



Interim Clinical Data Readout of Program HXP056 (Clinical Compound: HX9428)

Haixi Pharmaceuticals

HKEX Main Board Listing: 02637



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Haixi Pharmaceuticals – A Fully Integrated Innovative Pharma Company



Haixi Fuzhou New District Site

Solid Business Performance

- 2025 Revenue up 25% to RMB ¥582M (~\$85M); Net Profit up 30% RMB ¥177M (~\$26M); EPS up 26% to RMB ¥2.55 (~\$0.37);
- 2025 R&D Expenditure up 9% to RMB ¥73M (~\$10.7M);
- Gross profit margin 83%; net assets RMB ¥1.2B (~\$176M); debt-to-asset ratio 4.9%.

Experienced Management Team

Co-Founders



Dr. Kang Xinshan Chairman / General Manager

25+ Years of Pharma Industry Experience

- ◆ National High-Level Overseas Talent; Professor-level Senior Engineer
- ◆ Former Chief Pharmacist, Zhijiang Betta Pharmaceuticals
- ◆ Ph.D. in Chemistry, Princeton University



Ms. Feng Yan Executive Director

22+ Years of Pharma Industry Experience

- ◆ Former Laboratory Director at McMaster University; Research Manager at Yale School of Medicine
- ◆ Master's Degree, Chinese Academy of Sciences



Senior Management



Dr. Zhang Mingqiang President, R&D & Global Affairs

30+ Years of Pharma Industry Experience

- ◆ Multiple MNC roles: CTO/VP External R&D at Roche China; Corporate VP/Asia-Pacific R&D President at MSD; Corporate VP R&D/Asia R&D Head at Amgen
- ◆ Leading global expansion: overseas BD, innovative drug R&D and commercial partnerships



Dr. Chen Guangming Deputy GM / Chief Scientific Officer

30+ Years of Pharma Industry Experience

- ◆ Former Senior Research Fellow at PTC Therapeutics (Nasdaq); led development of multiple global innovative drugs
- ◆ Leads the company's R&D and responsible for program initiation and execution



Experienced, Global- Minded Management Team



- Average 20+ Years of Pharma Industry Experience



- R&D team of 90+ researchers; ~30% with Ph.D. or Master's degrees
- Core R&D team: avg. 10 years of pharma industry experience

Veteran MNC Executives in SAB



Dr. David Nicholson

30+ Years of strategic business and R&D leadership experience

- ◆ EVP & Chief R&D Officer, ALLERGAN
- ◆ CTO & EVP R&D, Executive Board Member, BAYER CROP Sci
- ◆ SVP Licensing & Knowledge Management, MSD
- ◆ SVP Global Project Management and Drug Safety, Schering-Plough
- ◆ EVP R&D, ORGANON
- ◆ Leadership contribution to large number of new medicines incl those in eye care (eg XEN Gel Stent, Durysta) & oncology (eg Keytruda)



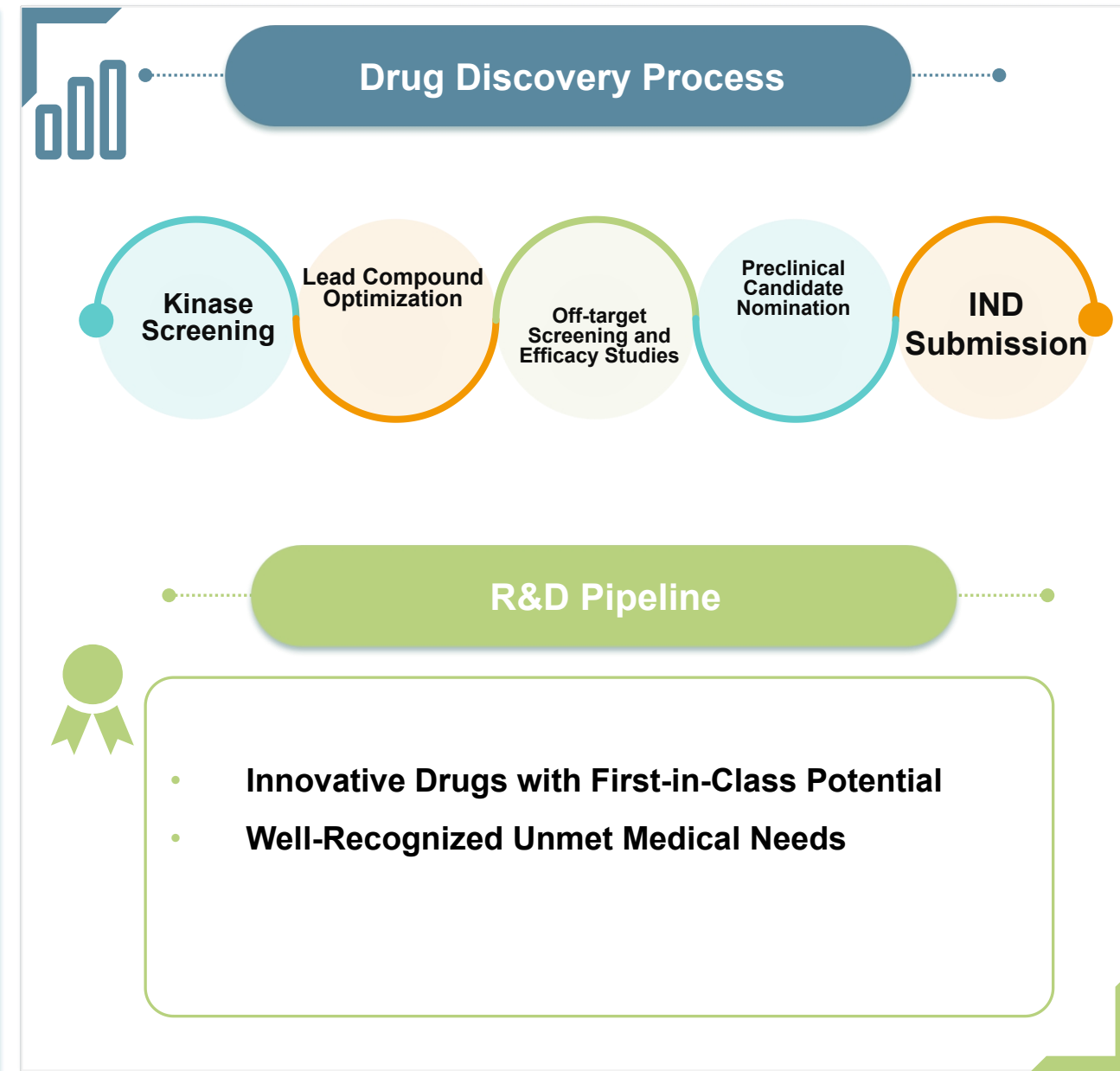
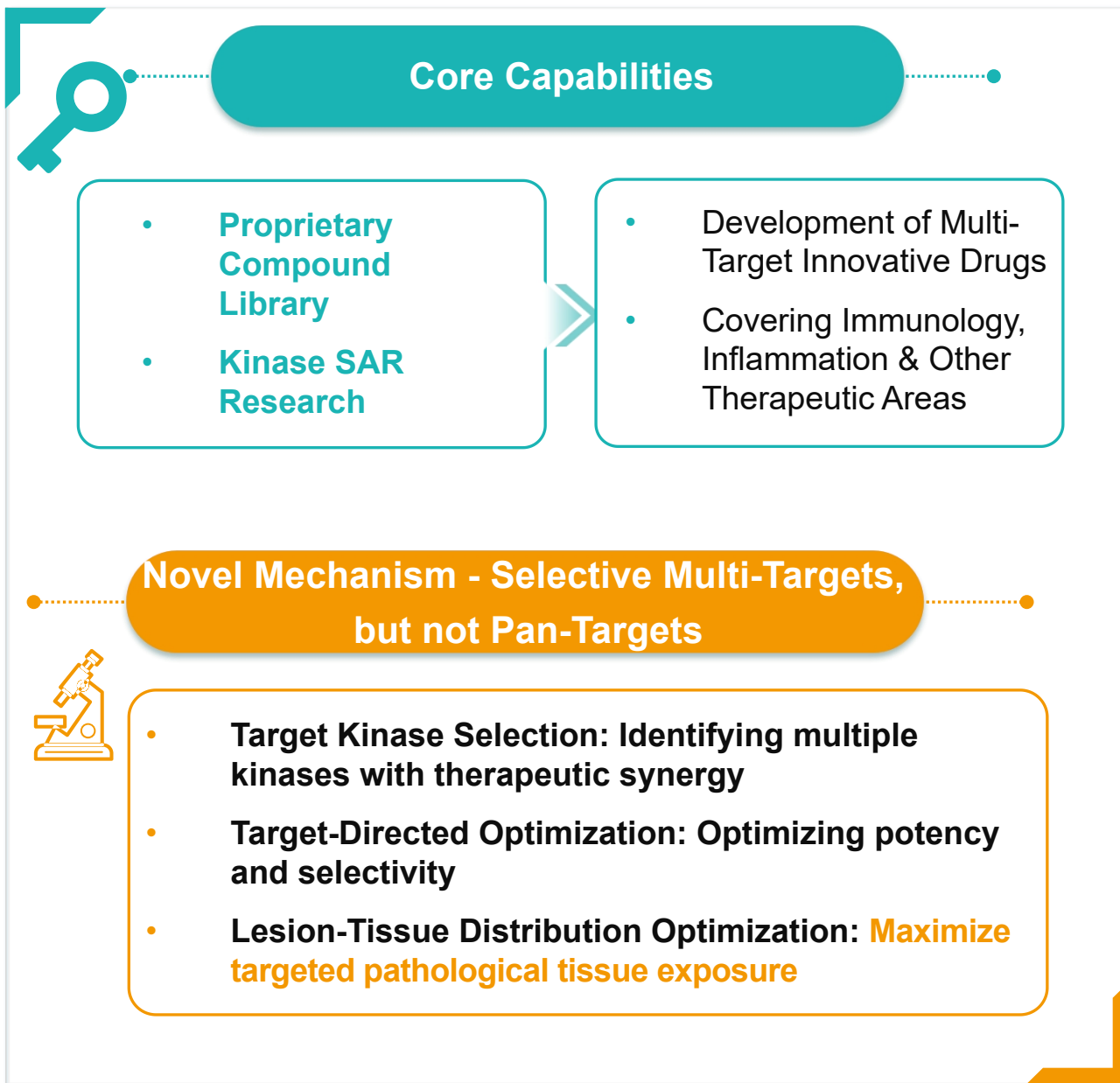
Dr. Stephen Fawell

30+ Years of oncology drug discovery R&D experience

- ◆ VP & Head Oncology Discovery, AstraZeneca
- ◆ VP & World-wide Franchise Discovery Head for Oncology, MSD
- ◆ Drug Discovery Head, Novartis Institutes for BioMedical Research
- ◆ Head of Oncology Research, Biogen Idec Inc
- ◆ Played pivotal roles in discovery & development of multiple oncology products, e.g. ribociclib (Kisqali), osimertinib (Tagrisso), olaparib (Lynparza), acalabrutinib (Calquence), capivasertib (Truqap), etc.



MultiSel-Opt Platform for Small Molecule Innovative Drugs

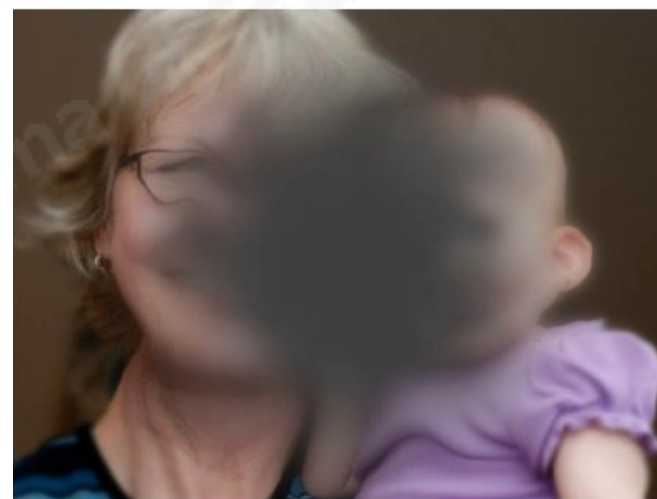


R&D Pipeline of Advanced Development Products

Programs	MoA	Indications	Pre-clinical	IND	P1	P2	P3
HXP019 (C019199)	CSF-1R/DDR1/ VEGFR2 Inhibitor	metastatic osteosarcoma monotherapy	China				
			USA				
		other cancer monotherapy (e.g. HER2- breast cancer)	China				
		combo with PD-1 Ab for triple negative breast cancer	China				
		Combo with PD-1 Ab for other cancers	China				
HXP056 (HX9428)	confidential	nAMD/DME/RVO	China	nAMD			
			USA	nAMD			
HXP089 (HX1408)	confidential	GBM	China				
HXP090	confidential	IPF	China				

HX9428 - A Phase II Small Molecule for Neovascular Age-Related Macular Degeneration (nAMD)

nAMD Degeneration



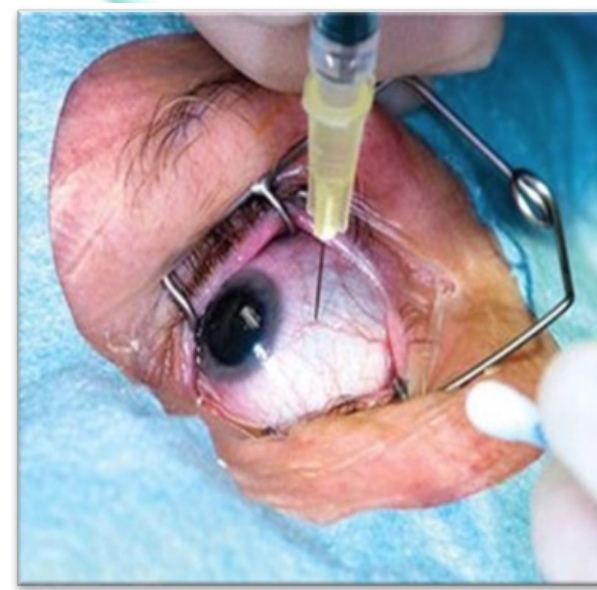
- > 200 million people globally suffer from AMD, with 10-15% of them are nAMD patients
- It is the leading cause of severe, irreversible vision loss in people over 60 years of age. The prevalence is projected to grow along the aging of global population
- Current standard-of-care involves repeated intraocular injection of anti-VEGF biologics (e.g., Eylea, Lucentis, Vabysmo; every 1-3 months) indefinitely to maintain vision
- Annual treatment cost easily reaches >\$10k-25k per patient per year with a total market size >\$13B and the projected CAGR of 5-8% by 2030

Drugs on Market: **All need intravitreal injections!**

Drugs (en)	Approval in US	Approval in China
Pegaptanib	09/2004	-
Ranibizumab	06/2006	11/2011
Conbercept	-	01/2013
Aflibercept	11/2011	05/2018
Faricimab	01/2022	12/2023
Bevacizumab	Off-label	Off-label

All are anti-VEGF antibodies or fusion proteins.

- 40-50% of patients do not achieve vision improvements
- 2/3 patients still suffer from bleeding or leakage below macula
- 25% patients experience vision decline after 12 months of treatment

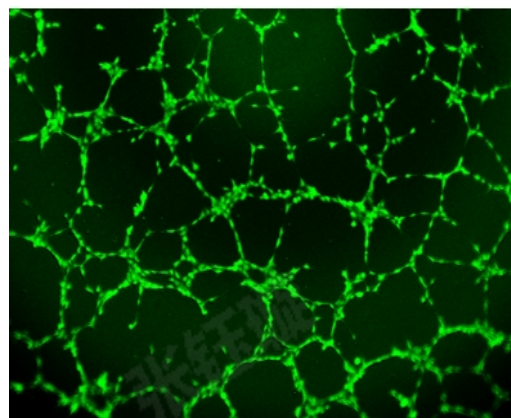


Injection may increase risks of inflammation, bleeding or damage to retina.

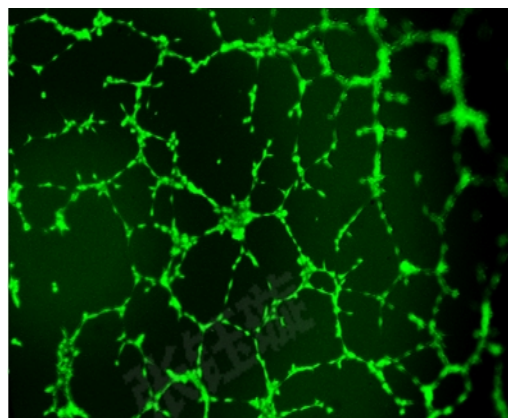
- ❑ Patient treatment rate and adherence are far from ideal;
- ❑ Both eyes need injections if both eyes have nAMD;
- ❑ Need refrigerated transportation;
- ❑ Treatment burden is high.



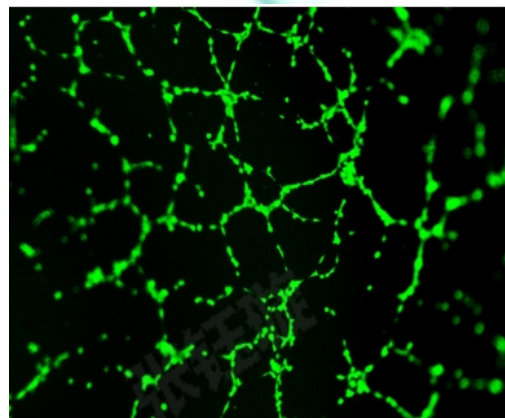
HX9428: Anti-angiogenesis in HUVECs



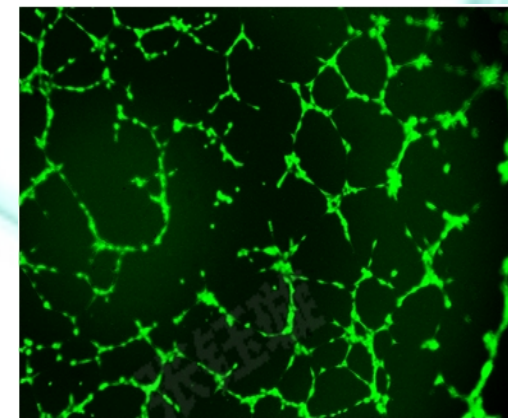
100 ng/ml VEGF



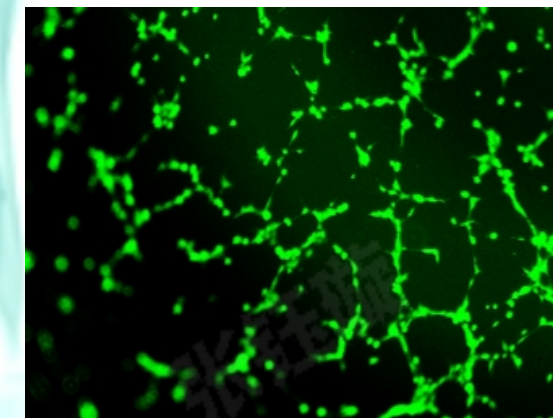
100 ng/ml VEGF + 0.5 mg/ml Avastin



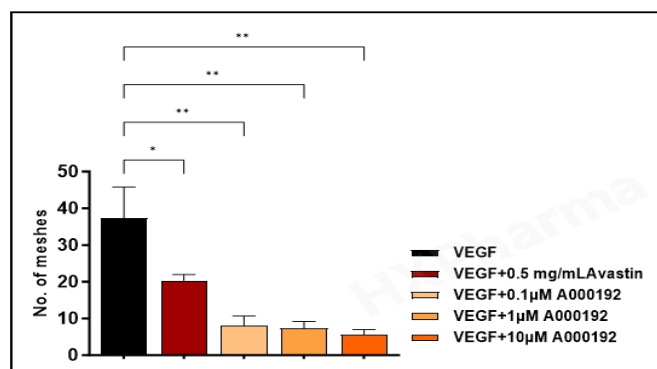
100 ng/ml VEGF + 0.1 μM A000192



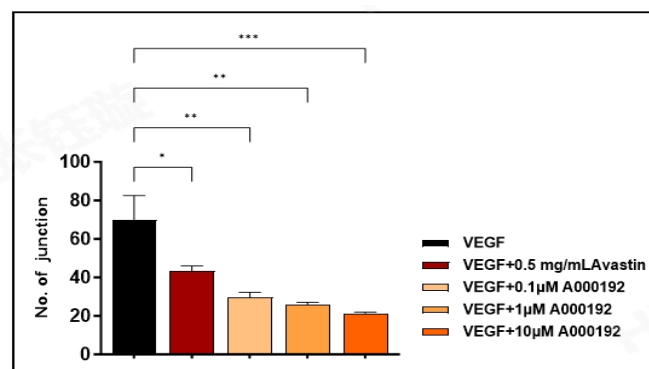
100 ng/ml VEGF + 1 μM A000192



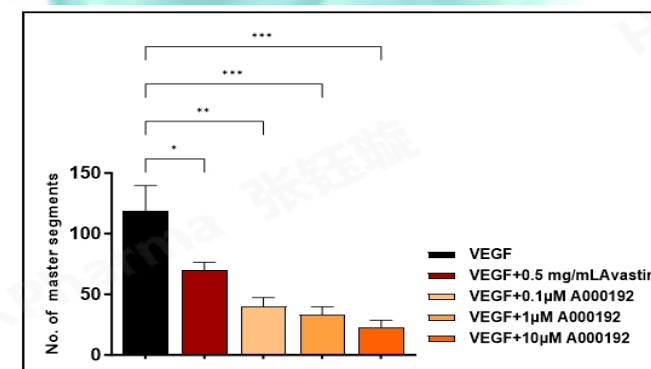
100 ng/ml VEGF + 10 μM A000192



each treatment group on mesh formation



each treatment group on junction formation

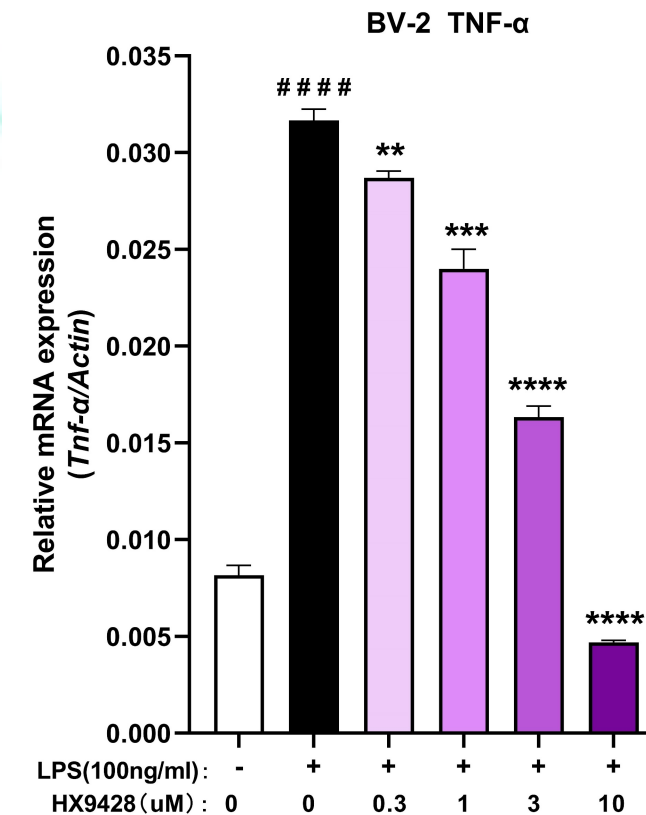
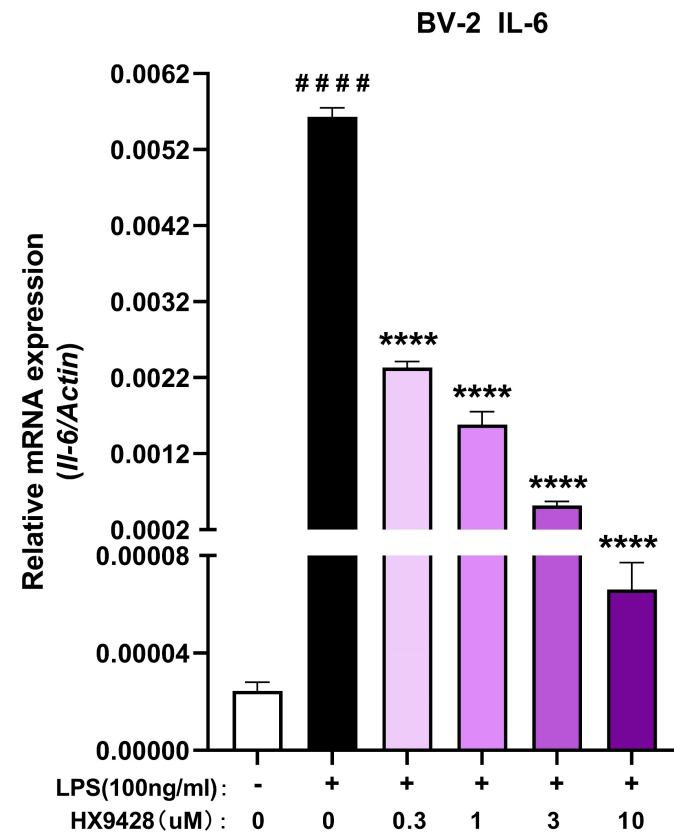


each treatment group on master segments

* A000192: HX9428

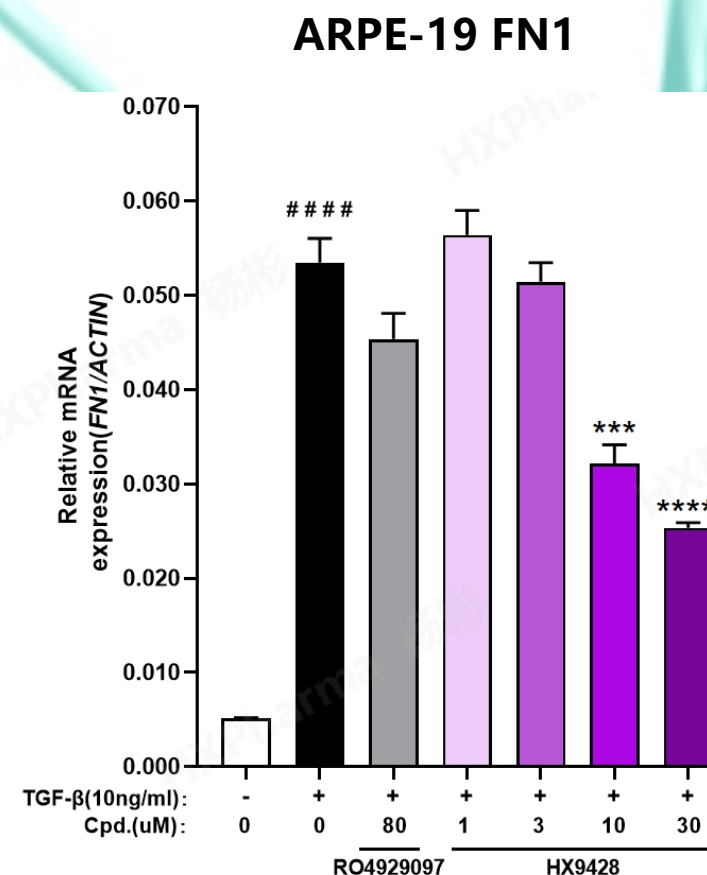
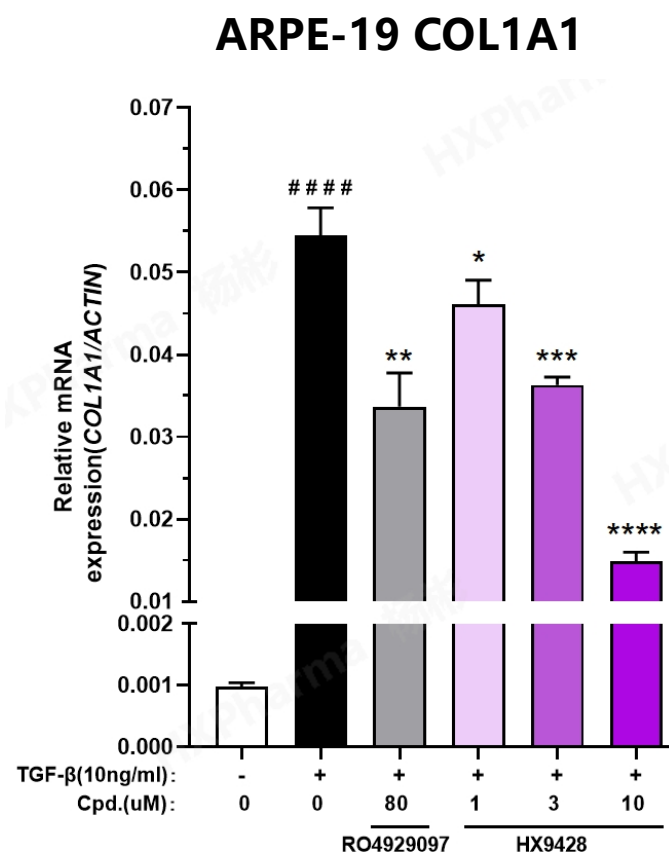
➤ HX9428 significantly inhibited angiogenesis in HUVECs *in vitro*

Anti-inflammatory effects of HX9428 in BV-2 microglial cells



➤ HX9428 dose-dependently suppressed LPS-induced IL-6 and TNFα expression (mRNA) in BV-2 microglia cells

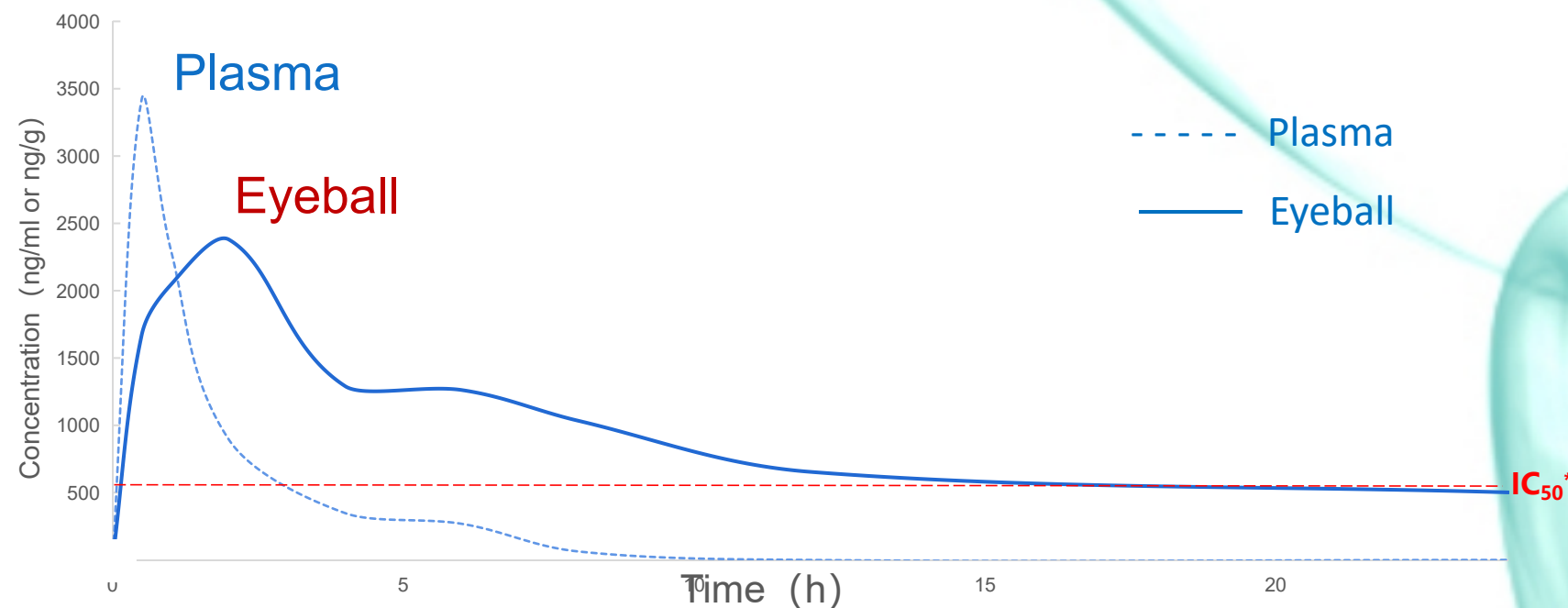
HX9428 affects TGF β -induced fibrotic phenotypic markers in ARPE-19 retinal pigment epithelial cells.



RO4929097, a γ -secretase inhibitor, represses fibrosis-related gene expression via blockade of Notch signaling activation.

- TGF β treatment significantly upregulated the mRNA expression of COL1A1 and FN1 in ARPE19 cells
- HX9428 significantly downregulated the mRNA expression of COL1A1 and FN1 in a dose-dependent manner

HX9428: Favorable PK Profile



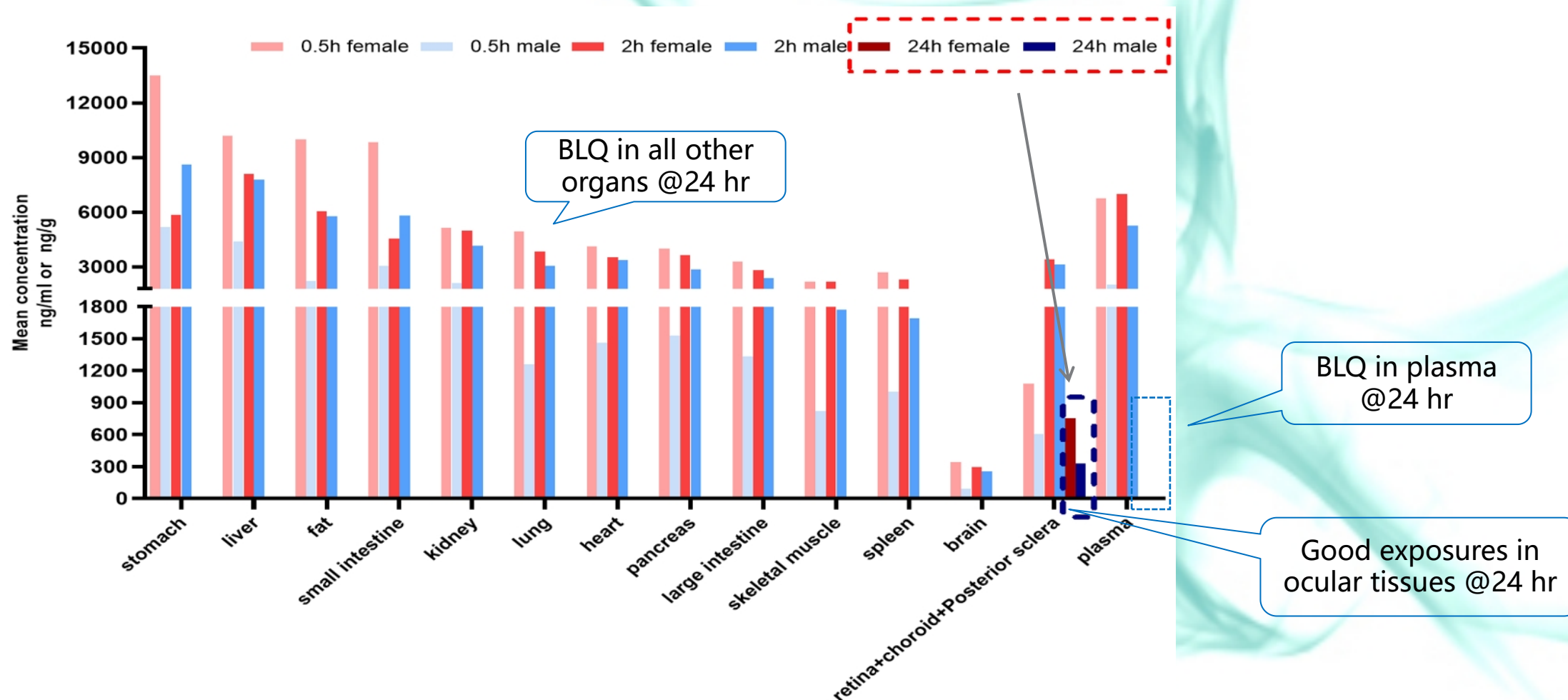
PK Profile of HX9428 - Eye Exposure and Quick Clearance in System

Drug	Animal	Dose mg/kg	Plasma		Eyeball		E/P (AUC)
			T _{1/2} (h)	AUC _{0-24 h} (h*ng/mL)	T _{1/2} (h)	AUC _{0-24 h} (h*ng/g)	
HX9428	C57 Mice	10	1.7	6076	19.9	31286	5.1

- **Fast** systemic metabolism with short $t_{1/2}$ & low exposure should lead to less AEs;
- **Long** eye tissue resident time with long $t_{1/2}$ and sustained exposure could bring better efficacy.

* The IC₅₀ herein represents the VEGFR2 kinase activity of HX9428

HX9428: Long Ocular Tissue Exposure



Single oral dose of HX9428 (10 mg/kg, BN rat), rapid systemic distribution at 24 hr post dose:

- plasma and all organ tissues below limit of detection
- retina-choroid and posterior sclera still at ~15% of peak level

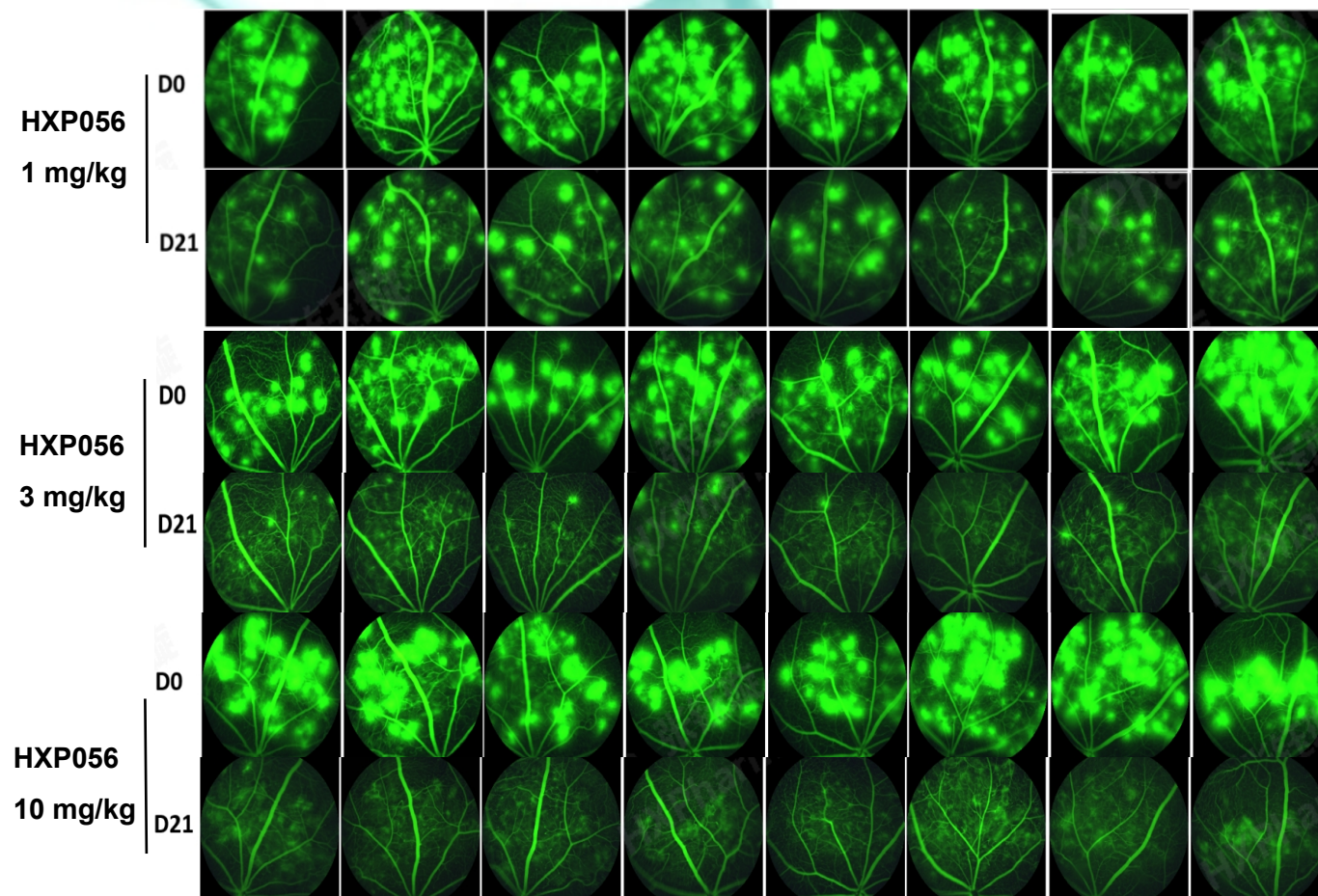
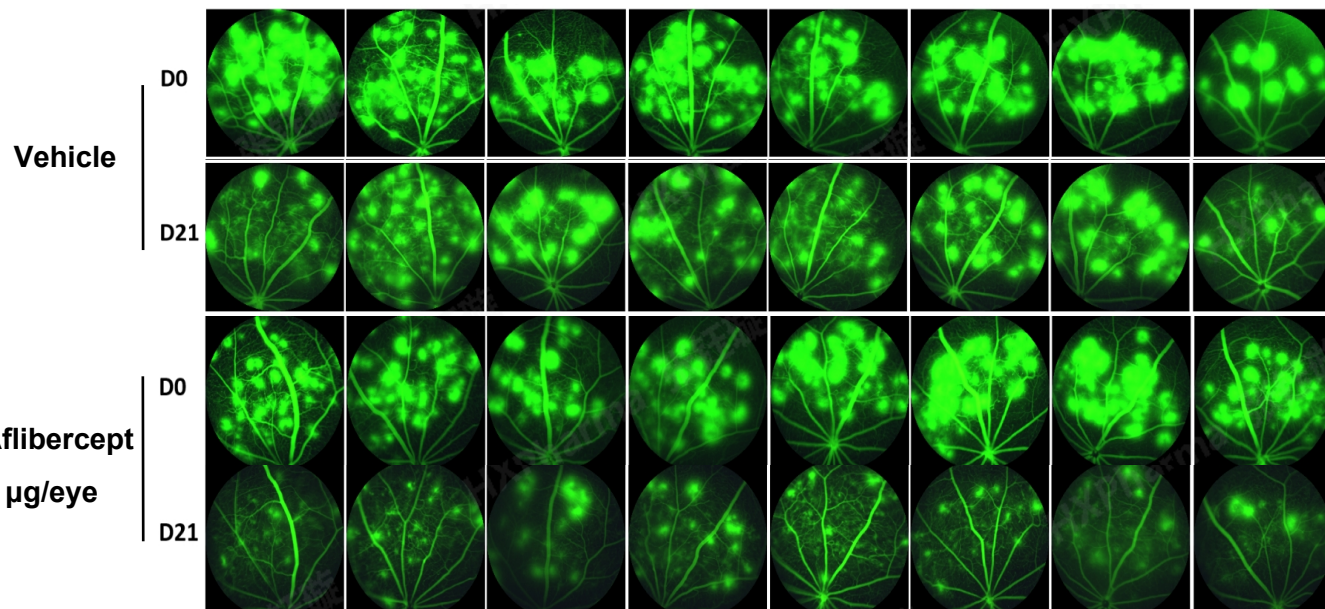
HX9428 in Transgenic Mouse Model

Animal: hVEGFA-TG mice

Dose: 1、3、10 mg/kg

Duration: qd×21 day

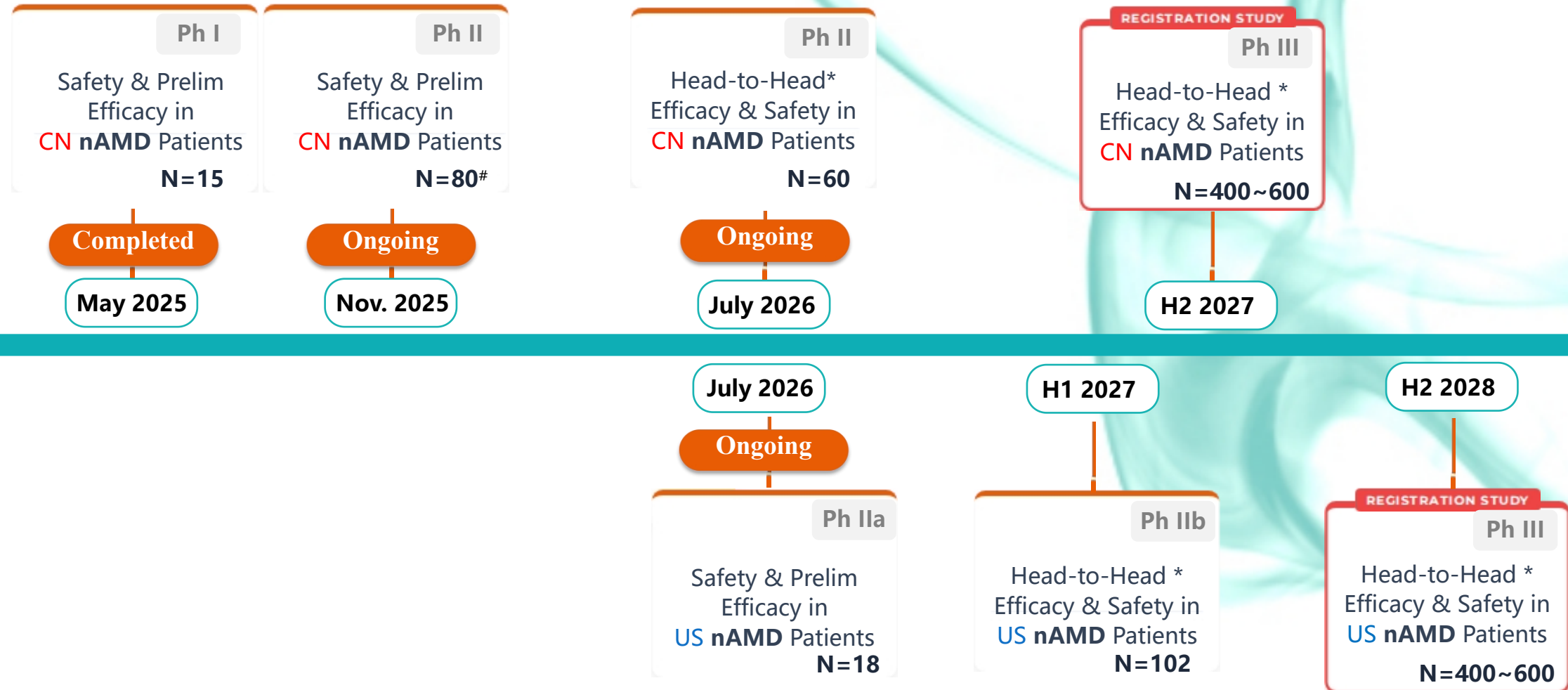
Efficacious Dose: **1 mg/kg**





海西新药
HXPharma

HX9428: nAMD Clinical Development Plan



* Head-to-Head: comparison with the standard-of-care drug Eylea

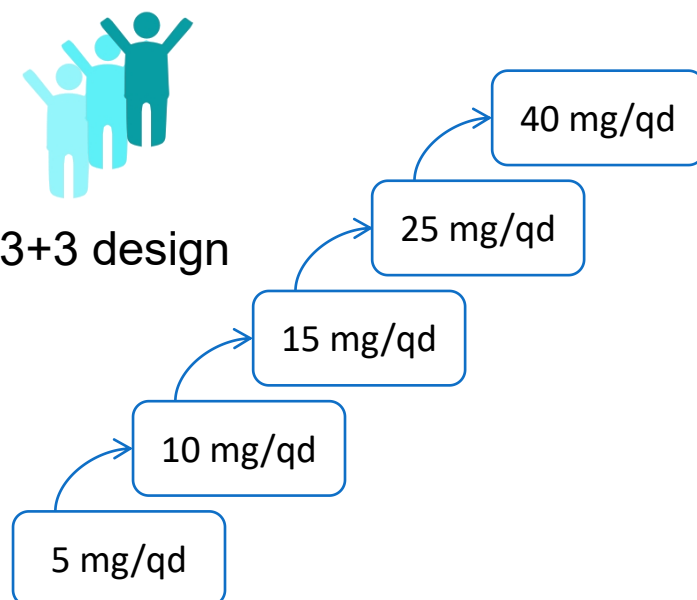
#Cut-off date: August 14, 2026

Phase I Dose Escalation Study

Main Inclusion Criteria

- Age ≥ 50 years, ≤ 85 years.
- FFA/OCT-confirmed active CNV.
- Anti-VEGF naive or treatment-free more than 3-months .
- ETDRS BCVA 19 to 78 letters

Dose Escalation Phase
(Loading period 3 d + Multiple doses 28 d)



Safety Assessment:

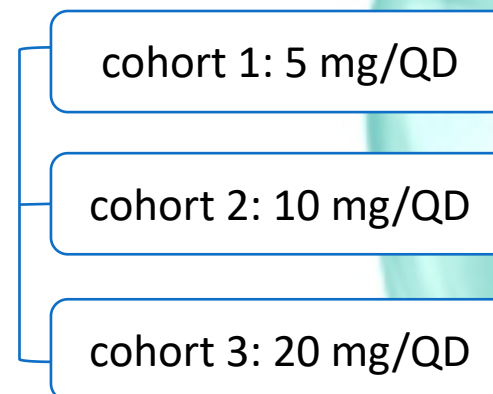
DLT observation period: W1, W4; after W4: Q4W.

Efficacy Assessment:

Ophthalmic exams (BCVA, OCT, etc.): Q4W;
FP and FFA: Q12W;
ICGA: screening period.

Phase II Study

Treatment Period
(Week 1 - Week 24)



Safety Assessment: Q4W.

Efficacy Assessment:

Ophthalmic exams (BCVA, OCT, etc.): Q4W;
FP and FFA: Q12W;
ICGA: screening period.

Endpoint Indicators

Primary endpoints

- Incident of all AE and SAE, n (%).
- Mean change of BCVA Improvement from Baseline.

Secondary endpoints

- Mean change in OCT retinal thickness from baseline (W24).
- Patients with BCVA improvement $\geq 15/10/5/0$ letters, n (%).
- Mean change from baseline in total lesion area and total CNV lesion area.
- PK Parameters of HX9428 in Patients with nAMD.

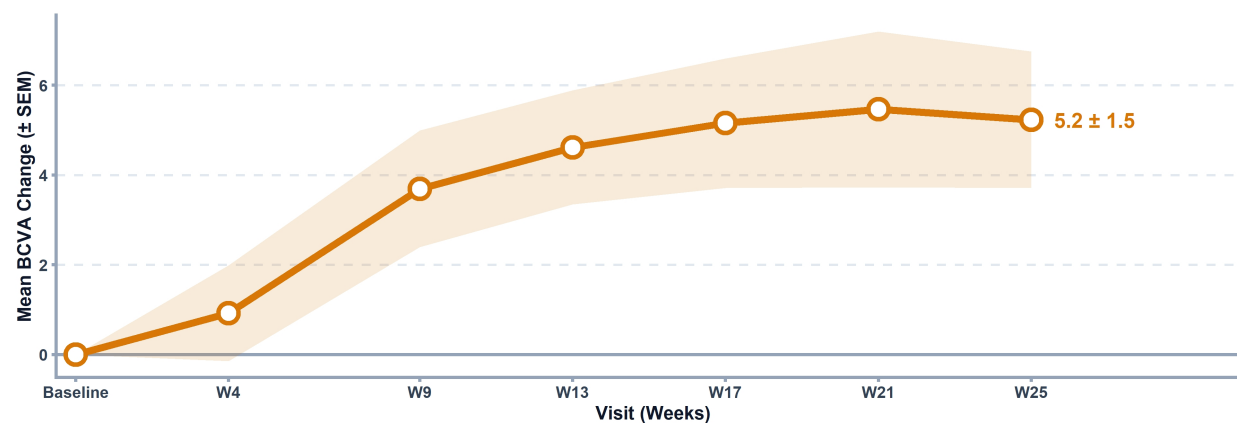
Jul. 2026 Completed

Ongoing

HX9428: The Efficacy of Phase I Trial

Phase 1: Overall Mean BCVA Change

Overall Mean Change Trajectory (All Dose Groups Combined)

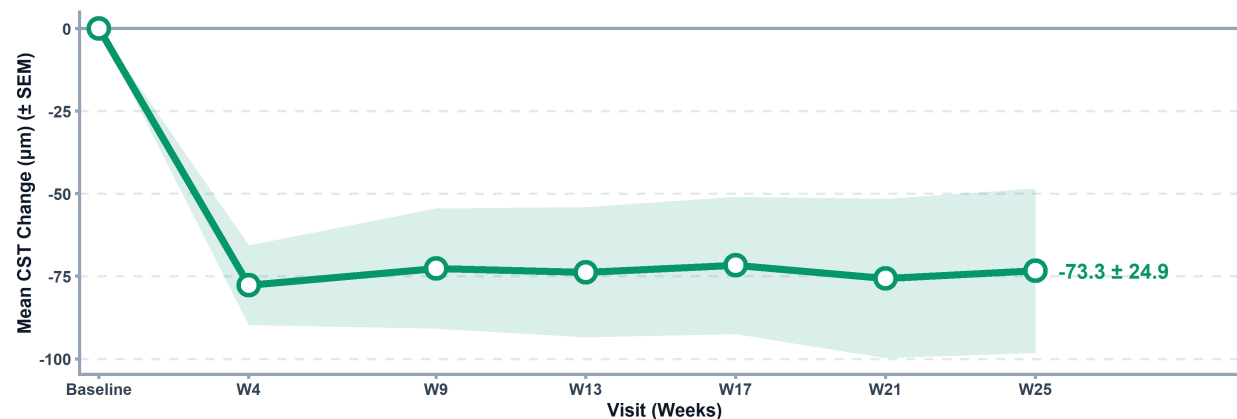


Mean change in BCVA

+5.2 letters

Phase 1: Overall Mean CST Change

Overall Mean Change Trajectory (All Dose Groups Combined)



Mean change in CST

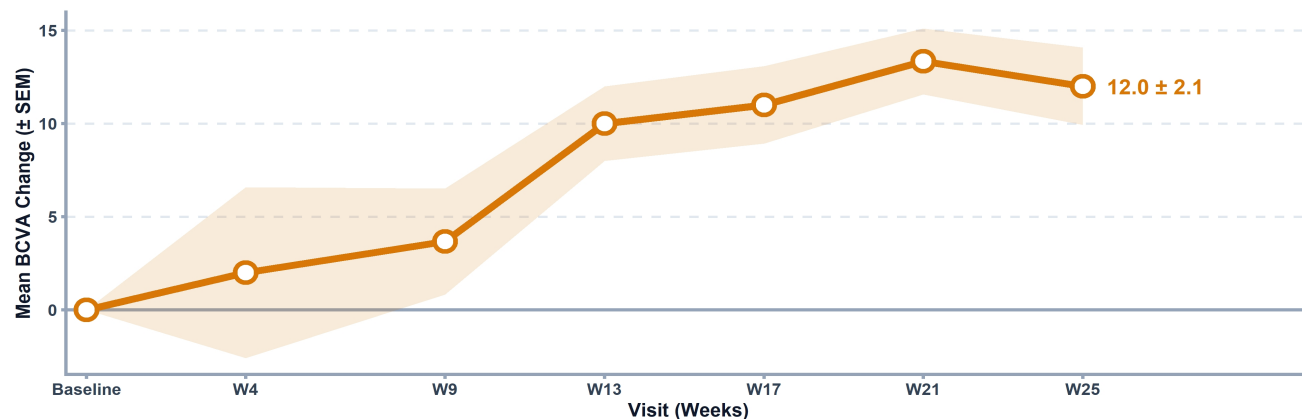
-73.3 µm

- Data include only patients who completed 24 weeks of treatment (N=13). One patient (40 mg) withdrew at week 4, and 1 (25 mg) was lost to follow-up at week 4.

HX9428: The Efficacy of Phase I Trial (Naive)

Phase 1 Treatment Naïve: Mean BCVA Change

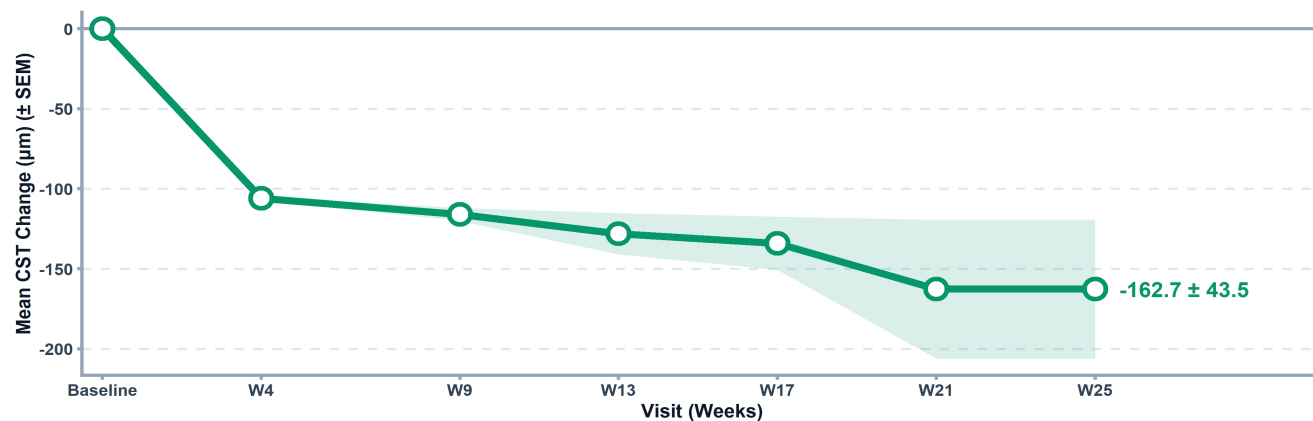
Overall Mean Change Trajectory (All Dose Groups Combined)



Mean change in BCVA
+12.0 letters

Phase 1 Treatment Naïve: Mean CST Change

Overall Mean Change Trajectory (All Dose Groups Combined)



Mean change in CST
-162.7 µm

* Data include only patients who completed 24 weeks of treatment (N=3). Of the four enrolled patients, two were in the 25 mg group, one was in the 40 mg group, and one (25 mg) was lost to follow-up at week 4.

HX9428: Safety in Phase I (TEAE)

- **No dose-limiting toxicity (“DLT”)** was observed with favourable tolerability;
- **No common gastrointestinal AEs** such as diarrhea, nausea or vomiting;
- No AEs of fatigue, or hair color change;
- With respect to hepatic and renal-related AEs, **one case of elevated ALT and one case of elevated AST**, both of which were **grade 1 and transient**.
- Hypertension-related adverse events mainly occurred in the higher dose cohorts:
 - One grade 3 AE (a single systolic blood pressure of 160 mmHg) in the **25 mg/QD** dose cohort
 - Two grade 3 AE in the **40 mg/QD** dose cohort
 - All were generally **manageable through routine monitoring and antihypertensive treatment**.
- All of the above adverse events occurred within the **first 3 months** after the initiation of treatment
- No new adverse events between the **3-month and 6-month** treatment period.

Phase II Study

Key Eligibility Criteria

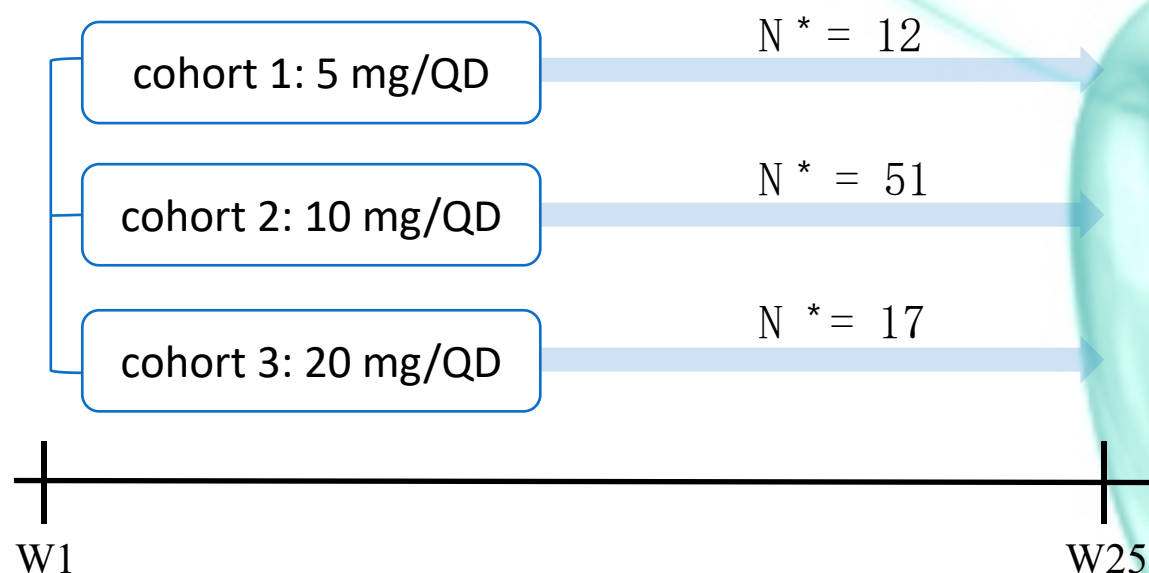
Inclusion Criteria

- Age ≥ 50 years, ≤ 85 years.
- FFA/OCT-confirmed active CNV.
- Anti-VEGF naive or treatment-free more than 3-months .
- ETDRS BCVA 19 to 78 letters.

Exclusion Criteria

- Systemic anti-VEGF treatment within 90 days prior to first dose.
- Intraocular surgery (e.g., cataract, trabeculectomy) within 90 days.
- Active ocular inflammation, infection, or uveitis in either eye.
- Macular surgery, PDT, or thermal therapy within 120 days.

Treatment Period (Week 1 - Week 24)



Safety Assessment: Q4W

Efficacy Assessment:

Ophthalmic exams (BCVA, OCT, etc.): Q4W; FP and FFA: Q12W;
ICGA: screening period

Endpoint Indicators

Primary endpoints

- Incident of all AE and SAE, n (%).
- Mean change of BCVA Improvement from Baseline.

Secondary endpoints

- Mean change in OCT retinal thickness from baseline (W24).
- Patients with BCVA improvement $\geq 15/10/5/0$ letters, n (%).
- Mean change from baseline in total lesion area and total CNV lesion area.
- PK Parameters of HX9428 in Patients with nAMD.

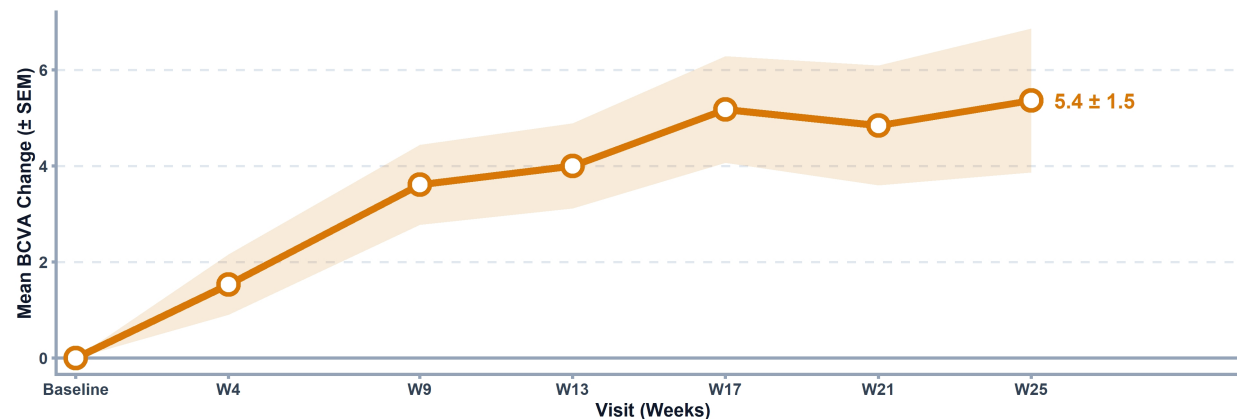
* Enrollment is ongoing, with patient counts updated as of August 14, 2026

Ongoing

The Efficacy of Phase II (Interim)

Phase 2: Overall Mean BCVA Change

Overall Mean Change Trajectory (All Dose Groups Combined)

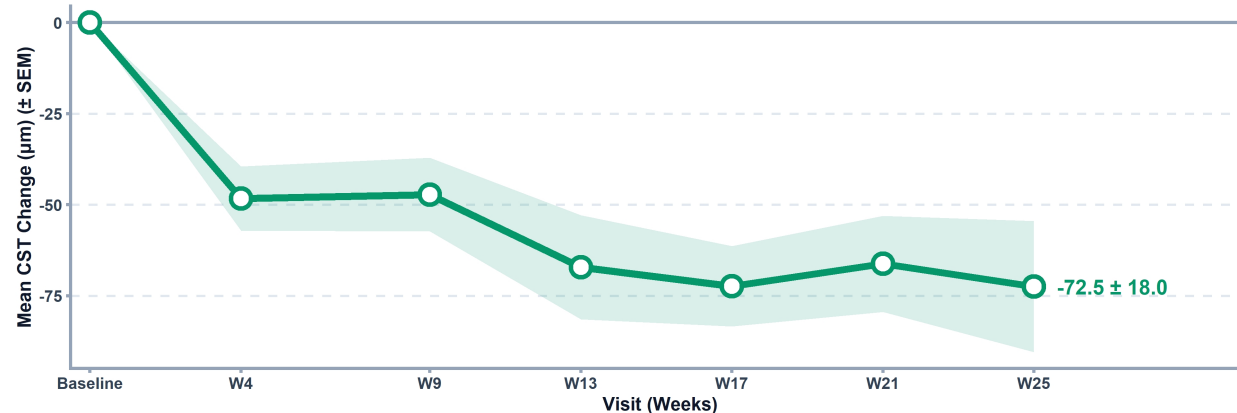


Mean change in BCVA

+5.4 letters

Phase 2: Overall Mean CST Change

Overall Mean Change Trajectory (All Dose Groups Combined)



Mean change in CST

-72.5 µm

- The interim results for Phase II as of Aug.14 2026 are consistent with the trend seen in Phase I

Patients	N
Phase II Enrolled	80
Week 13 Completed	45
Week 25 Completed	11

HX9428: Safety in Phase II (Interim)*

- **Overall tolerability is largely consistent with Phase I;**
- **No common gastrointestinal AEs** such as diarrhea, nausea or vomiting;
- **No AEs** of fatigue, or hair color change;
- AEs were mostly of **low grade**;
- Further safety indicators and long-term benefit-risk profile will continue to be monitored.

Phase I/II Clinical Studies of HX9428 in China:

- Phase I: All 5 dose levels (5-40 mg/QD) of SAD/MAD study have finished
- Phase I: All 5 dose levels of the drug are well tolerated, with no DLTs observed
- Phase I: Efficacy observed among majority of patients even in the lowest dose of 5 mg/QD
- Phase II: Dose expansion study with many more patients is ongoing;

Interim safety and efficacy observations are consistent with Phase I results

HX9428: Recent Milestones



US FDA nAMD Phase II Clinical Trial

IND was approved and granted Fast Track Designation (**FTD**) In Q3 2026

- Phase II clinical trial for **nAMD** in **US**



CN NMPA DME Phase II Clinical Trial

IND in Q3 2026

- **Phase II** clinical trial for **DME** in **CN**

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