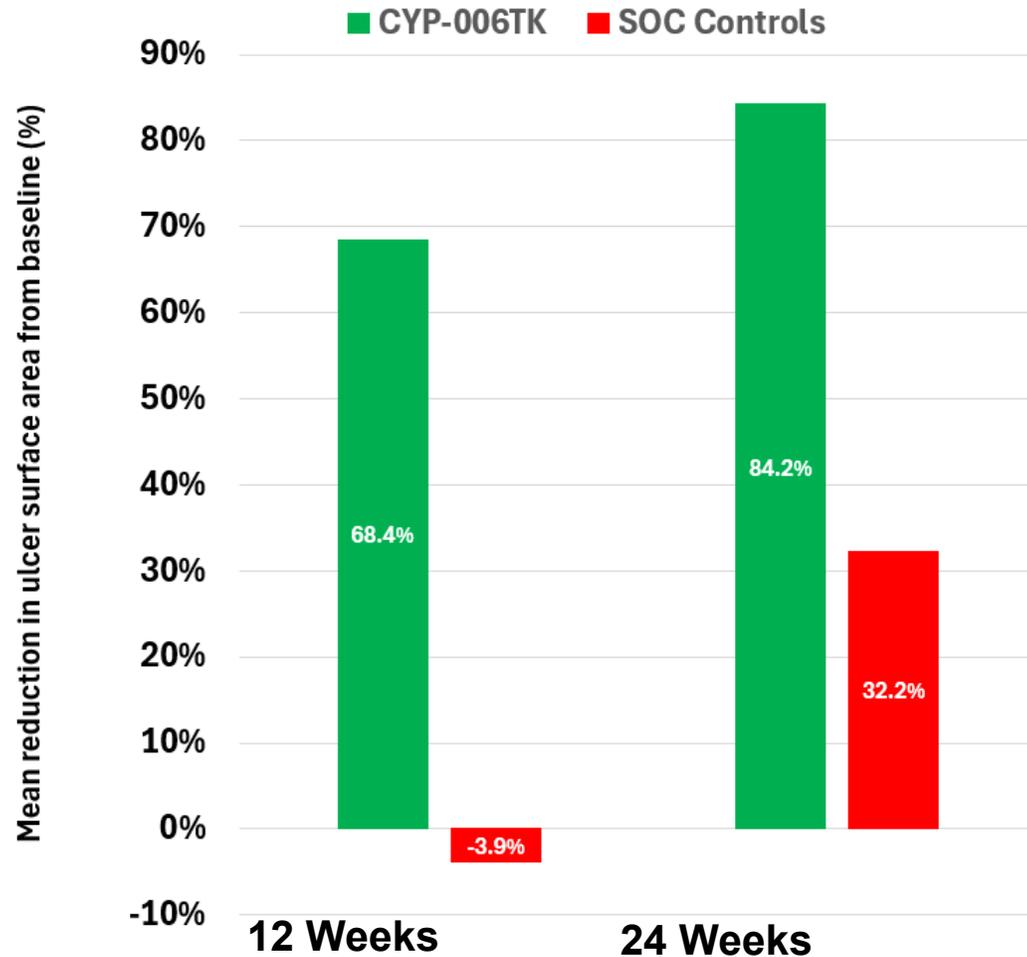
Larger wounds measuring $>200 \text{ mm}^2$

Mean change in wound surface area (mm^2)



Larger wounds measuring $>200 \text{ mm}^2$

Mean change in wound surface area (%)



CYP-006TK

Mean reduction (improvement) by percentage was similar in larger wounds compared to in all wounds:

- 12 weeks: 68.4% (large wounds); 64.6% (all)
- 24 weeks: 84.2% (large wounds); 83.6% (all)

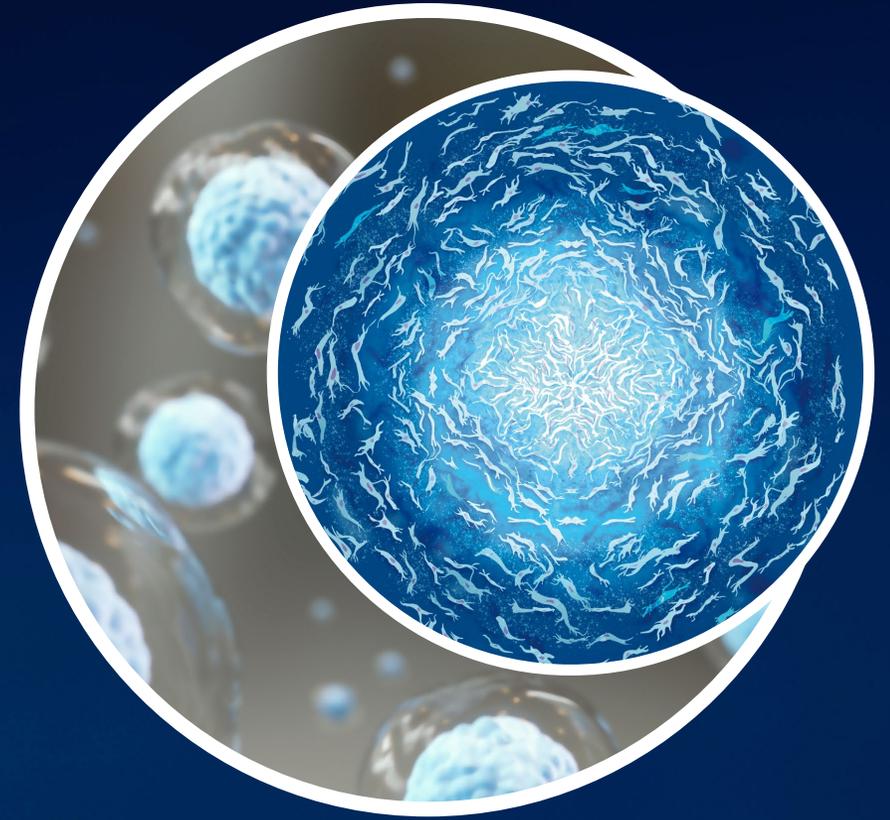
Indicates benefit of CYP-006TK in wounds of all sizes

Standard of Care

Mean change by percentage was markedly worse in larger wounds than in all wounds.

- 12 weeks: increase of 3.9% (large wounds); reduction of 22% (all)
- 24 weeks: reduction of 32.2% (large wounds); 47.8% (all)

Outlook and commercial potential



Commercial Attractiveness



 Proprietary Platform Technology	<ul style="list-style-type: none">• Ability to produce MSCs consistently and at scale allows for MSCs to be used in multiple indications = Platform Technology appeal
 Platform Technology	<ul style="list-style-type: none">• Platform Technology allows CYP to target multiple multi-billion dollar indications
 Multiple Multi-Billion Dollar Indications	<ul style="list-style-type: none">• Four clinical indications currently targeted have total combined market opportunities of ~US\$27.7 billion• All indications capable of being out-licensed / partnered
 Commercial interest	<ul style="list-style-type: none">• In 2019 (post Phase I results in GvHD), the Company received a non-binding indicative offer to acquire all shares in Cynata for \$2 per share (The parties subsequently withdrew from discussions as a result of being unable to reach agreement on satisfactory terms)• Cynata anticipates significant commercial interest following any positive read-outs• Three further read-outs expected by H1 CY2026
 Seeking Partnership Opportunities	<ul style="list-style-type: none">• Following the successful DFU results, Cynata will now continue discussions with potential commercial partners and engage with regulatory agencies (including FDA) as part of its strategy for further clinical development

Industry connections

- Upcoming catalysts will accelerate and broaden partnering discussions
- We attend leading conferences in our sector, to tell our story and open new discussions
- Following on from multiple events earlier this year, selected key events going forward include:

**BIOTECH
SHOWCASE™**

JP Morgan BioWeek/Biotech Showcase
San Francisco, January 2025

Company presentation and
partnering meetings

**advanced
THERAPIES**

Advanced Therapies Congress
London, March 2025

Company presentation and
partnering meetings

**Bio International
Convention**

BIO International
Boston, June 2025

Partnering meetings

BioJapan **RI-MJ**
Regenerative
Medicine
Japan

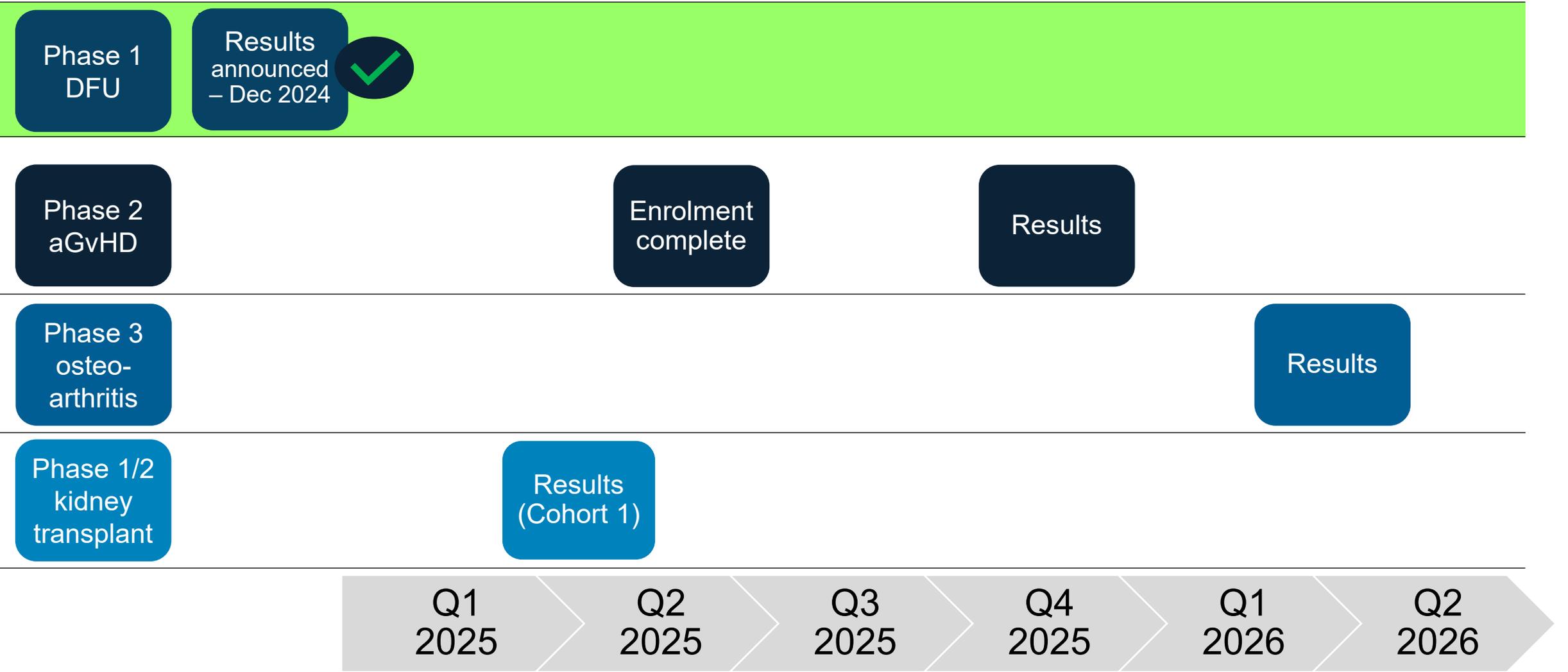
BIO Japan, RM Japan
Yokohama, October 2025

Partnering meetings

- We will also attend further key events in the sector (ARM, ISCT, ISSCR) and in the regions

Upcoming catalysts*

DFU results announced Dec 2024; results from THREE further trials expected by 1H 2026





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