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# PARADIGM BIOPHARMA

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39<sup>th</sup> Annual JP Morgan Healthcare Conference | January 11 - 14, 2021



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# Chief Executive Officer

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Paul Rennie





# Disclaimer

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# Changing the **paradigm** around where the greatest potential lies.

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Paradigm Biopharma ASX:PAR is approaching unmet needs from a completely different angle.

As repurposing experts, we are developing new solutions by identifying under-utilised molecules and unlocking their full value.

Combing cutting-edge science with industry-leading experience, our team is uniquely qualified to connect the promise a molecule has shown in the past with the proof that we were incapable of gathering before today.

We are challenging conventional wisdom. We are looking at disease states with fresh eyes. And we are finding connections never considered before.



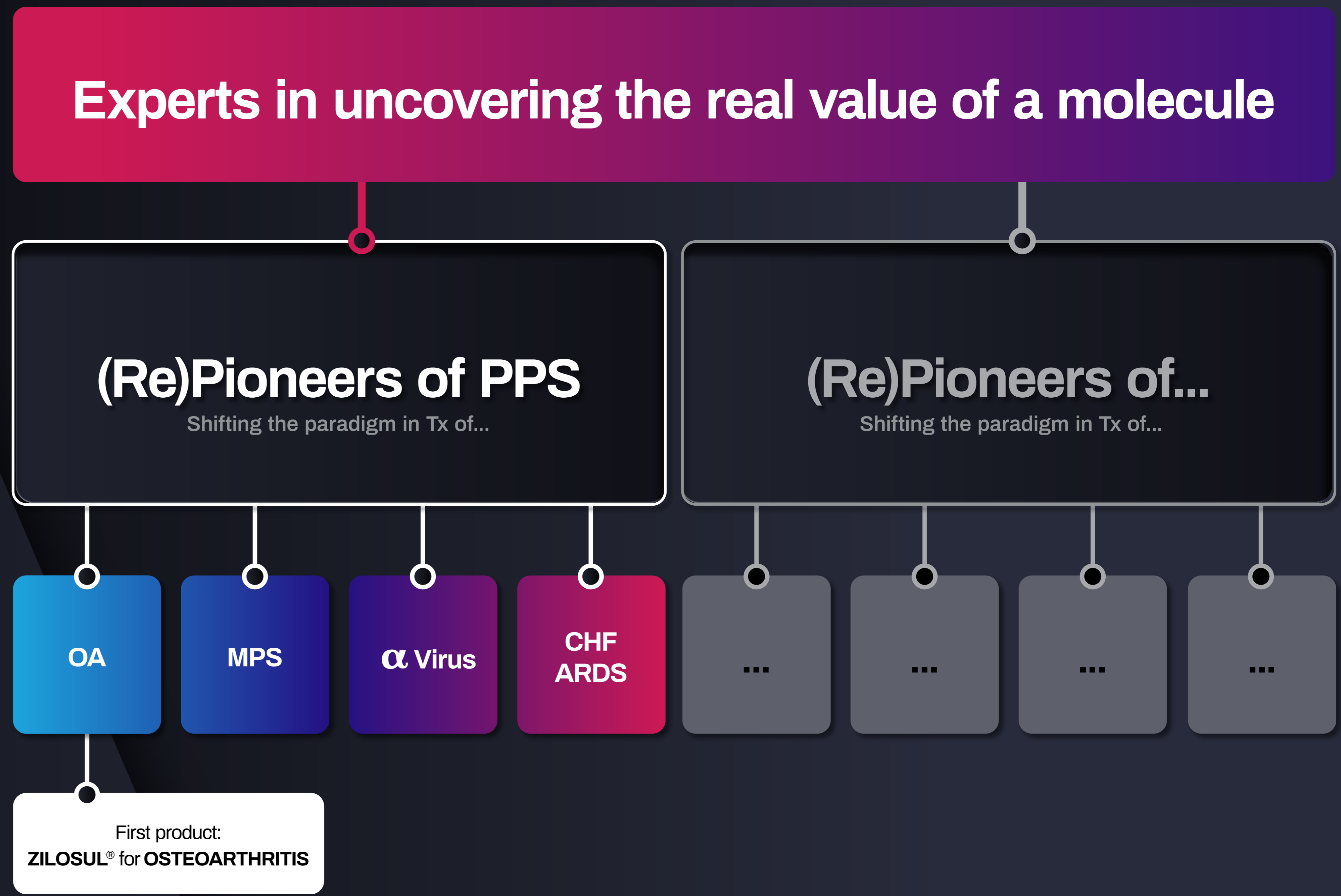


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# Paradigm Biopharma is a commercially focused drug repurposing company.

## Our approach:

- Take an existing, approved drug with demonstrated safety in its approved indication,
- Repurpose to a new patented therapeutic application with high unmet need.
  - Reduced time, cost and risk



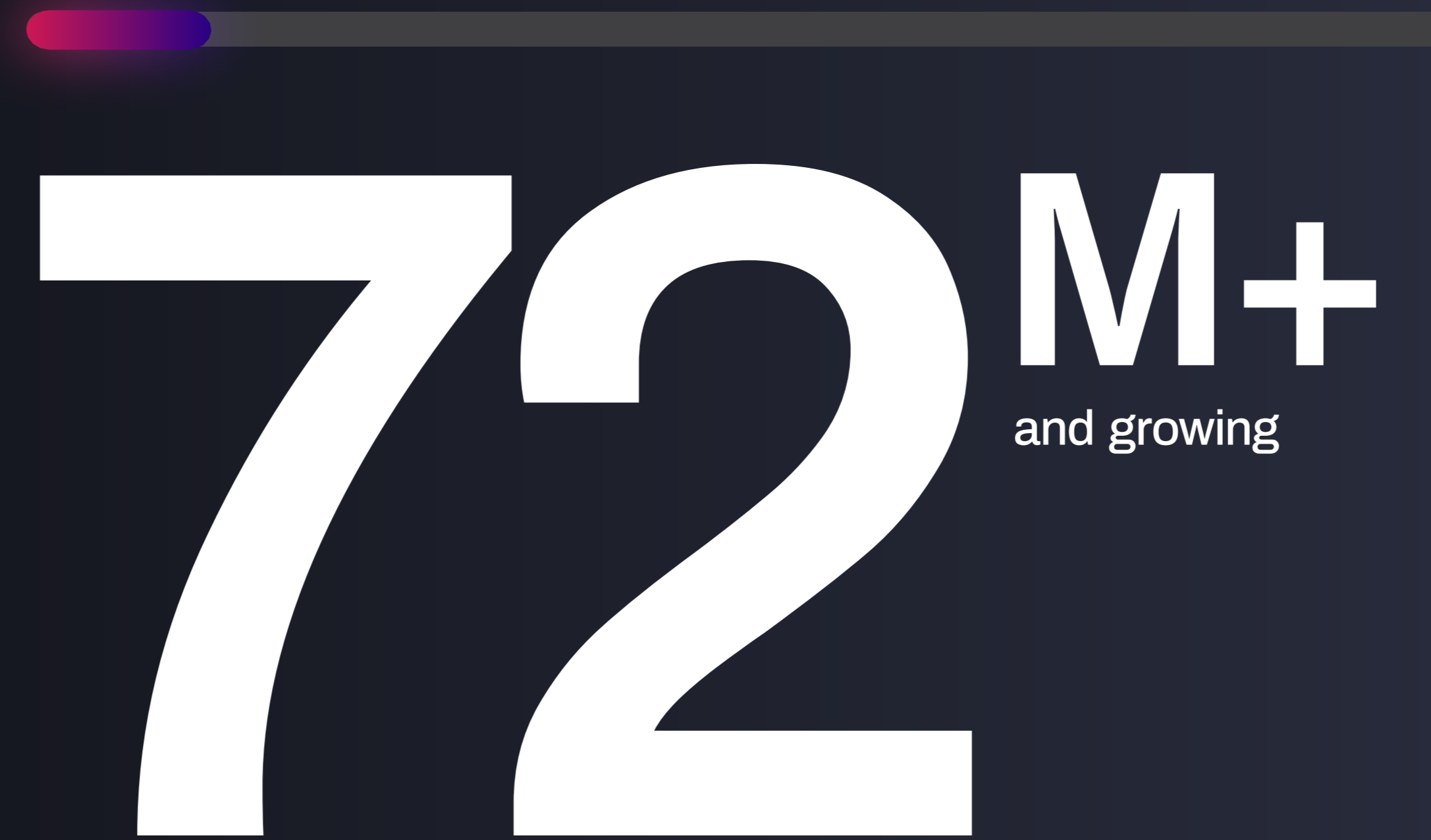


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# Blockbuster market opportunity

Zilosul<sup>®</sup> meets a significant unmet need in osteoarthritis

Total prevalence of OA in key markets

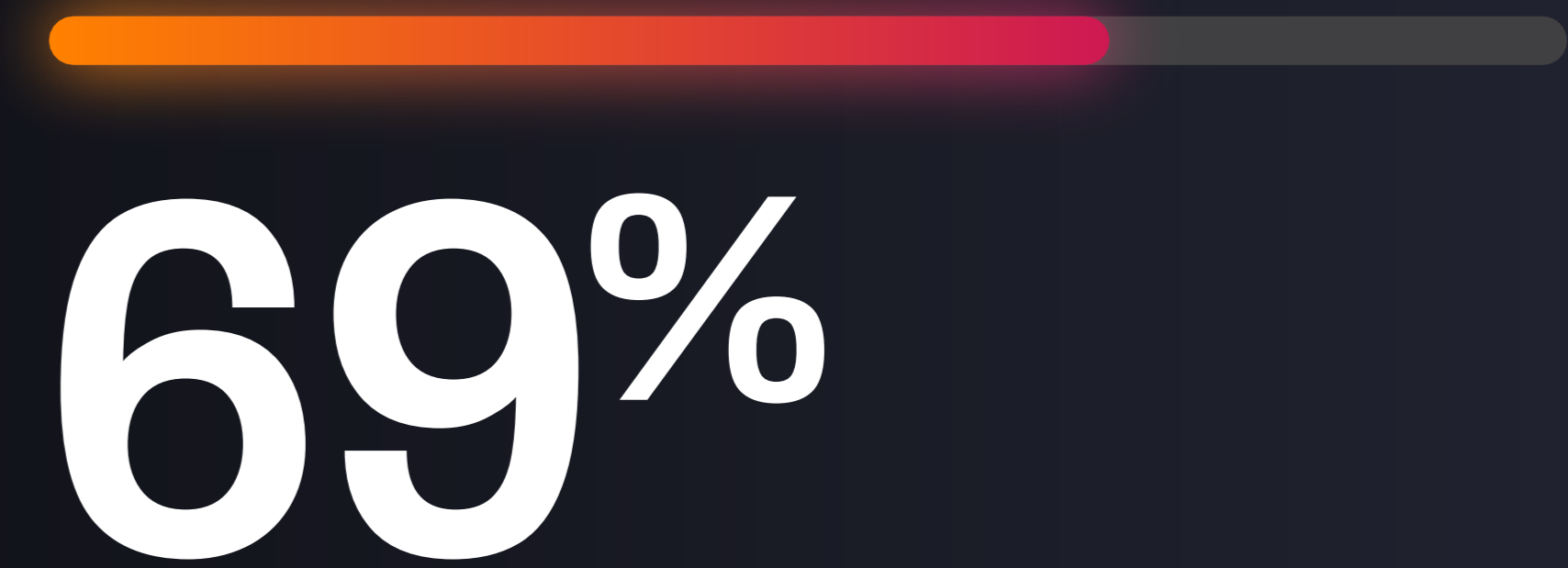


- USA
- CAN
- EU5
- AUS

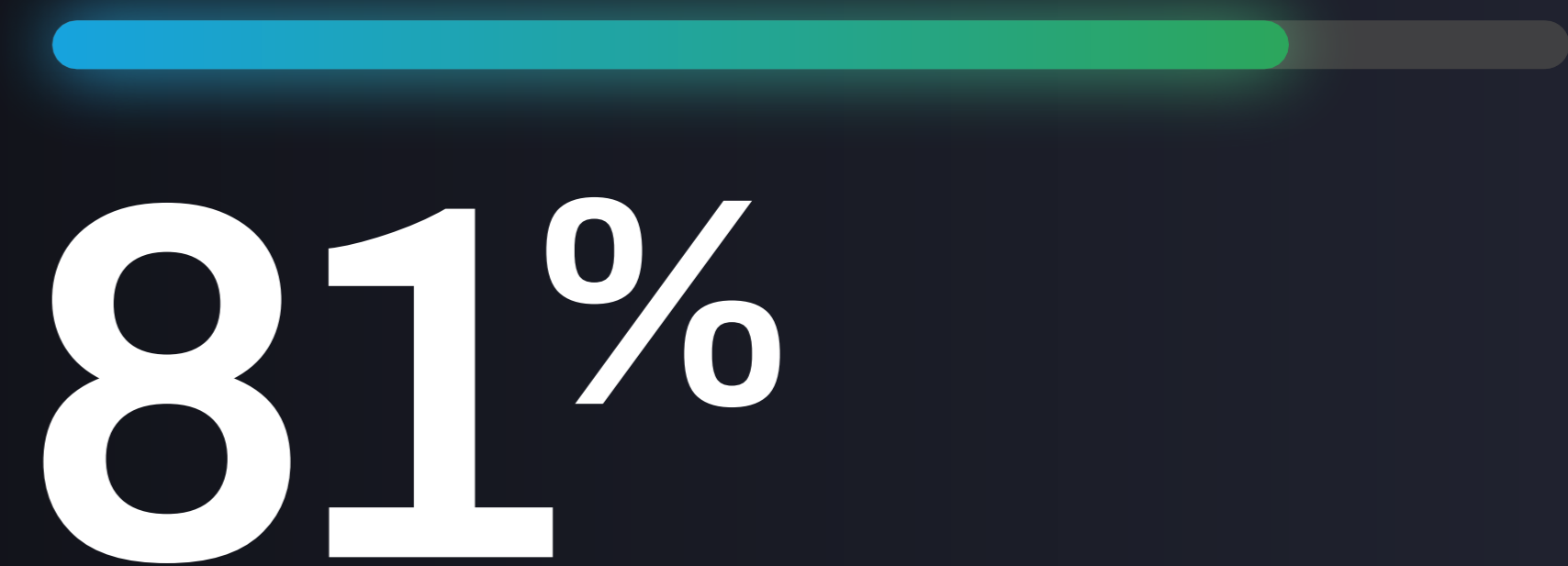
Rheumatoid Arthritis

- Prevalence: 7.2M patients
- 2020 market valuation: ~\$33Bn

Knee and Hip



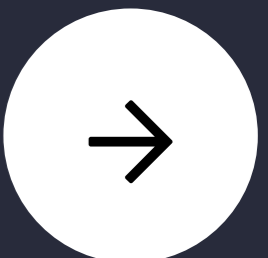
OA patients dissatisfied with current treatments<sup>1</sup>



Target uptake: 10% dissatisfied market<sup>1</sup>

Zilosul<sup>®</sup> indicative price: US\$2500 per year<sup>2</sup>

1. National Institute of Health; Emerging drugs for osteoarthritis; Hunter DJ and Matthews G 16(3): 479–491; 2011 September.  
 2. Pricing elasticity research commenced.  
 EU5: Germany, UK, Spain, France, Italy










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# Recent OA Transactions

## Highlights Pharma Interest In OA

COMPANIES	COMPOUND	REGION	UPFRONT	TOTAL VALUE	STATUS
	Anti-NGF	Global	US\$200m	US\$1.8bn	NDA Submitted
	Anti-NGF	Global	US\$250m	US\$1.25bn	Phase 3
	Corticosteroid	Global	Take-over*	US\$1.0bn*	Commercialised
	Anti-NGF	Global (ex Japan)	US\$50m	US\$435m	Discontinued
		Global Av.	<b>US\$166m</b>	<b>US\$1.12bn</b>	
	ADAMTS-5 Inhibitor	EU	Unknown	US\$346m	Discontinued
	Gene therapy	Japan	US\$24m**	US\$434m**	Handed Back
	Gene therapy	Japan	US\$27m	US\$591m	Phase 3
	Anti-NGF	Asia	US\$55m	US\$325m	Phase 3
		Regional Av.	<b>US\$35m</b>	<b>US\$424m</b>	

Sources: Bloomberg, company filings; \*Sanofi-Flexion take-over rumoured – Fierce Biotech; \*\*Mitsubishi handed back rights to TissueGene who executed deal with MundiPharma

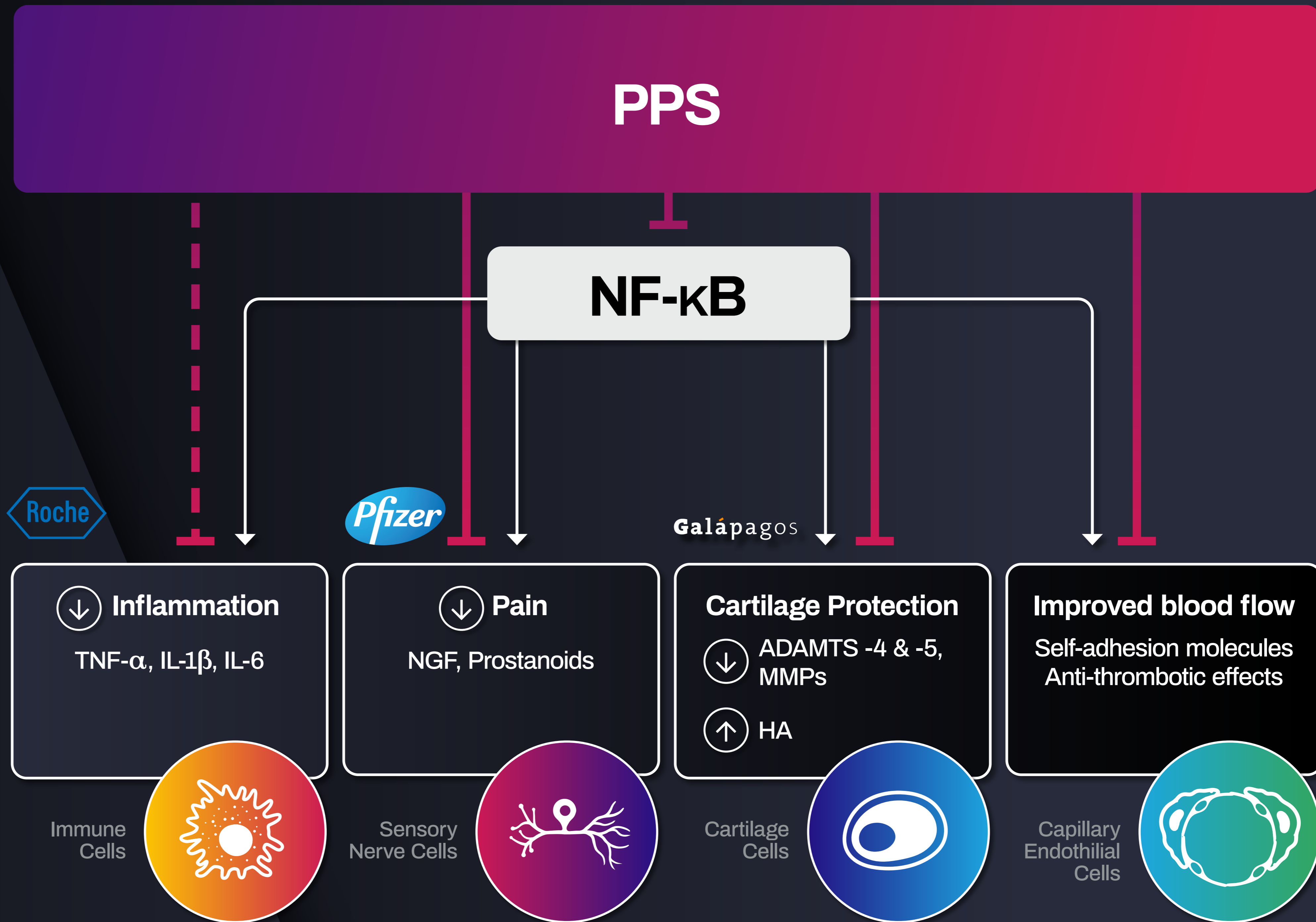




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# Confident of clinical success

- Multiple modes of action
- Previous Phase IIb, SAS and EAP experience
- Global harmonised clinical trial consultation

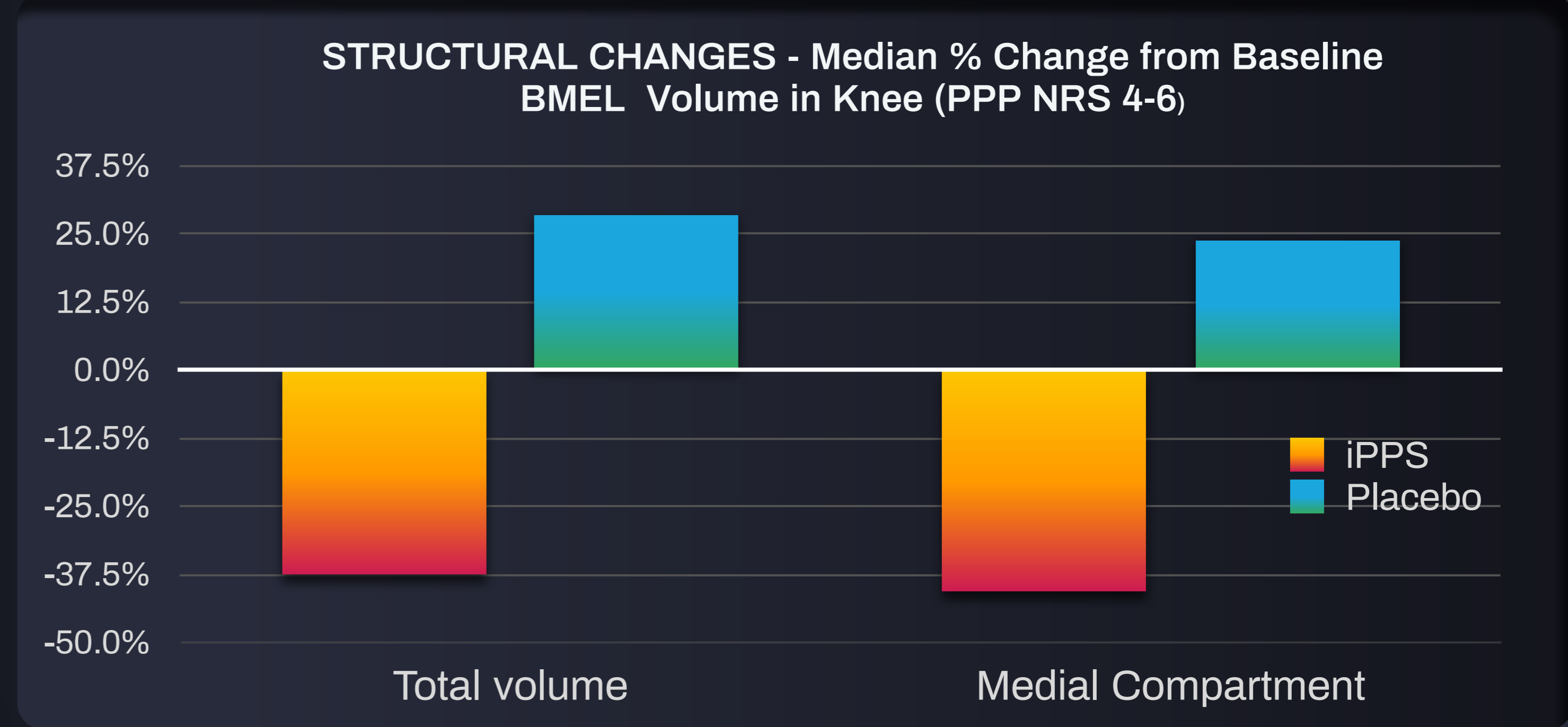
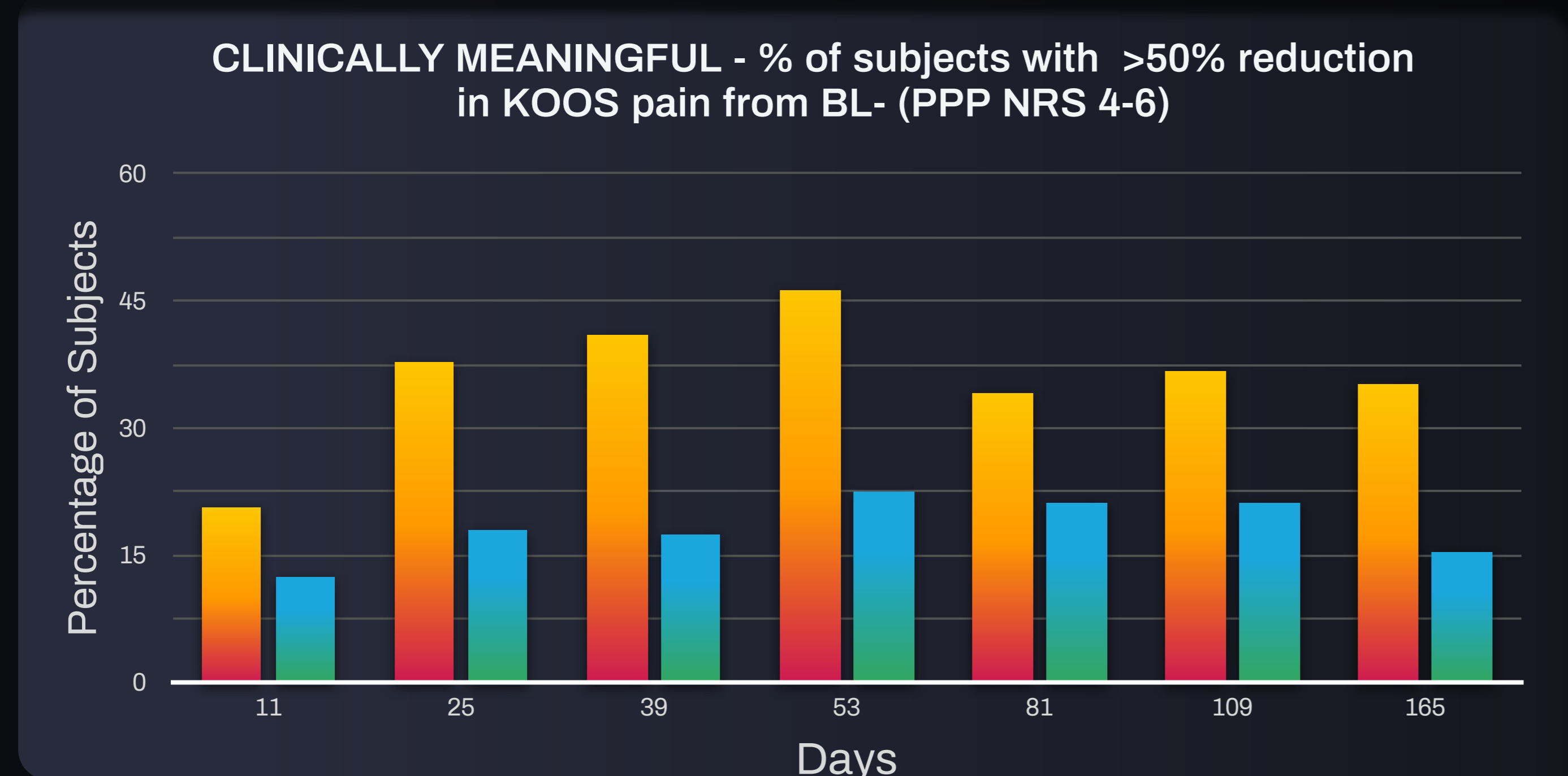
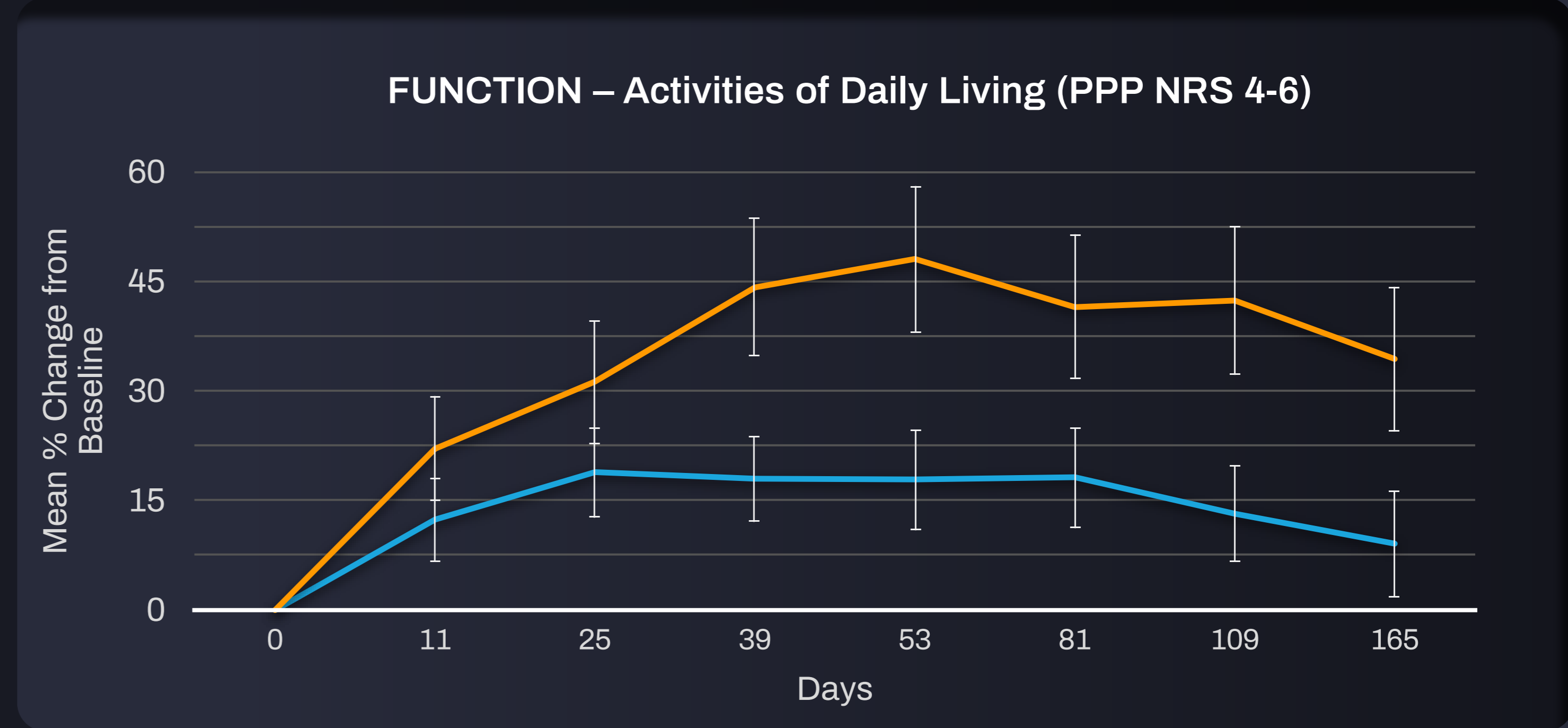
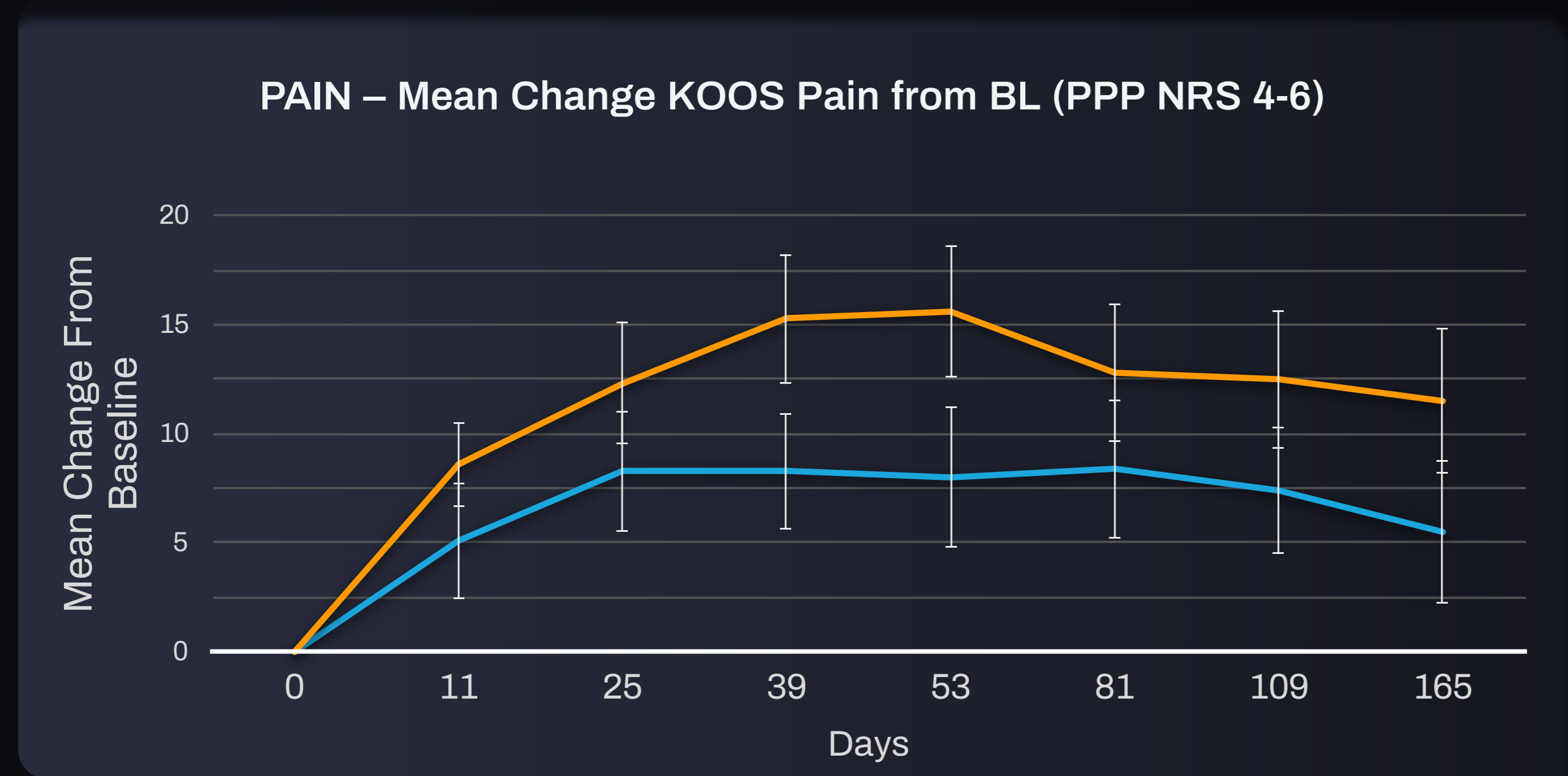




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# Summary Phase 2B data

Phase 2B double blinded, placebo controlled trial. N=112

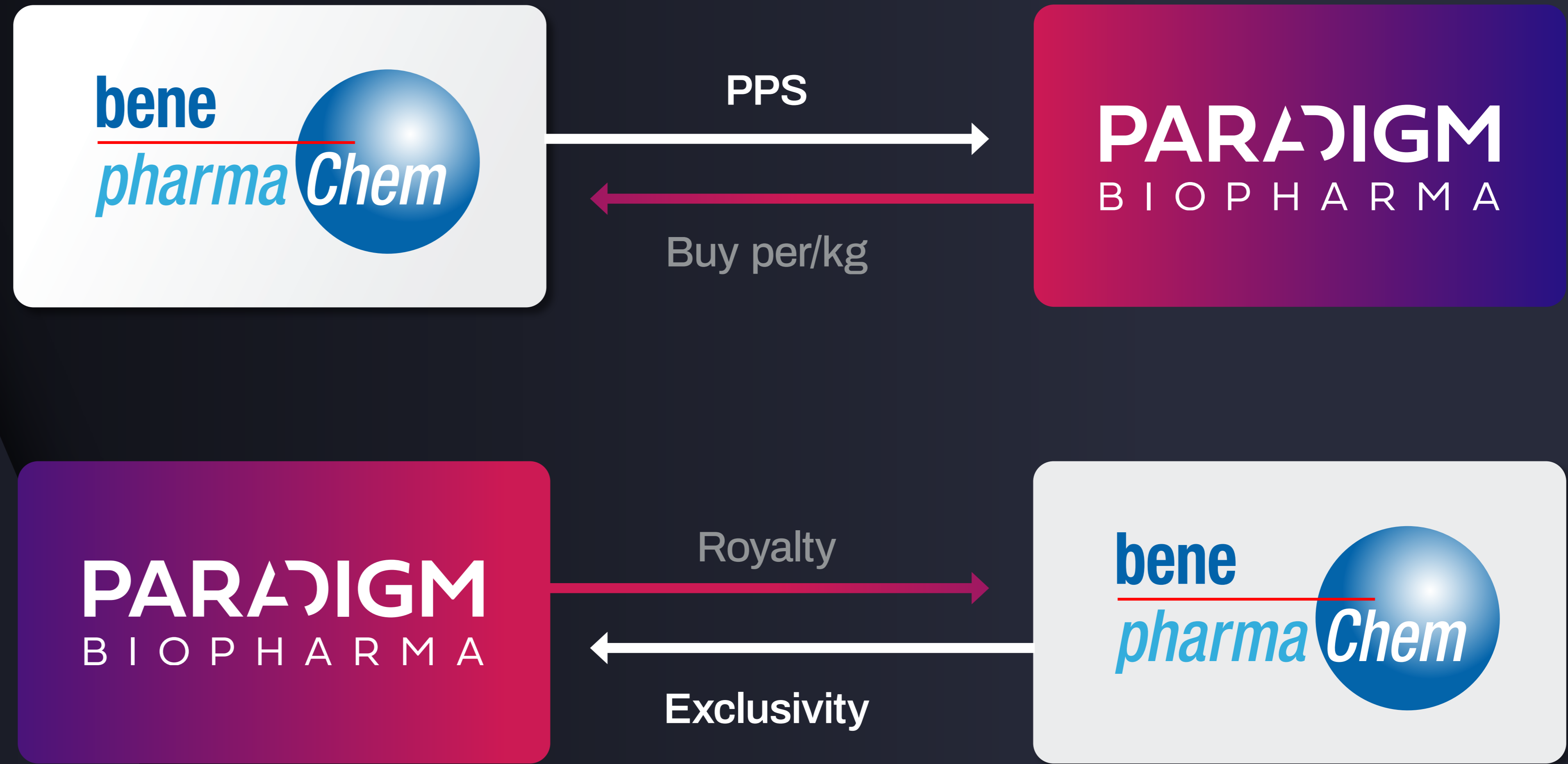




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# Exclusive Supply & Manufacturing

- Long term exclusive supply agreement with bene pharmaChem GmbH
- Bene pharmaChem: original developer of PPS and **only FDA-approved manufacturer.**
- Johnson & Johnson have been sourcing PPS from bene for a different application (bladder pain)
- Manufacturing methods are highly complex and a well kept trade secret
- Agreement grants exclusive supply of only FDA approved PPS for Paradigm's orthopaedic and respiratory programs
- Paradigm to pay bene pharmaChem small single digit (2% on net sales) royalty on commercial sales







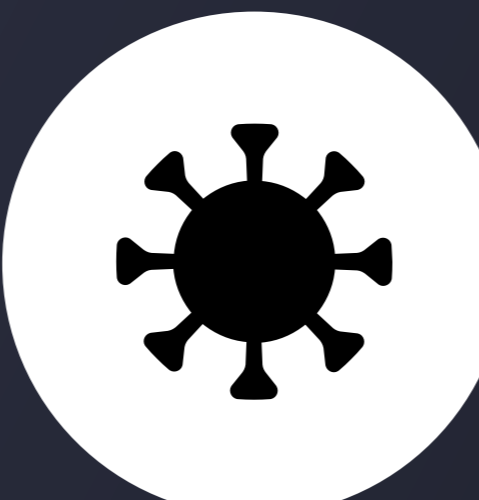
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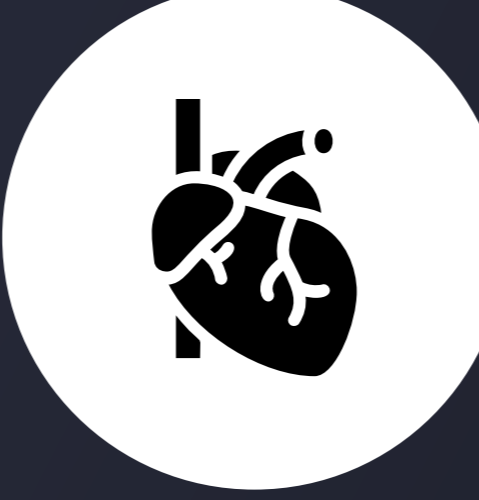
# Strong Patents & IP Position

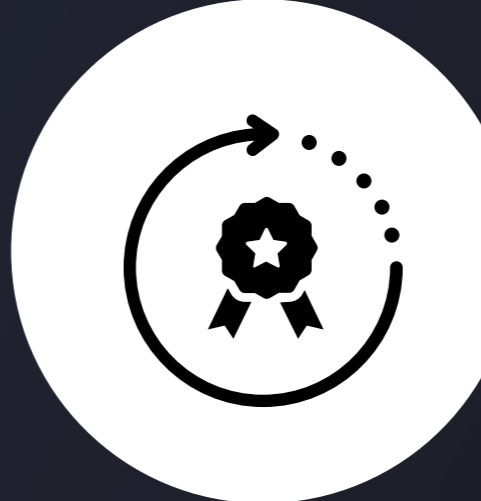
Multi-faceted IP protection increases barriers to entry for potential competitors


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Patent protection using PPS for new indications
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Established regulatory exclusivity and trademarks
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Patent applications for Ross River virus and Chikungunya virus
- 

Patent for Heart Failure indication
- 

Minimum life on patents is 2030 and beyond for more recent patents i.e. 2035 - 2040
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Patents for MPS (ex Japan) + Orphan Status
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Patent applications for osteoarthritis
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Prosecuting new patent applications

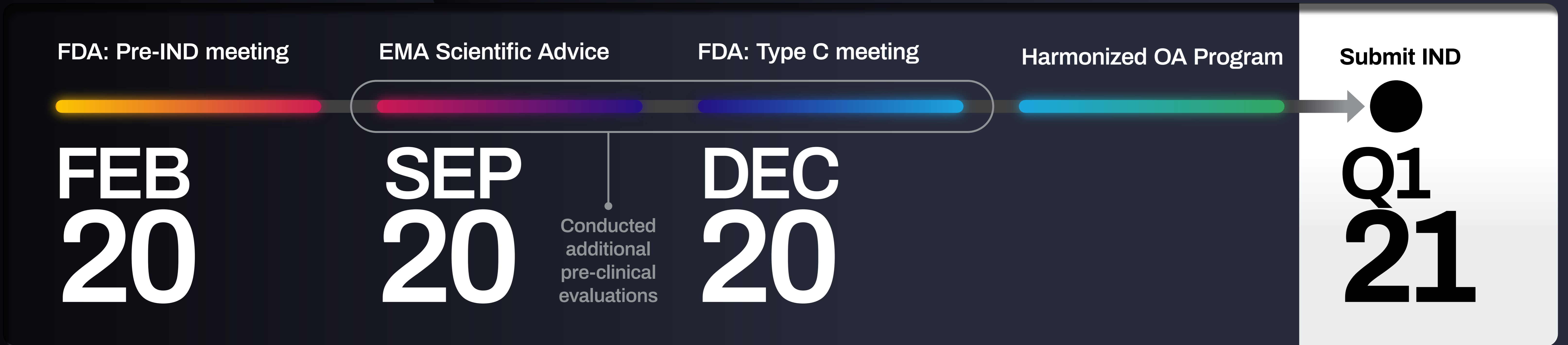




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Feedback from EMA + FDA:

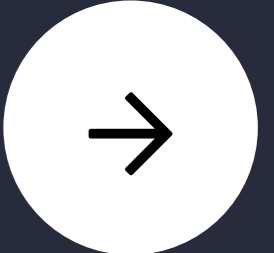
# Global Harmonisation



**Revised Clinical Trial Program will:**

- Confirm minimally effective dose
- Evaluate increased patient numbers to account for potential dropouts related to COVID-19 and aged population, and meet regulatory requirements to collect adequate safety data of iPPS
- Measure confirmed clinical endpoints of WOMAC pain & function
- Confirm Phase III pivotal & confirmatory study
- Improve and expand label for simultaneous registration globally

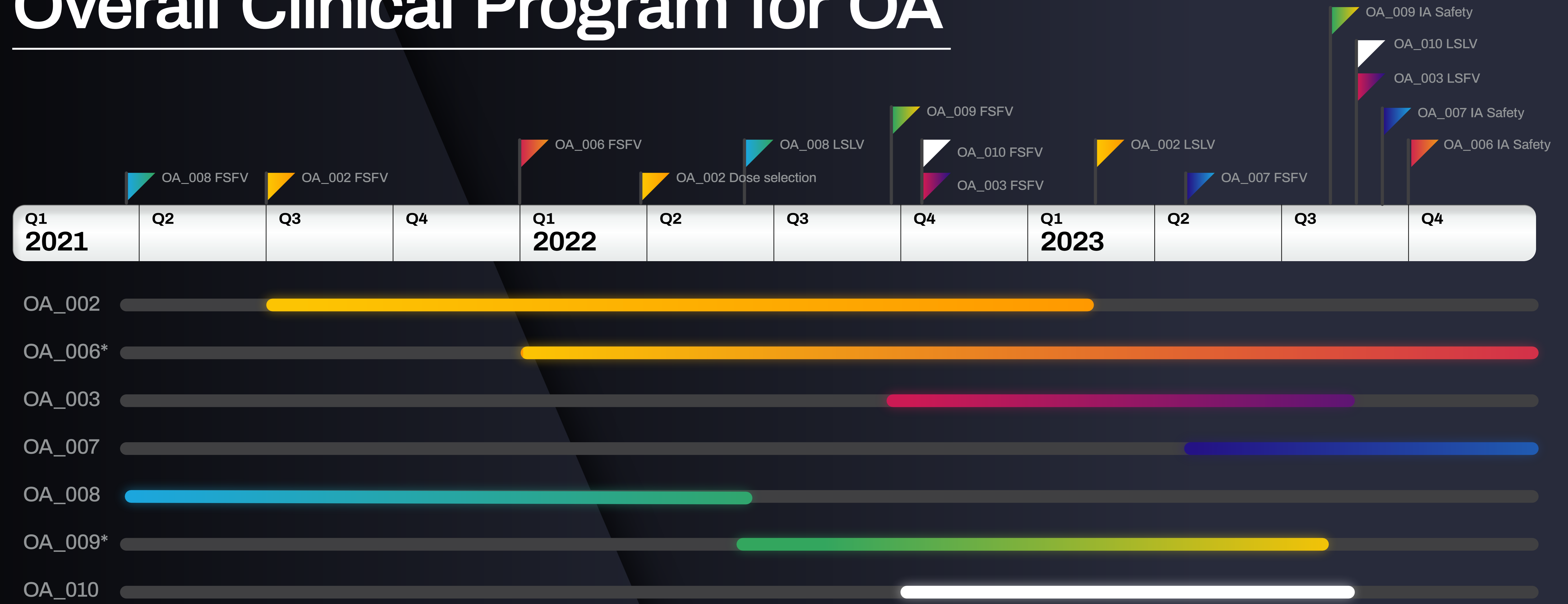
**De-risks overall project**





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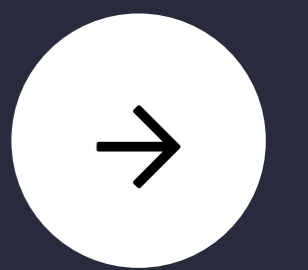
# Overall Clinical Program for OA



NB: Reflects current plans and may be subject to change

\*Safety data cut only, study continues to end 2024

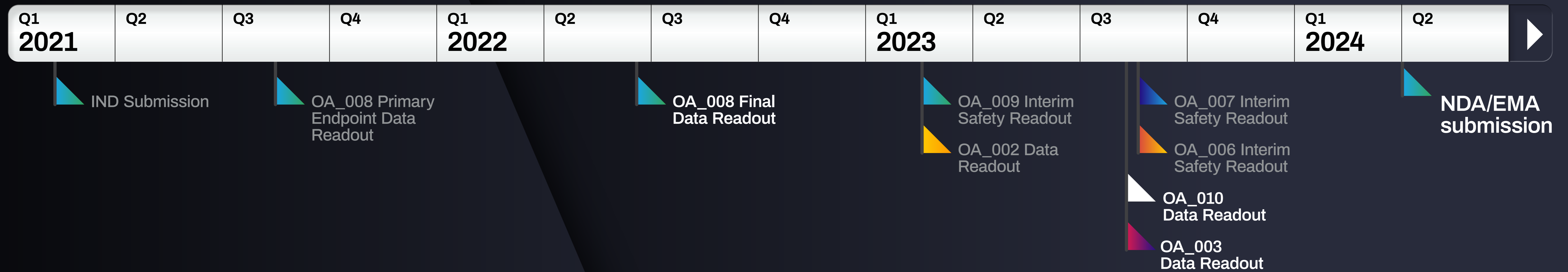
FSFV = First Patient Treated | LSLV = Last Subject Treated | IA Safety = Safety Interim Analysis





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# Milestones and Newsflow



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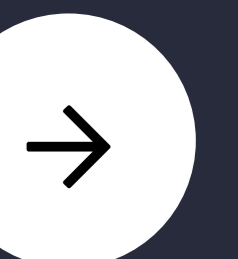




# Summary

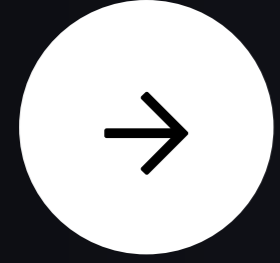
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- Repurposing experts - developing new solutions and addressing unmet needs
- **PPS - first asset - with multi-faceted IP and patent protection**
- Exclusive, scalable supply agreements
- Unique multi-modal action - rich pipeline
- **Lead indication in OA - block-buster opportunity**
- De-risked program through harmonised regulatory and clinical strategy





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