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IMPACT OF CHINA'S NRDL VALUE-RATING SYSTEM ON REIMBURSEMENT & **PRICING OF INNOVATIVE THERAPIES**

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SUMMARY

- In 2023, a new value-rating framework was formally introduced into the NRDL assessment process to provide an objective evaluation of a product's clinical benefits during expert review
- The framework classifies drugs into four tiers based on clinical characteristics such as efficacy, safety, innovation, fairness, and potential replaceability by existing NRDL-listed products
- During the 2024 NRDL negotiations, this value-rating framework was used in the expert review stage to determine which candidates would proceed to the negotiation phase
- However, the National Health Security Administration (NHSA) does not currently disclose the value rating results or the rationale behind them, and no published literature has yet examined the relationship between value ratings and final pricing outcomes

INTRODUCTION & OBJECTIVES

- The 2024 NRDL listing, released at the end of November 2024, showed a modest decrease in negotiation success rates, dropping from 85% in 2023 to 75% in 2024
- Most of the drugs were filtered out during expert review (clinical and economic assessments), where the new value-rating system was leveraged, resulting in only 28% of products being eligible for negotiations or bidding
- This research aims to assess the impact of the value-rating system on innovative products' reimbursement and pricing outcomes

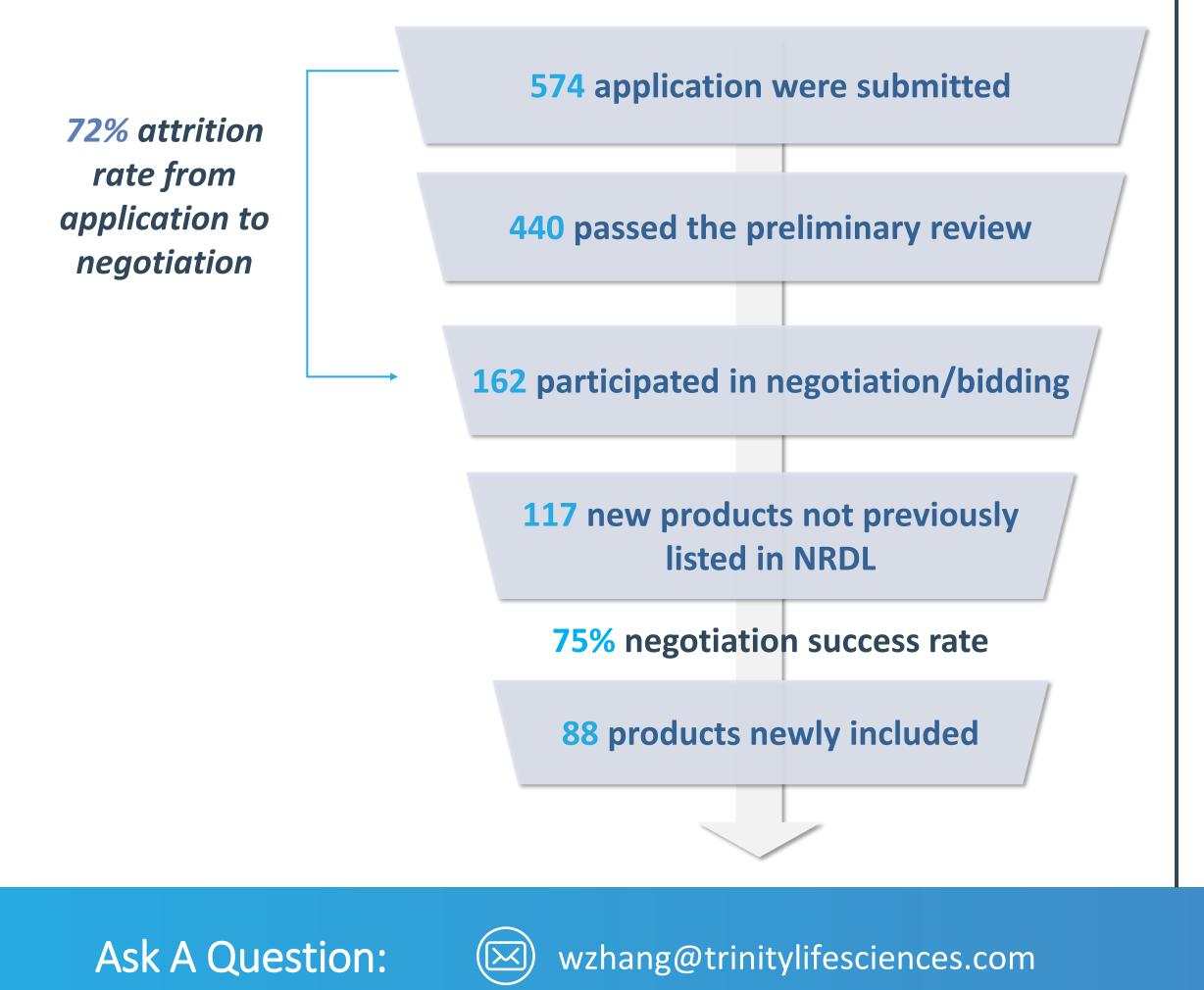
METHODS

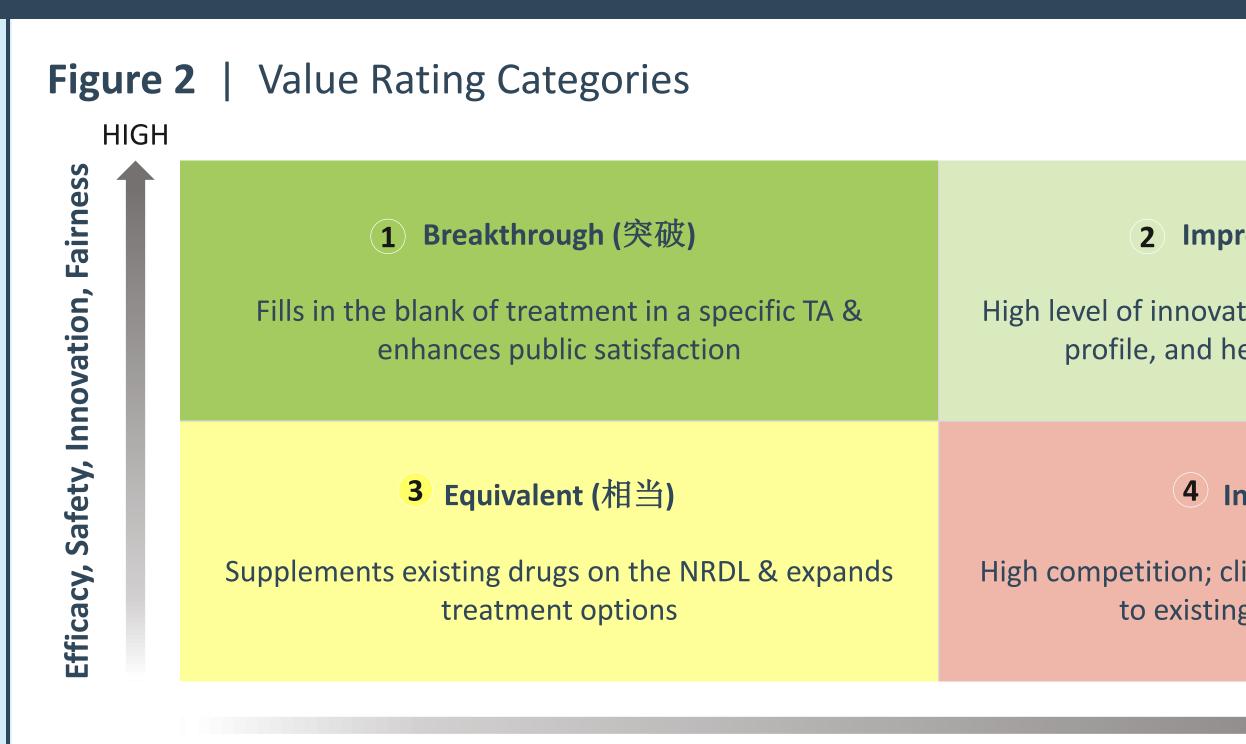
An in-depth analysis of the 2024 NRDL Negotiation results was performed to evaluate how the value ratings of participating drugs may influence their pricing outcomes. Our analysis employs a three-step approach:

- 1. Identify key successful drug candidates from the 2024 NRDL negotiation, focusing on oncology treatments
- 2. Evaluate the added clinical benefit compared to standard of care/ NRDL-listed competitor(s) and estimate their likely value ratings
- 3. Examine the potential relationship between the likely value ratings and pricing outcomes for these therapies

RESULTS

Figure 1 | 2024 NRDL Negotiation Results Overview





LOW

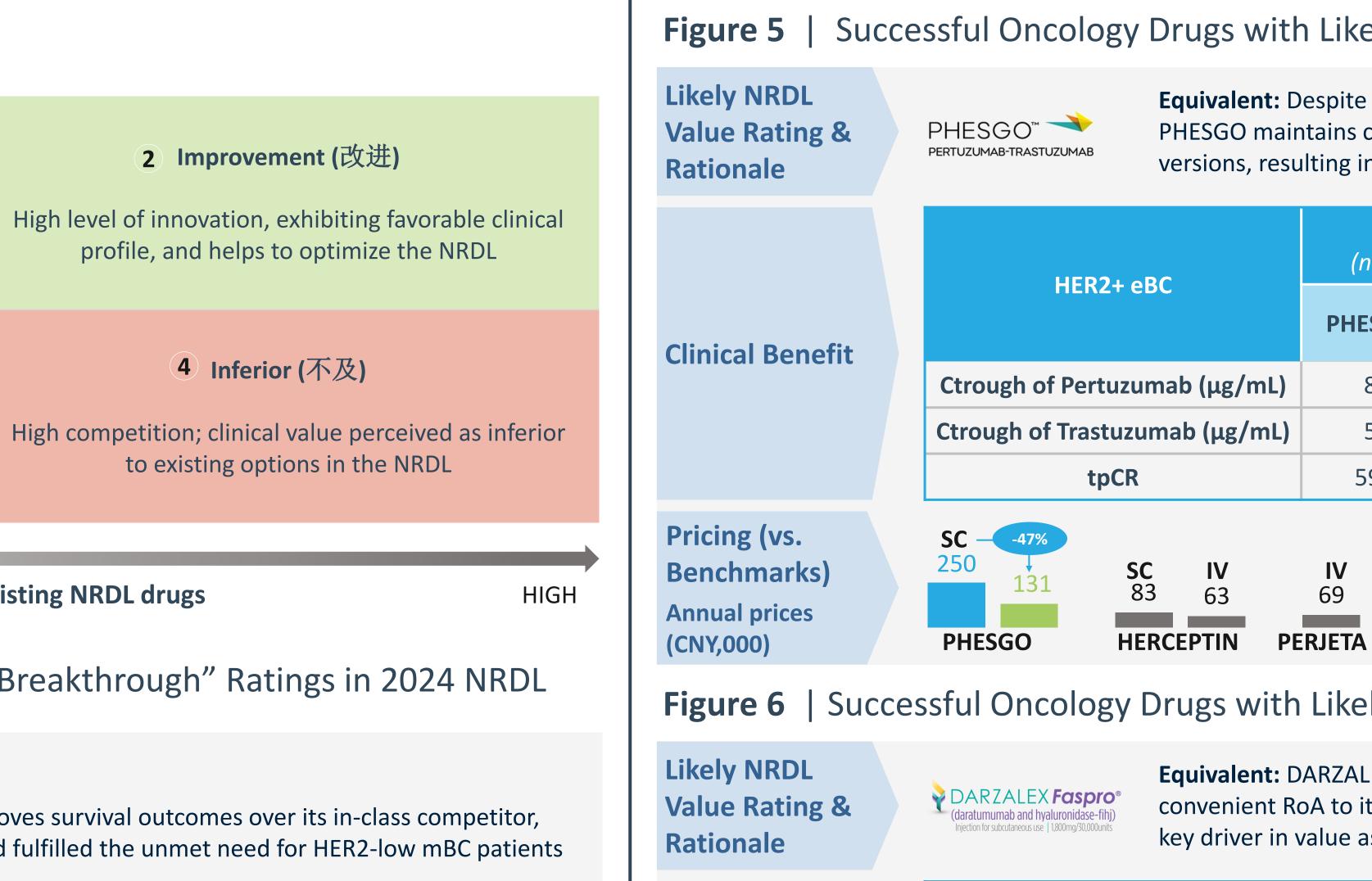
'Replaceability' by existing NRDL drugs

Successful Oncology Drug with Likely "Breakthrough" Ratings in 2024 NRDL Figure 3

	HER2+ mBC		3 H2H Trial (<i>CHN sites</i>)	HER2-low mBC		Ph3 RCT g CHN sites)
Clinical Benefit		ENHERTU	KADCYLA		ENHERTU	Chemo
Denent	mOS (mo.)	52.6	42.7	mOS (mo.)	23.4	16.8
	mPFS (mo.)	28.8	6.8	mPFS (mo.)	9.9	5.1
Pricing (vs. Benchmarks) Annual prices (CNY,000)	389		34 KA	HERTU achieved a sig DCYLA, which is indic pulation in both early	ated for a slight	ly larger

Successful Oncology Drug with Likely "Improvement" Ratings in 2024 NRDL Figure 4

Likely NRDL Value Rating & Rationale	POLIVY™ polatuzumab vedotin-piiq		nly treatment in e showing superi	•	•			
	1L DLBCL	Global Ph (including CH		r/r DLBCL	Global Ph1 (no CHN includ	l sites	China P	h3 RCT
Clinical Benefit	ILDEDEL	POLIVY+R-CHOP	R-CHOP		POLIVY+ BR	BR	POLIVY +BR	BR
				ORR	57.5%	20%	28.6%	14.3%
	2-year PFS	76.7%	70.2%	mOS (mo.)	12.4	4.7	10.6	6.5
	rate			mPFS (mo.)	5.6	3.7	4.6	2.0
Pricing (vs. Benchmarks) Annual prices (CNY,000)	296	-39% 249 180 ADCETR	subtypes, PC ADCETRIS (A	POLIVY and AD DLIVY targets a LCL, MF, cHL),	a broader po	pulation	(DLBCL) t	
Pre-NRD		IRDL Price 🔳 Benchi	mark Current Pri	ce All prices	are annual	prices (C	NY.000)	



Pricing (vs. Benchmarks) Annual prices (CNY,000)	SC47% 250 131 PHESGO	SC IV 83 63 HERCEPTIN F	IV vs. F 69 at pa PERJETA two
Figure 6 Succ	essful Oncolog	y Drugs wit	h Likely "Equi
Likely NRDL Value Rating & Rationale	CARZALEX Faspro (daratumumab and hyaluronidase-fihj) Injection for subcutaneous use 1,800mg/30,000units	convenient	DARZALEX FASPRO RoA to its IV version value assessment
	r/r MM		l Ph3 RCT ites included)
		SC	IV
Clinical Benefit	mOS (mo.)	28.2	25.6
	mPFS (mo.)	5.6	6.1
	ORR	44%	40%
Pricing (vs. Benchmarks) Annual prices (CNY,000)	478 -50% 240 DARZALEX FASPRO	IV 204 DARZALE	With similar c DARZALEX FAS X
Despite devees		alinical part	

remains a critical guardrail in China's system

DISCUSSION

- medicines in China
- product value

CONCLUSIONS

- As a result, the value tiering system may indirectly influence NRDL pricing outcomes

REFERENCES

1. National Health Security Administration (NHSA). http://nhsa.gov.cn/, 6 January 2025; 2. PharnexCloud Database

ABBREVIATIONS

IV – Intraveneous | NHSA – National Health Security Administration | NRDL – National Reimbursement Drug List | OS – Overall Survival | **ORR** – Objective Response Rate | **PFS** – **P**rogression-Free Survival | **SC** – Subcutaneous | **tpCR** – total Pathologic Complete Response





Figure 5 | Successful Oncology Drugs with Likely "Equivalent" Ratings in 2024 NRDL

Equivalent: Despite offering a more convenient subcutaneous option, PHESGO maintains consistent outcomes vs. the combination of its IV versions, resulting in similar pricing outcomes

		Ph3 RCT es included)	China Ph3 RCT		
	PHESGO SC	HERCEPTIN IV +PERJETA IV	PHESGO SC	HERCEPTIN IV +PERJETA IV	
ıb (μg/mL)	88.7	72.4	74.6	69.9	
ab (µg/mL)	57.5	43.2	52.1	33.6	
	59.7%	59.5%	55.6%	56.4%	

ESGO demonstrated non-inferior clinical data PERJETA IV + HERCEPTIN IV, and was priced arity to the combined treatment cost of the IV drugs

uivalent" Ratings in 2024 NRDL

O provides comparable efficacy and a more on, DARZELEX; however, RoA is not likely the

r/r MM	Global Ph1 Trial		
	SC		
ORR	52%		
	China Ph1 Trial		
r/r MM	China Ph1 Trial SC		

clinical efficacy compared to DARZALEX, ASPRO is priced at parity to its IV counterpart

Despite demonstrating superior clinical performance, several high-cost innovative therapies failed to secure pricing agreements with the NHSA and were excluded from the 2024 NRDL highlighting that, unlike in Germany where clinical value alone ensures reimbursement, pricing

While no official guidelines delineate its role in NRDL pricing, the value rating system provides a practical and directional framework for assessing pricing and access outcomes for innovative

Although budget impact and pricing thresholds remain critical to NRDL negotiations, the increasing significance of the value rating system has revealed emerging pricing trends tied to

• Our analysis indicates that products with higher value ratings (e.g., "breakthrough") are more likely to achieve premium to NRDL alternative than those with lower ratings (e.g., "equivalent")