



# BRIM Biotechnology

June 14, 2023

Beyond Research and Innovative Medicines

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# BRIM'S TEAM

Together, Everyone Achieves More

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**BRIM** 全福生物科技  
biotechnology

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# Chairman of the Board



林羣  
Andrew Lin, MBA

董事長  
Chairman

- 
- Chairman of TaiRx, Inc.
  - Chairman of Nuwa Healthcare
  - Founding partner of Affinity Capital
  - Independent Board of Directors for Fubon Insurance
  - Former Chairman of Lotus Pharmaceutical
  - Former Chief Executive Officer of Hasumi Biotechnology International
  - Former Chief Strategy Officer for Chicony Electronics/Clevo Group
  - Former Managing Director with Macquarie Capital
  - Former Chief Financial Officer for Lite-On Technology Group
  - Former Chief Investment Officer for ABN AMRO Asset Management Taiwan
  - Former General Manager for J.P. Morgan Securities Taiwan

# Board of Directors



簡海珊 博士  
Haishan Jang, PhD  
Vice Chairwoman

Founder of BRIM,  
Former Chairwoman  
and CEO of BRIM



曾惠瑾 會計師  
Audrey Tseng,  
MBA

Former Deputy  
Chairman of PwC  
Taiwan



以賽亞資本  
Isaiah Capital LLC  
代表：李誠志  
Rep: Bernard Lee

Angel investor  
since Series A



中加顧問  
CIDC Consultants  
代表：李懿欣  
Rep: Yihsin Lee

Venture capital



安富大健康一號  
Affinity Capital  
代表：程淑芬  
Rep: Sophia Cheng

Private equity

# Independent Board of Directors



李鍾熙 博士  
Johnsee Lee,  
PhD, MBA

Former ITRI President  
Honorary Chairman of  
Taiwan BIO



郭宗銘 會計師  
Howard Kuo,  
MBA

Former Deputy  
Chairman of PwC  
Taiwan



程守真 律師  
James Cheng,  
JD

Partner of Tsar & Tsai Law  
Firm

# C-Suite Team



徐文祺 博士  
WenChyi Shyu, PhD

總經理  
Chief Executive Officer  
超過30年經驗  
30+ years experience

- Former VP and global head of DMPK at Takeda
- Former group director of Discovery Medicine and Clinical Pharmacology at BMS
- Lead approval of over 20 new drugs, including maribavir, dapagloflozin, brentuximab vedotin, and vedolizumab
- Over 100 IND submissions



郭美慧  
Mei-Hui Kuo

營運長  
Chief Operation Officer  
超過30年經驗  
30+ years experience

- Former COO of Senhwa Biosciences
- Former VP and COO of BRIM
- Former VP of operation at Development Center for Biotechnology
- Former Director of New Product Development at TTY Biopharm
- Former Senior VP and Board Member at CDIB Bioscience Venture Management

# C-Suite Team/ Founders



簡海珊 博士  
Haishan Jang, PhD

國際策略長  
Chief Global Strategist  
超過30年經驗  
30+ years experience

- Former Chairman and CEO of BRIM
- Previously a member of Senior Management at Centocor
- Former Manager at DuPont and Sanofi
- Former President at TWI Biotechnology (Taiwan)
- Drug development of Uroxatral, Tirazon, Remicade, Simponi, and Stelara



Frank W. Lee, PhD

研發長  
Chief Scientific Officer  
超過41年經驗  
41+ years experience

- Former Vice President of DMPK at Takeda
- Former member of Senior Management at Millennium Pharmaceuticals and DuPont Pharma
- Drug development of Naprosyn, Anaprox, Ticlid, Toradol, Avodart, Flonase, Imitrex, Zofran, Sustiva, Velcade, Entyvio® and Ixazomib

# Project Team



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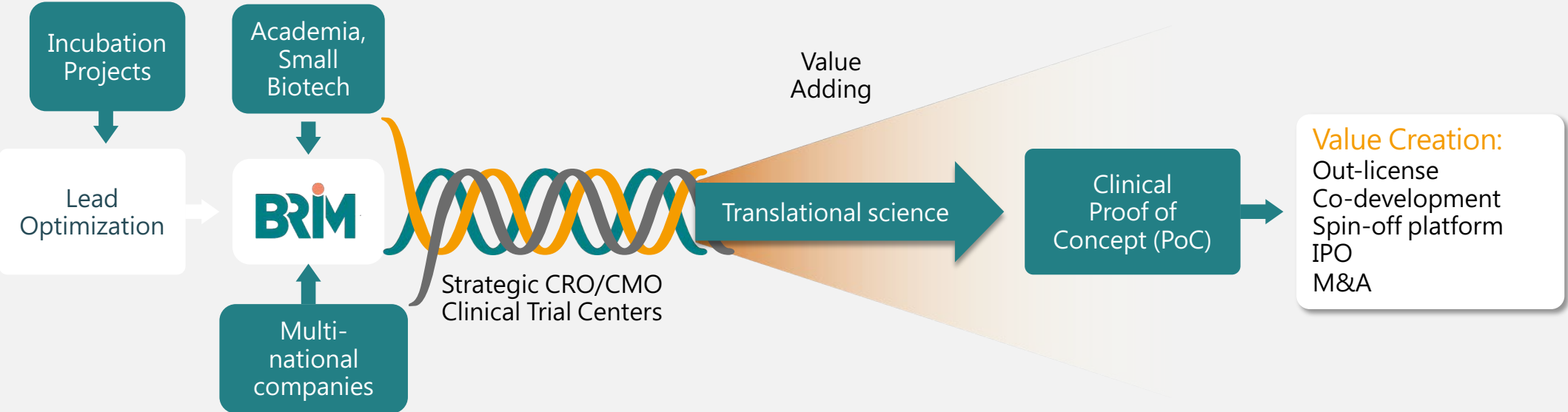


# Our Approach

Maximize ROI through early exit at clinical proof of concept (PoC)

Reduced IND enabling time (1.5-3 years from lead ID to IND submission)

Good budget control of both R&D and fixed costs



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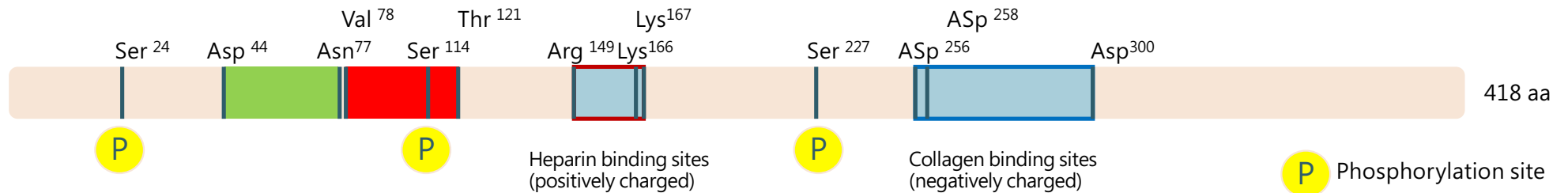


# Regenerative Peptide from PDSP Platform

PEDF-Derived Short Peptide

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# Functional domains of PEDF



34-mer peptide region (Asp<sup>44</sup>-Asn<sup>77</sup>)

- Receptors: Laminin receptor (PEDF-RA;60KDa), LRP6,  $\beta$ -subunit ATP synthase
- Function: anti-angiogenesis, pro-apoptotic tumor cells (anti-tumor)

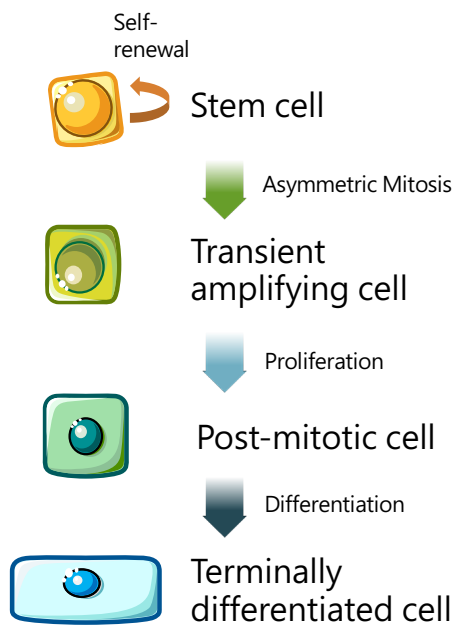


44-mer peptide region (Val<sup>78</sup>-Thr<sup>121</sup>) ; **BRM421 (29-mer): Ser 93-Thr 121**

- Receptors: PEDF-R (PEDFRN/PNPLA2/ATGL;80KDa; P1)
- Function: neurotrophyl, neuroprotective activity, stem cell regeneration, anti-inflammation

# PEDF-derived Short Peptide (PDSP) Platform

Unique features well suited for the discovery and development of new therapeutics



**Promotes the proliferation and differentiation of stem cells** and then repairs damaged tissues

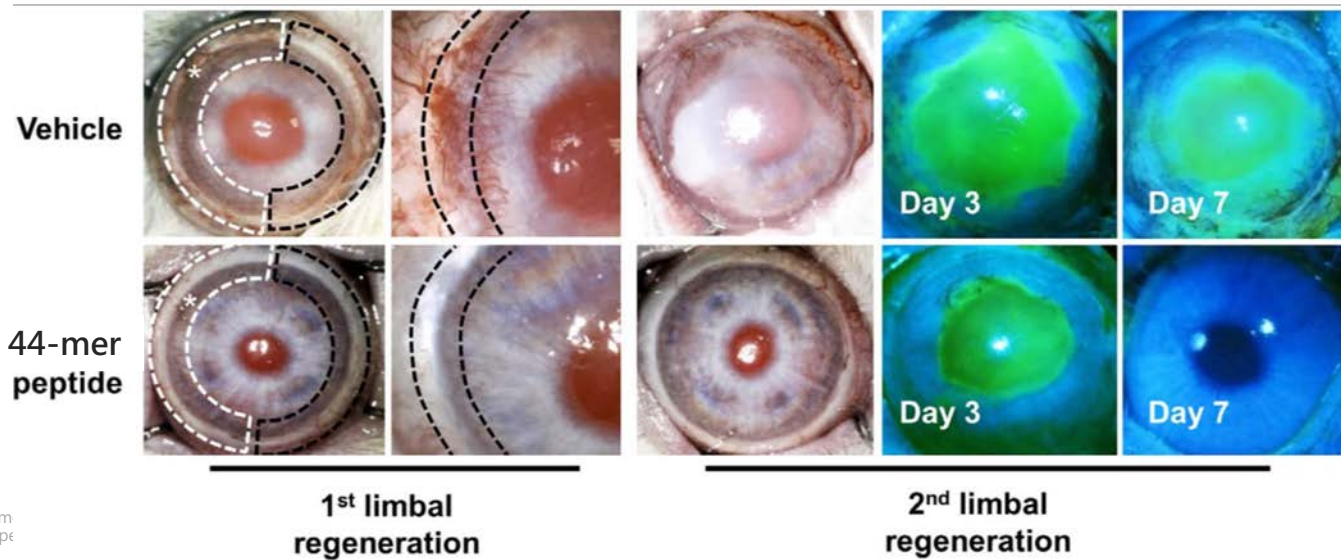
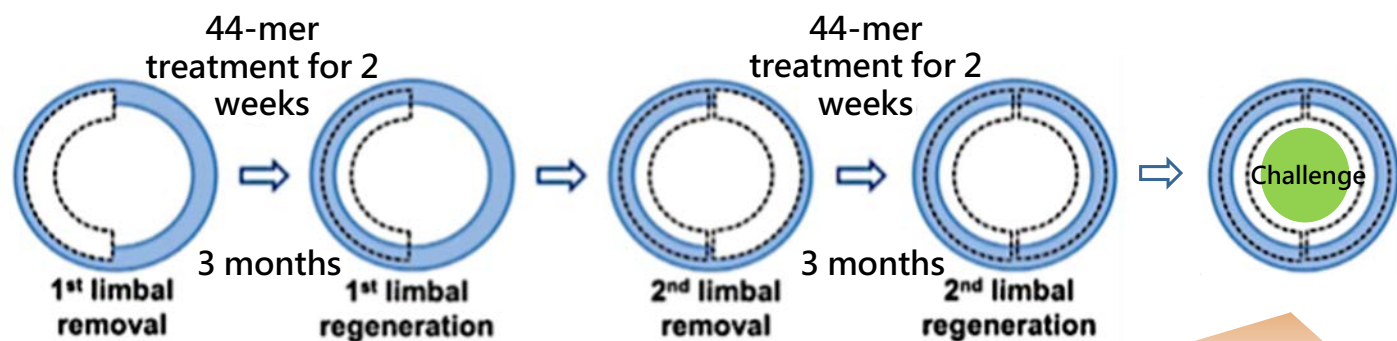
**Early-onset potential** in various disease animal models

**Low immunogenicity** due to short peptides

**No endotoxin risk** with drug substance produced by solid-phase peptide synthesis (SPPS)

**High pharmaceutical stability** with formulation optimized

# PDSP can regenerate limbus after severe damage

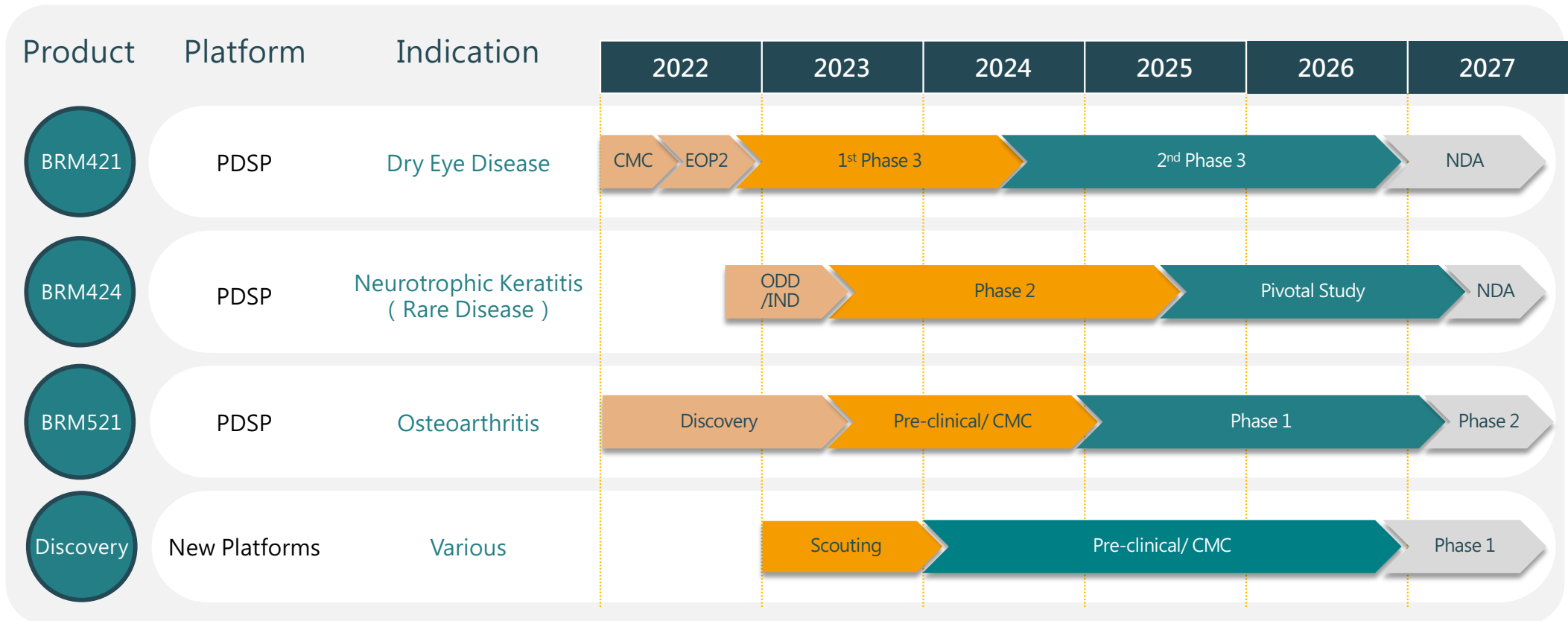


*Invest Ophthalmol Vis Sci.* 2016 May 1;57(6):2629-36.

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# Development Milestones



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# BRM421 for Dry Eye Disease (DED)

First-in-class regenerative peptide

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Global DED  
population:

915 million

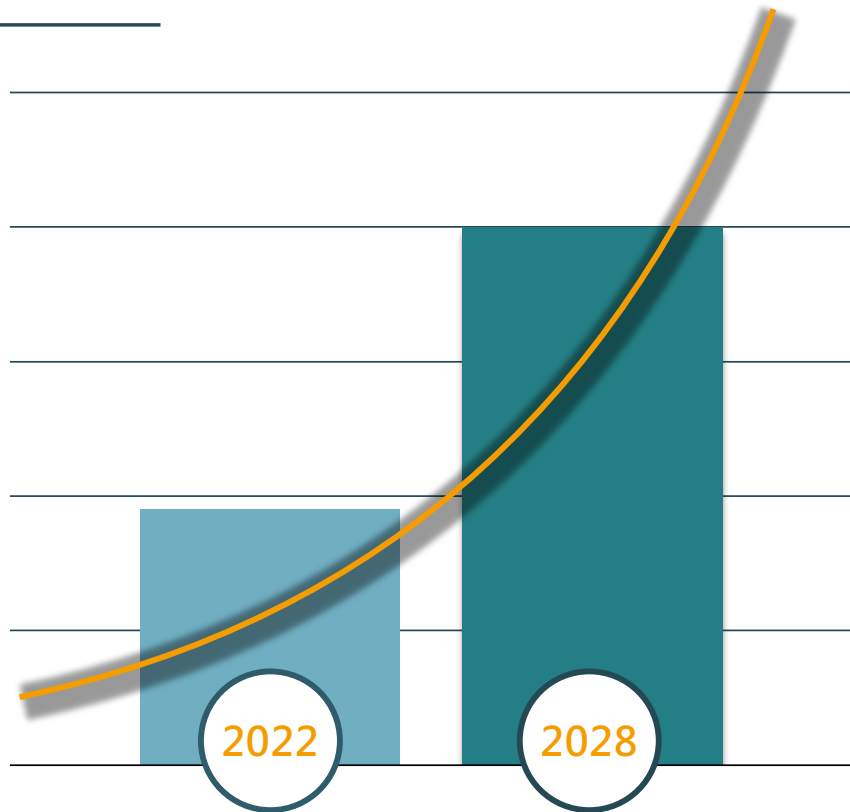
Severe DED:

~90 million





# DED Market



2022 Global market size:

**4.5 Billion USD<sup>1</sup>**

2028 Global market size projection:

**~6.3 Billion USD<sup>1</sup>**

CAGR (2022-2028)

**4.8%<sup>1</sup>**

References:

1. <https://www.researchandmarkets.com/reports/5732359/dry-eye-syndrome-market-global-industry-trends>

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# DED competitors on market

COMPANY/ DRUGS	DRUG TYPE	MOA / API	STATUS	ONSET (WEEKS)	FREQUENCY	SIDE EFFECT	PATENT	COMMENTARY
BRIM/ BRM421	peptide	stem cell regeneration/ PEDF-derived peptide	US Phase 3	2	3x daily	instillation site reaction (37%)	2043	visual improvement
Novartis/ Xiidra	small molecule	anti-inflammation / LFA antagonist	US approved EU withdrawn	12	2x daily	irritation (18%), dysgeusia (13%)	2033	\$7,600/yr
Allergan (AbbVie)/ Restasis	peptide	anti-inflammation / ciclosporin	US approved CN trial	24	2x daily	burning, stinging (17%)	2024	\$7,600/yr
Kala/ Eysuvis	small molecule	anti-inflammation / nano particle steroid	US approved	2	4x daily	conjunctivitis	2033	steroid may have risks for IOP
Oyster Point/ Tyrvaya	small molecule	tear production/ nicotinic acetylcholine receptor agonist	US approved	4	2x daily	sneezing (82%), cough (16%), throat irritation (13%)	2035	nasal spray; poor patient adherence
B&L/ Miebo	small molecule	artificial tear/ semifluorinated alkane	US approved	8	4x daily		2038	for mild DED patients
Essex / bFGF	protein	cornea repair / FGF	CN approved	2	6x daily	cannot use over two weeks	N/A	increases cancer risk
UNI-BIO / rhEGF	protein	cornea repair / EGF	CN approved	2	4x daily	cannot use over two weeks	N/A	increases cancer risk
Santen/ Diquas	small molecule	tear quality / P2Y2 receptor agonist	JPN approved CN approved US P3	4	6x daily	hypersensitivity, itching, irritation, conjunctivitis	2023	NA
Otsuka/ Mucosta	small molecule	tear quality / prostaglandin agonist	JPN approved US failed	4	4x daily	dysgeusia (9.7%)	2026	NA

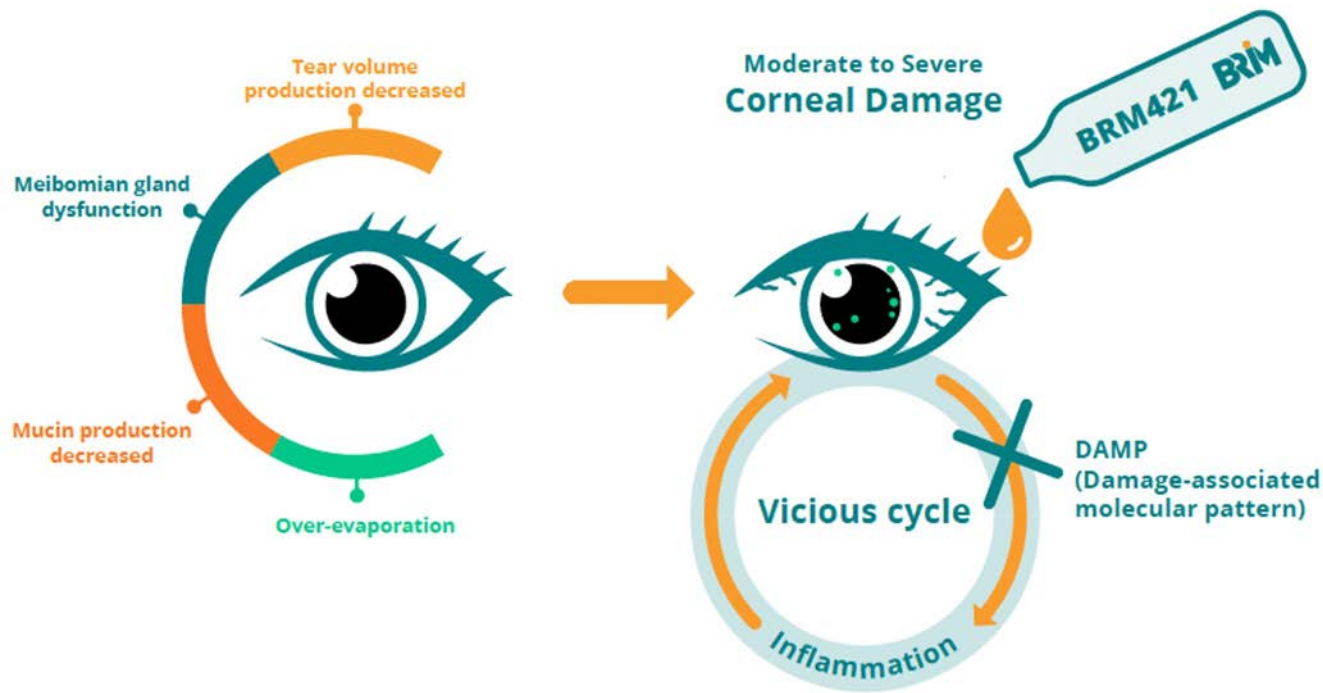
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# DED competitors in development

COMPANY/ DRUGS	DRUG TYPE	MOA / API	STATUS	ONSET (WEEKS)	FREQUENCY	SIDE EFFECT	PATENT	COMMENTARY
BRIM/ BRM421	29mer peptide	stem cell regeneration/ PEDF-derived peptide	US Phase 3	1-2	3x daily	instillation pain (37%)	2043	visual Improvement
Aldeyra/ reproxalap	small molecule	anti-inflammation/ RASP inhibitor	US NDA Nov, 2023	0-12	4x daily	instillation pain (>90%)	2037	patient withdrawal due to AEs
Allysta/ ALY688	10mer peptide	anti-inflammation + cell regeneration/ adiponectin analogue	US Phase 2b/3	8 (2)	2x daily		2037	expect results in Q2, 2023
HanAll/ tanfanercept	protein fragment	anti-inflammation/ TNFa inhibitor	US/CN Phase 3	8	2x daily	conjunctivitis and redness (6%)	2033	2 more P3 ongoing; AE pt withdrawal
Allergan/ tavilermide	cyclic tripeptide	growth factor/ NGF mimetics	US Phase 3	4	2x daily		2028	(MIM-D3) discontinued
RegeneRx/ RGN-259	43mer peptide	cell migration/ thymosin β4	US Phase 3	2-4	4 x daily	instillation pain (6%)	2035	pre-BLA on 2/28 NK P3
Stuart/ ST-100	peptide	restore structure/ collagen mimetic	US Phase 2	2-4	2x daily		2037	CMP is an old tech
Kala/ KPI-012	protein mixture	stem cell regeneration/ MSC secretome	US Phase 2b	1-4	2x daily		2040	for PCED trial

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# Proposed MoAs of PDSP for DED treatment



**Accelerate corneal repair**  
Activate limbal stem cells

**Improve tear quality**  
Maintain goblet cell number  
Restore meibomian glands

**Improve visual functions**  
Promote neurotrophic tissue protection

**Break vicious cycle**  
Inhibit inflammation

# BRIM has licensed BRM421 CN rights to China Grand Pharm

## China Grand Pharm (CGP), HK: 0512

large healthcare group in China  
with vast ophthalmology  
distribution channels

**远大医药(中国)有限公司**  
GRANDPHARMA(CHINA)CO.,LTD.

Over  
**USD 85M**  
total deal size

**China  
Hong Kong  
Macau**  
regional rights

# BRIM established strategic alliance with ORA

## ORA, Inc Ophthalmology CRO

execute over 70% of DED trials  
in the US



ORA owns  
stacks in  
BRM421 P3 trial  
as a strategic  
partner

Share sales  
royalty

Assist BRM421  
global out-  
licensing

# BRM421's price is competitive

Product/ Company <sup>1</sup>	Package	Daily	Treatment Cycle	Retail Price <sup>2</sup>	Price/ cycle	2022 Sales
Xiidra/ Novartis (lifitegrast 5%)	60 ampules/ Box	2 times	3 months	US\$671.83/ Box/ month	US\$2015.49	487m
Restasis/ AbbVie (cyclosporin 0.05%)	60 ampules/ Box	2 times	6 months	US\$633.96 (US\$156.70 generic) / Box/ month	US\$3803.76 (US\$940.20)	1.29b
Cequa/ Sun Pharma (cyclosporin 0.09%)	60 ampules/ Box	2 times	3 months	US\$551.69/ Box/ month	US\$1655.07	est. 100m
Eysuvis/ KALA (corticosteroids 0.25%)	1 bottle	4 times	2 weeks	US\$493.08/ bottle/ 14 days	US\$493.08	9.4m (2021)
Tyrvaya/ Oyster Point (0.03mg/ spray)	2 bottle/ carton	2 times	1 month	US\$623.86/ carton/ month	US\$623.86	1.2m, 2021 Q4 13m, 2022 Q1-3
BRM421/ BRIM	42 ampules/ Box	3 times	2 weeks	<US\$150.00/ Box/ 14 days <sup>3</sup>	<US\$150.00	N.A.

Notes:

- 1. All products listed are US products.
- 2. Prices for marketed products are retrieved from goodrx.com on 2023-04-24.
- 3. Assuming the best estimate of the gross profit margin of **over 90%** from COGS

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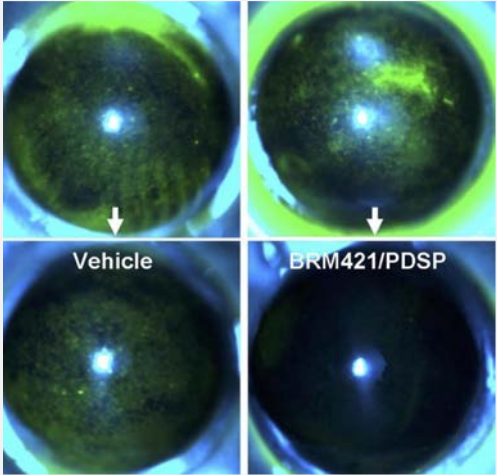
# BRM421 efficacy in mouse DED model

## Topical BRM421 treatment in mouse DED model

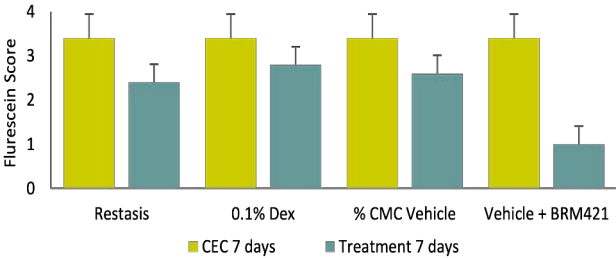
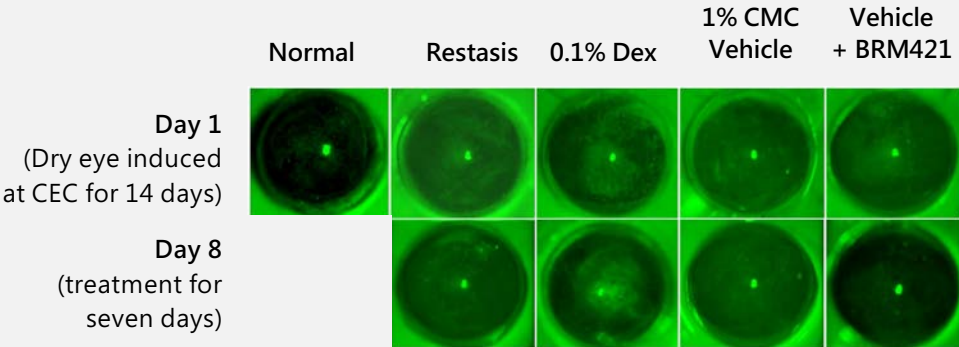
Mice housed at CEC for 14 days without topical treatment



Pre-treatment



Post-treatment (topical 7 day)



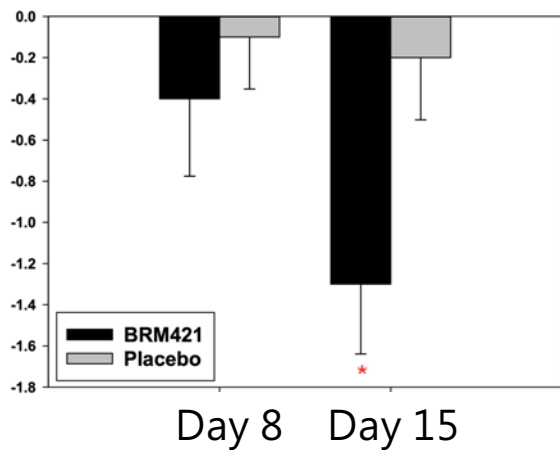
Dex: Dexamethasone  
CMC: Carboxymethyl cellulose

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# First-in-Human study showed a positive trend

## Sign



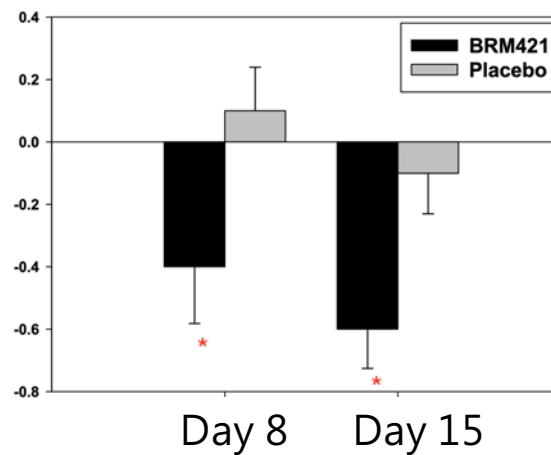
### Ad Hoc Analysis:

Mean change from Baseline

Fluorescein total corneal staining scores

Moderate to severe DED patients

## Symptom



### Ad Hoc Analysis:

Mean change from Baseline

Dryness from Ora Calibra® Ocular Discomfort & 4-Symptom

Moderate to severe DED patients

\* p < 0.05

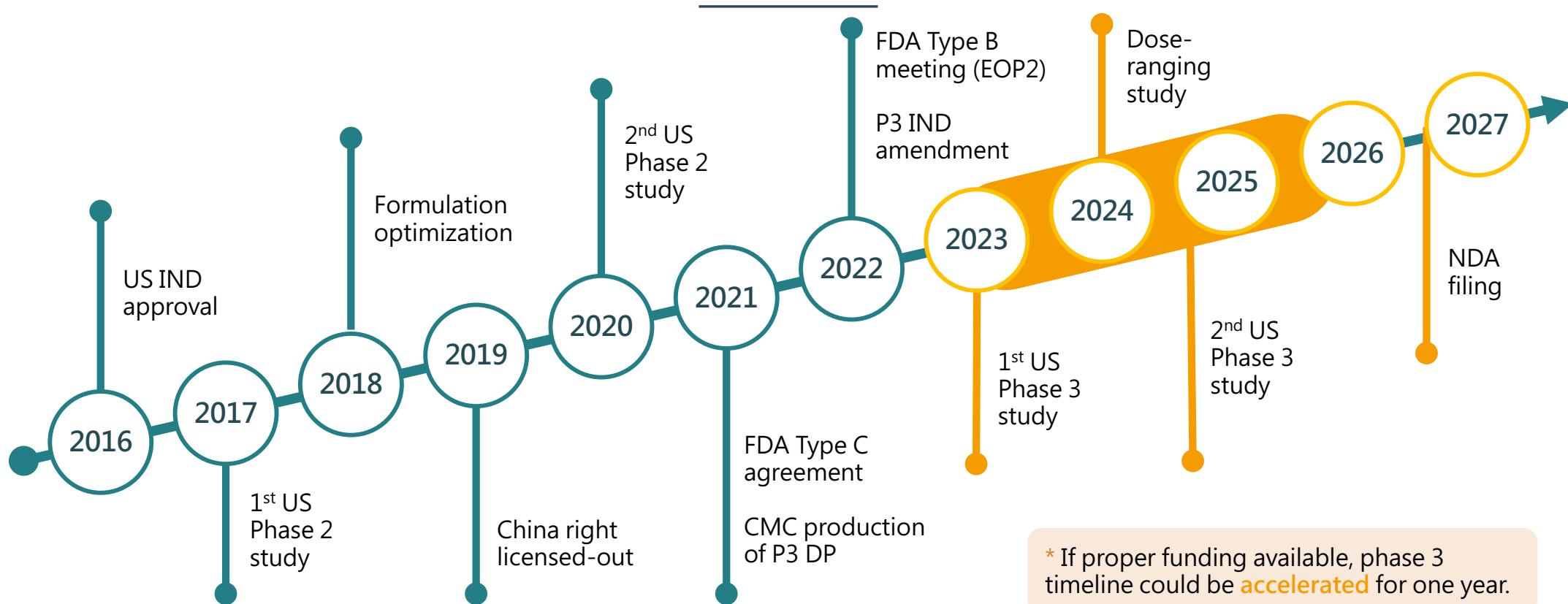
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# BRM421 is in Phase 3 study

	Phase 2/3	Phase 3	
Enrollment Criteria	Moderate-to-severe	Moderate-to-severe	* same design
Duration	14 days	14 days	* same design
Endpoint: Sign	Fluorescein total corneal staining at Visit 4 (Day 15)	Fluorescein total corneal staining at Visit 4 (Day 15)	* same design
Endpoint: Symptom	Ocular Discomfort & 4-Symptom Dryness at Visit 4 (Day 15)	Visual Analogue Scale (VAS) Burning and Stinging at Visit 3 (Day 8)	* based on SIH data; FDA agreed (EOP2)
Formulation Stabilizer	High concentration	Low concentration	* no additional tox needed; FDA agreed (Type C)
Enrollment Number	220	~700	* calculated from SIH patient variability

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# BRM421 development timeline



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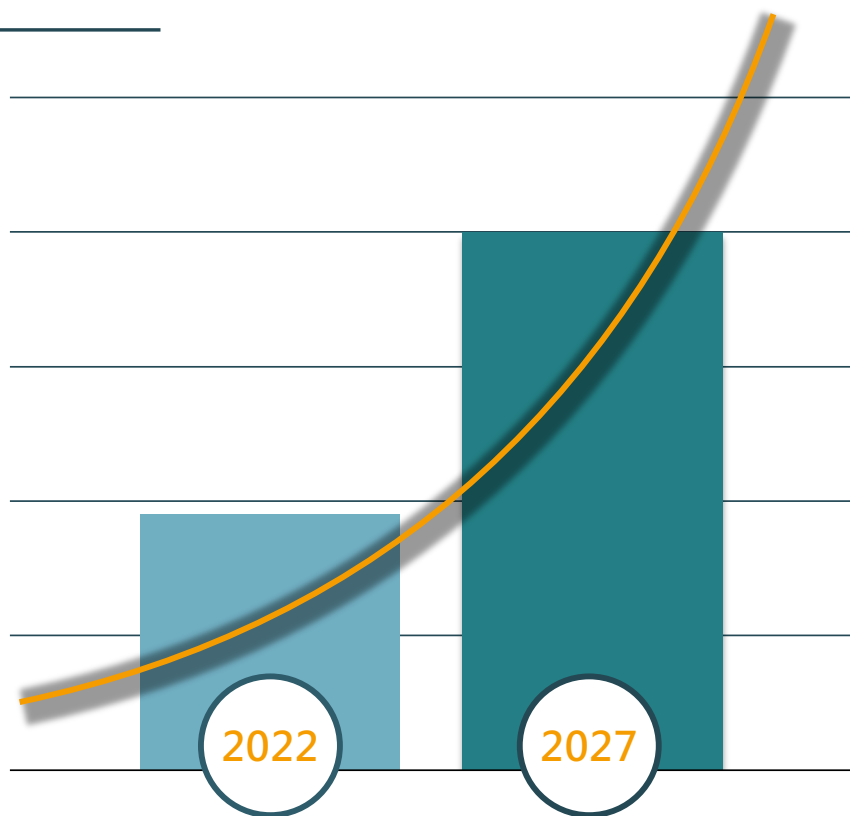
# BRM424 for Neurotrophic Keratitis (NK)

First-in-class regenerative peptide

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# NK Market



2022 Global market size:

**146.7 Million USD<sup>1</sup>**

2027 Global market size projection:

**321.6 Million USD<sup>1</sup>**

CAGR (2022-2027)

**17%<sup>1</sup>**

References:

1. <https://www.sdki.jp/press-details/neurotrophic-keratitis-market/917#>

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# Oxervate

API	rhNGF (nerve growth factor) 118 a.a., 13kDa/ produced in E. coli
MOA	NGF support corneal integrity by: 1) corneal innervation; 2) tear secretion; 3) cell proliferation and differentiation
Effective Onset	8 weeks
Side Effects	eye pain; eye inflammation; corneal deposits; ocular hyperemia; foreign body sensation
NDA	P1/2 plus P2 trials; 204 patients
Endpoint	percentage of patients with completed healing
Storage	-20°C at pharmacy; 4°C up to 14days
Cost/ year	US\$96,992 (\$1,732/vial x 56 days x 1 cycles/year)

\*PDSP 29mer is synthesized by SPPS

\*29mer can activate stem cells and has neurotrophic effects

\*29mer has early onset effects (1-2 weeks for DED)

\*29mer is well tolerated with mild irritation during instillation

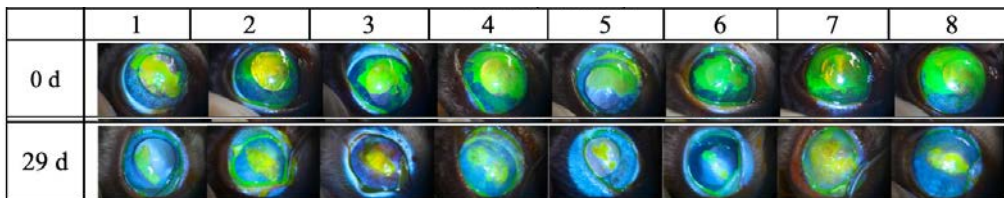
\*29mer in current formulation can be stored at 4°C long term

\*29mer can be priced affordably

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# BRM424 promoted complete corneal healing in NK

Vehicle



BRM424

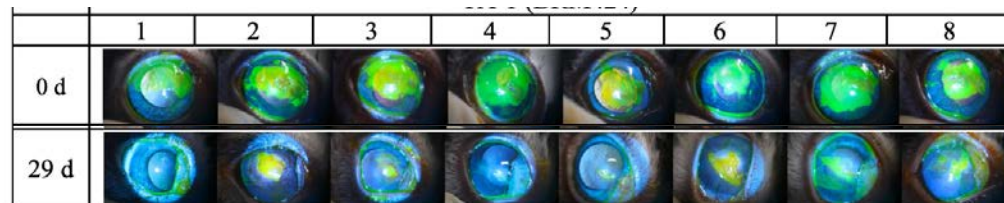
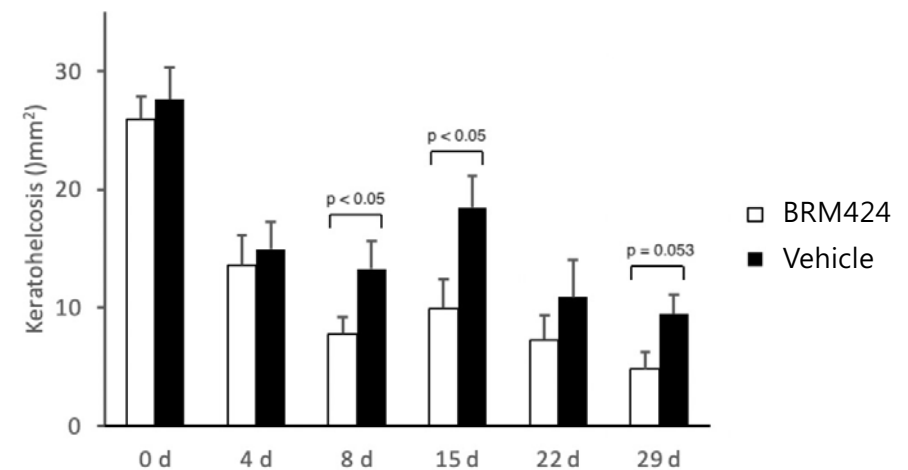


Figure 1. Corneal Ulcer Area versus Day Plot

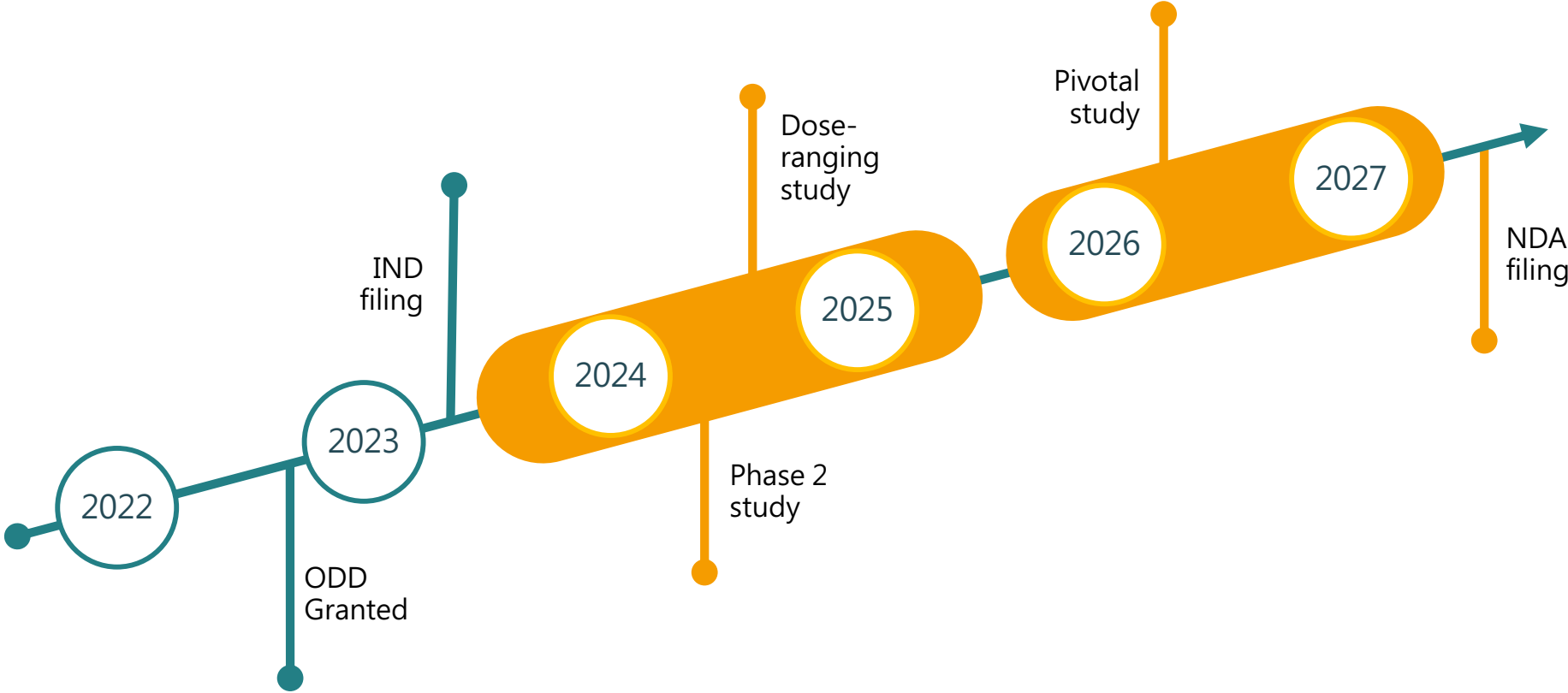


## Chinchilla Rabbit Neurotrophic Keratitis Model:

- The ophthalmic nerve (V1) of the trigeminal nerve is injured with sodium hydroxide (NaOH) unilaterally 5 days prior to treatment.
- Usually, corneal epithelial defects are developed 3-5 days post-surgery, and the corneal ulcer is developed 5-7 days post-surgery.

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# BRM424 development timeline



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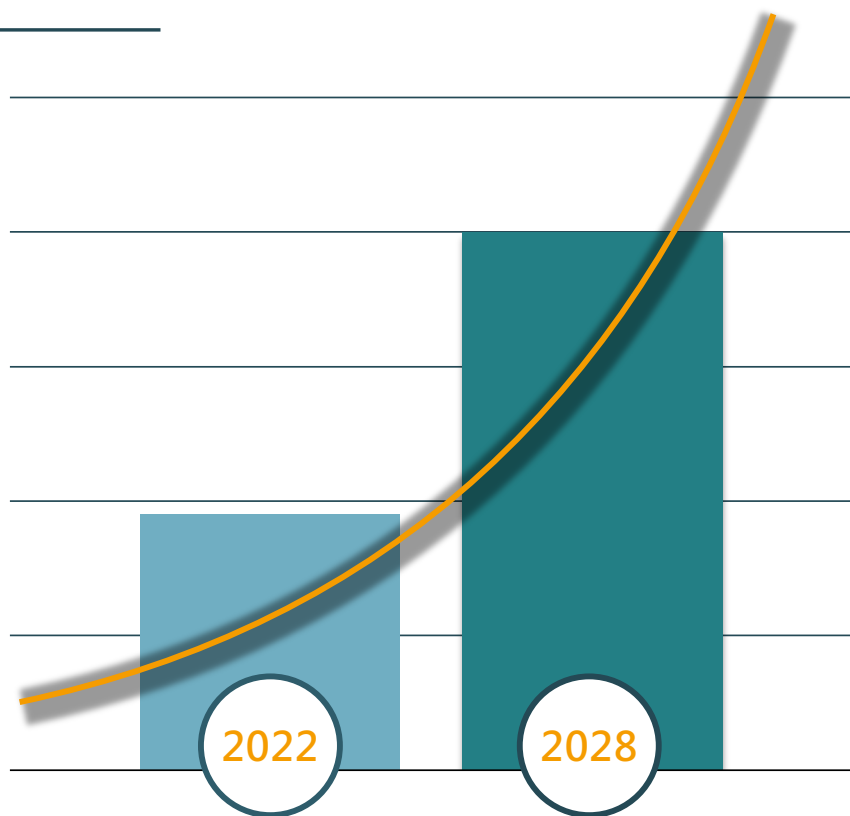


# BRM521 for Osteoarthritis (OA)

First-in-class regenerative peptide

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# OA Market



2022 Global market size:

**7.3 Billion USD<sup>1</sup>**

2028 Global market size projection:

**~11.7 Billion USD<sup>1</sup>**

CAGR (2022-2028)

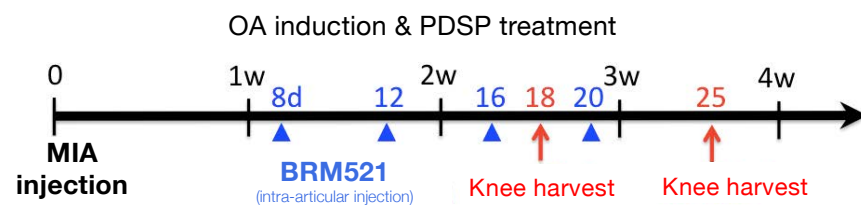
**8.18%<sup>1</sup>**

References:

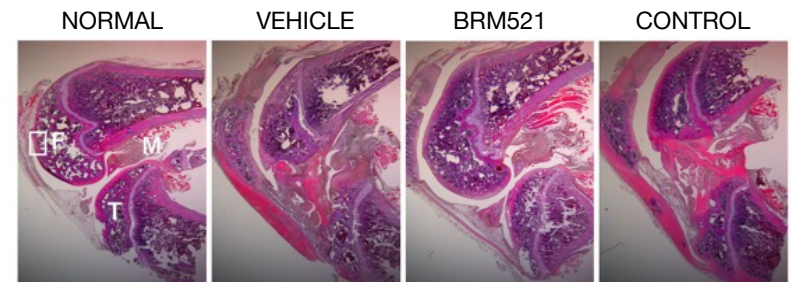
1. <https://www.researchandmarkets.com/reports/5769366/osteoarthritis-therapeutics-market-global>

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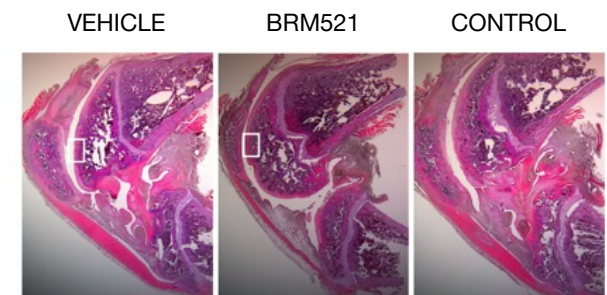
# BRM521 promotes joint cartilage regeneration after MIA injection



Post MIA  
18 days



Post MIA  
25 days



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# Effectively relieves OA pain in MMT model at day 7

## Measurement:

**Treatment:** IA injection on Week2 post-MMT, weekly for 3 weeks

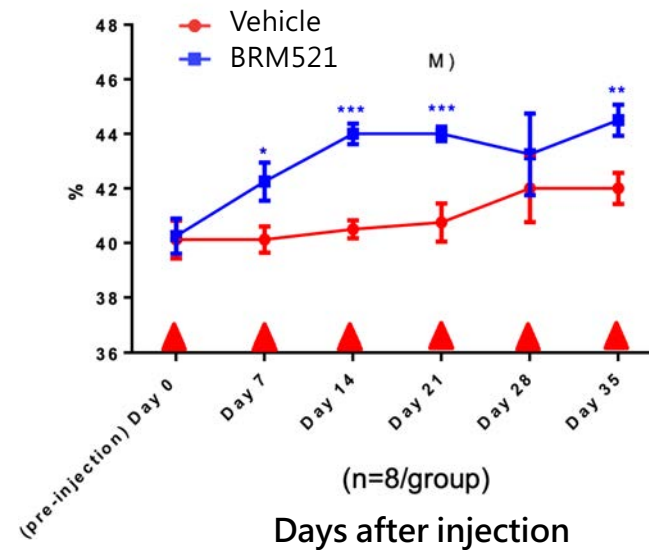
**Sacrifice:** after 1-week final IA injection

Weight-bearing ratio (%) =

Weight on right (OA) leg

Weight on right + left legs

## Weight-bearing ratio ( pain level )



BRM521 vs Vehicle :  
\* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$

Day 0 : 7 days after surgery

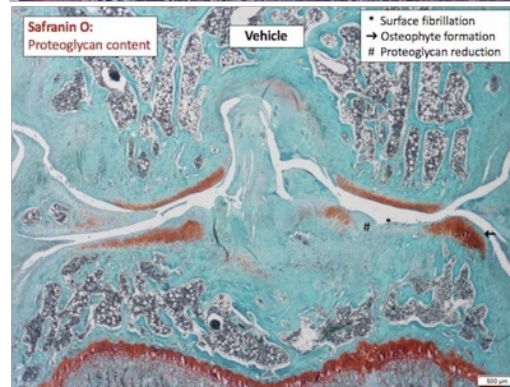
Error bar: SEM

# BRM521 promotes joint cartilage regeneration in the MMT model

## Vehicle

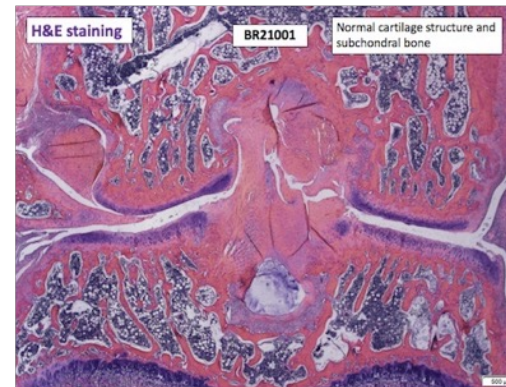


- Fibrous stroma in bone marrow
- Subchondral bone collapse
- Cartilage matrix loss

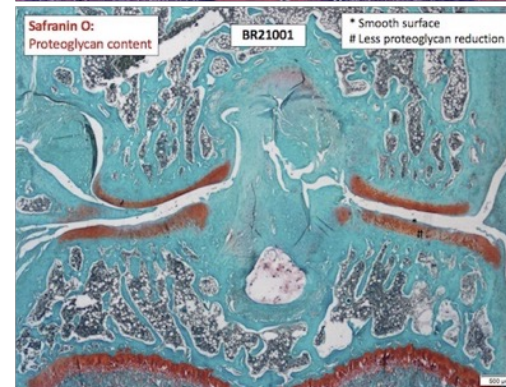


- Surface fibrillation
- Osteophyte formation
- Proteoglycan reduction

## BRM521



- Normal cartilage structure
- Normal subchondral bone



- Smooth surface
- Less proteoglycan reduction (by Safranin O staining)

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# Thank you

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Beyond Research and Innovative Medicines

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