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WHITE PAPER

2023 NRDL Pricing Implementation and Market Access Outcomes Update

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Context

The National Reimbursement Drug List (NRDL) negotiations are expected to conclude by November 2024, with pricing outcomes gradually being revealed starting in January 2025. The Trinity Life Sciences team has reviewed the 2023 NRDL inclusion and pricing results, drawing some key learnings.

Key Takeaways from the 2023 NRDL Update

Continued Importance of the NRDL

Although the private insurance market is growing, NRDL remains the primary access pathway in China, offering opportunities for broad penetration and high volume of uptake despite significant price discounts required

Accelerated Access for Innovative Drugs

Access for novel therapies has accelerated in China as the NRDL continues to prioritize the assessment of innovative drugs. In 2023, the negotiation success rate for novel therapies was as high as 92%

Evolving NRDL Policy and Payer Landscape

Despite seven rounds of NRDL updates, the NRDL policies and payer landscape are constantly evolving. This year, the National Healthcare Security Administration (NHSA) has launched a brand-new value-rating system

NRDL Access Landscape

The 2023 NRDL update represented the seventh consecutive year of negotiation, with three significant updates observed, intended to enhance support for innovative therapies.

Three Significant Changes in the 2023 NRDL Update

Optimized Review Process

The 2023 NRDL update provided a more generous timeframe for expert review and the negotiation/bidding process, with both deadlines extended by one month compared to the 2022 NRDL timeline. The expert review process has been streamlined from three steps (pharmacy-clinical-pharmacy) to a single, joint review by pharmacology and clinical experts.

Policies Supporting Existing Innovative Therapies

Negotiated innovative products that have been included in NRDL Category B List for eight years will now transition to NRDL Category A, ensuring higher reimbursement rates and broader access. Innovative products may opt to renegotiate during NRDL renewal, potentially receiving a discount less than the prespecified rate within the simplified renewal process.

Introduction of the NRDL Value Rating Framework

The 2023 NRDL update placed a stronger emphasis on product efficacy, requiring manufacturers to outline in their applications the strengths and weaknesses of their product's efficacy compared to others in the same therapeutic area within the NRDL. Additionally, a new value rating framework was introduced in the 2023 NRDL Update to categorize products into four tiers primarily based on various product characteristics, clinical profiles, unmet needs and "replaceability" by existing NRDL drugs. Despite the rating being representative of a drug's value, payers note that no correlation between the rating and pricing has been observed yet, likely due to the system being newly launched and still evolving.

2023 NRDL Process and Timeline

The 2023 NRDL followed a similar process as previous years, but with an accelerated timeline from application to results announcement. Looking ahead, the 2024 NRDL will follow the same process but with an even earlier schedule, with negotiations and bidding starting from late September and the final results expected by November 2024.

Step 1. Application
July – August 2023

First, manufacturers with eligible products submitted applications to the NHSA through an online system. The submission packages were subsequently reviewed and a list of drugs that met the requirements was published. These drugs were considered to have passed the formality review to be considered for NRDL inclusion and adjustment.

Step 2. Expert Review
September – October 2023

A detailed application review was then conducted for each of the 386 products that passed the formal review stage by an NRDL expert panel, including clinical, policy and health economics and outcomes research (HEOR) experts as well as NRDL fund managers. To ensure a balanced assessment, both therapeutic area generalists and specialist experts were involved in the panel review process.

Step 3. Negotiation/Bidding
November – December 2023

For products selected for price negotiation, manufacturers were required to submit additional economic evidence (e.g., cost-effectiveness/budget impact analyses) to assist payers in determining their "offer price." Manufacturers were then invited to negotiate this "offer price" and agree on a final NRDL price. Informal annual price ceilings of CNY 500K and CNY 300K have historically been observed as thresholds for eligibility to negotiate and achieve NRDL listing.

Step 4. Results
December 2023

Finally, the list of 121 drugs that successfully passed the 2023 NRDL negotiation was announced in December 2023. However, there was a time lag between the finalization of negotiations and the publication of prices, as the post-NRDL negotiation prices did not take effect until January 2024.

Figure 1. Overview of the 2023 NRDL Process and Timeline

Key Features of the 2023 NRDL Update

During an in-depth analysis of the 2023 NRDL update, a few notable outcomes emerged:

1. Highest negotiation success rate and number of new inclusions in history

The 2023 NRDL update saw an unprecedented negotiation success rate of 85%, with 121 products included in the list, marking the largest formulary expansion in the NRDL's history. As the NRDL enters its seventh round of updates, both payers and manufacturers have likely gained experience and the know-how to put forward applications, enabling a higher success rate.

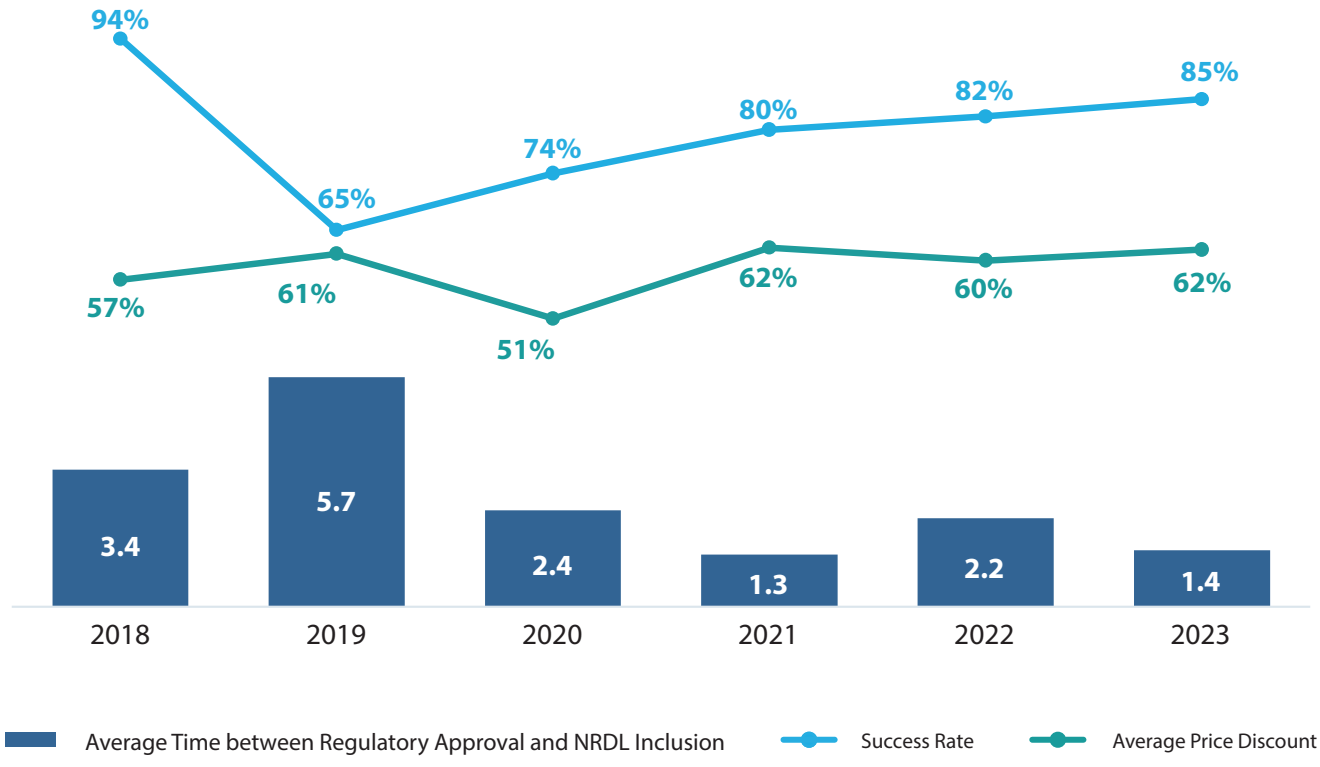
2. Consistent level of price cuts vs. previous years

The average level of price cut observed pre- and post-NRDL this year across all negotiated products was 61.7%, consistent with previous years. While a ~60% price cut may seem aggressive, the magnitude of price cuts required for NRDL inclusion often varies by therapeutic area. In indications where innovative drugs are prioritized by payers (e.g., oncology/rare disease), the percentage price cuts are typically milder.

3. Increasing focus on newly launched drugs and reduced time lag between approval and access

The time gap between regulatory approval and NRDL inclusion has notably decreased in recent years. Among innovative drugs, 85% achieved NRDL inclusion in 2023 within two years of launch. NRDL payers are increasingly prioritizing the assessments for newly launched and innovative drugs. With the opportunity to achieve NRDL listing shortly after launch, manufacturers should strategically plan to prepare their NRDL submission and negotiation strategy prior to the product's launch.

Figure 2. Key Statistics for NRDL 2017-2023



Oncology and Rare Disease Deep Dive

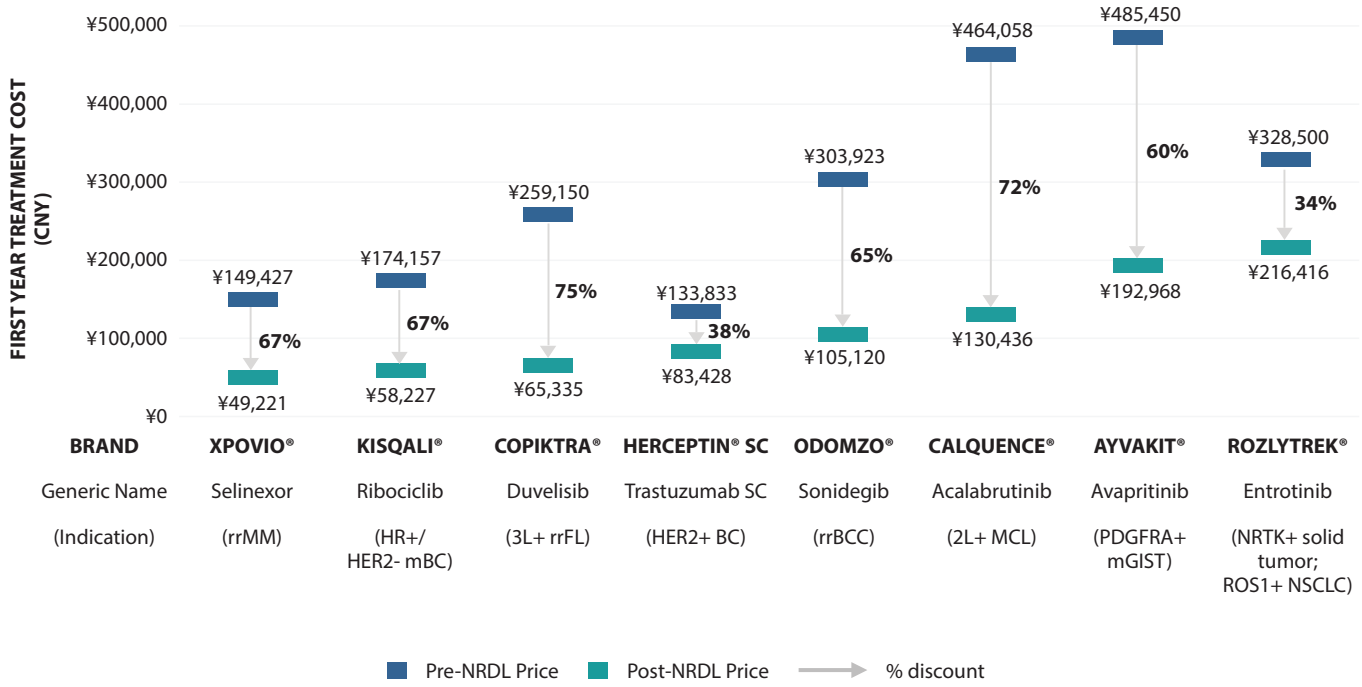
Annual treatment costs under informal price ceiling

As in previous years, all oncology multinational corporation (MNC) drugs fell under CNY 500K for negotiation eligibility and CNY 300K for NRDL inclusion, indicating that informal price ceilings remain effective and there was little flexibility to go beyond these thresholds.

Lack of correlation between the size of the population and post-NRDL prices

Despite CHN payers' heavy consideration of budget impact, limited correlation was observed between a product's indicated population size and its final post-NRDL annual price. This suggests various economic factors may have influenced the final pricing outcome beyond budget impact such as pricing benchmarks, cost-effectiveness and international reference price.

Figure 3. 2023 NRDL Newly Negotiated MNC Oncology Branded Drugs



Oncology Case Studies – Successful Listings

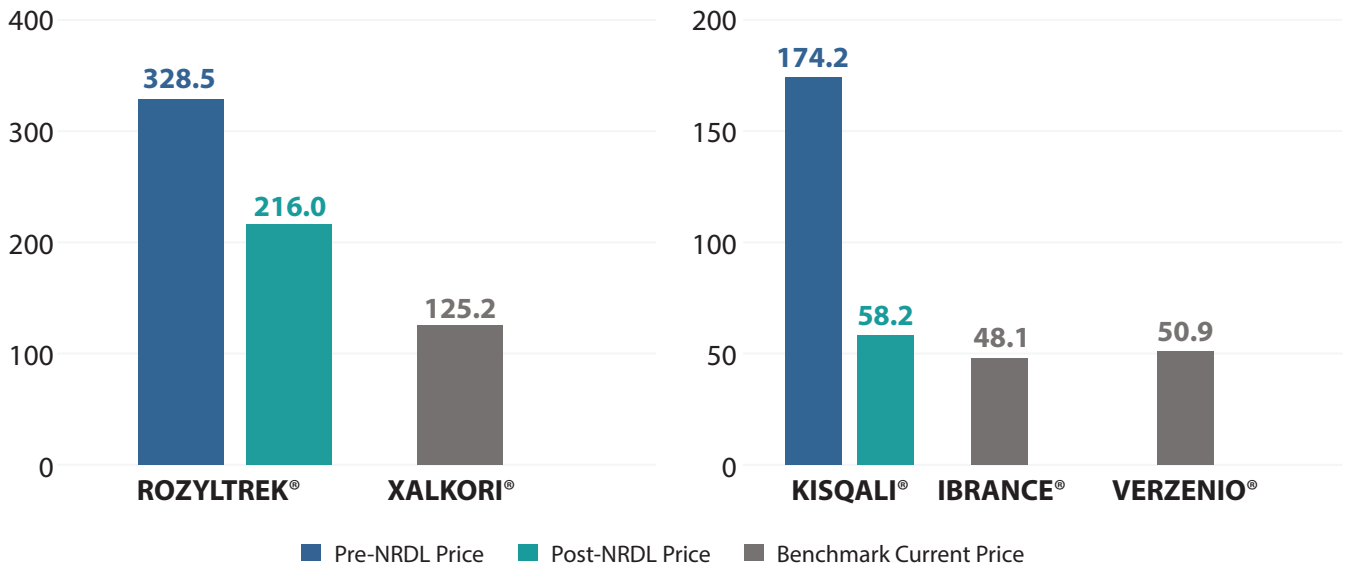
In 2023, three oncology products – ROZLYTREK®, KISQALI® and HERCEPTIN® SC, successfully secured listing, achieving price premiums over their pricing benchmarks.

Notably, ROZLYTREK was the first treatment indicated for NTRK+ solid tumors to address a clear unmet need. It demonstrated significant OS benefits in single-arm trials, with a mOS of 37.1 months for NTRK+ solid tumors and 47.7 months for ROS1+ 1L NSCLC. This compelling clinical profile supported ROZLYTREK to achieve a significant premium (42%) vs. XALKORI® – its pricing benchmark indicated for a larger indication (ALK+ and ROS1+ NSCLC).

Meanwhile, KISQALI demonstrated a 63.9-month OS benefit in its placebo-controlled trial, with its clinical superiority further illustrated through a matching-adjusted indirect comparison vs. IBRANCE®. This clinical superiority enabled KISQALI to achieve a modest premium (13%-17%) over the two NRDL-listed CDK4/6 inhibitors, IBRANCE and VERZENIO®.

The larger price premium achieved by ROZLYTREK vs. KISQALI highlights that payers may place higher value on breakthrough treatments addressing the white space vs. treatments that offer incremental improvements.

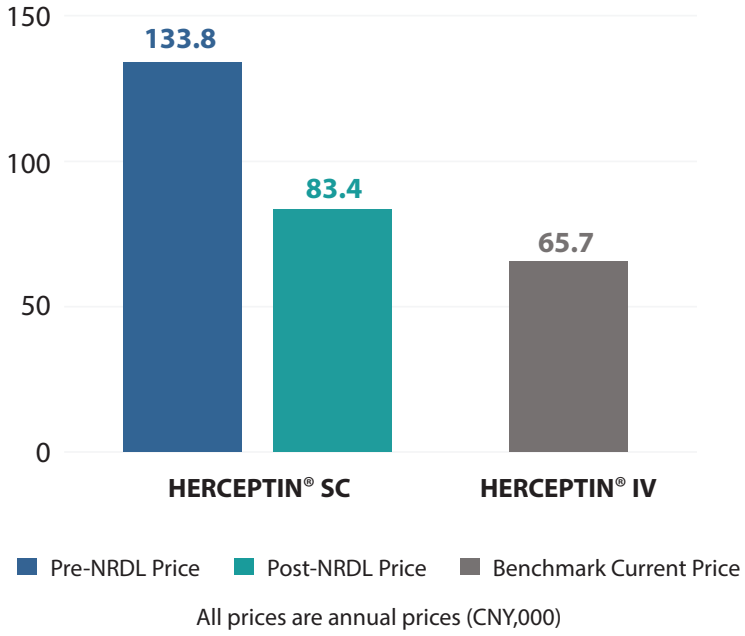
Figure 4. Case Studies of Successful Listings from NRDL Update: ROZLYTREK and KISQALI



All prices are annual prices (CNY,000)

HERCEPTIN SC achieved a 20% price premium over its IV formulation by demonstrating consistent pathological response rates and event-free survival in a head-to-head trial. Additionally, a subsequent study on patient preference revealed that 90% of patients preferred the SC formulation over IV. While the premium for HERCEPTIN SC suggests that CHN payers may have valued the improved route of administration, it is important to note that HERCEPTIN SC has a smaller budget impact and expected market share compared to its IV counterpart and biosimilars, which may have also contributed to the premium.

Figure 5. Case Studies of Successful Listings from NRDL Update: New Formulation HERCEPTIN SC (A Reformulation of HERCEPTIN)

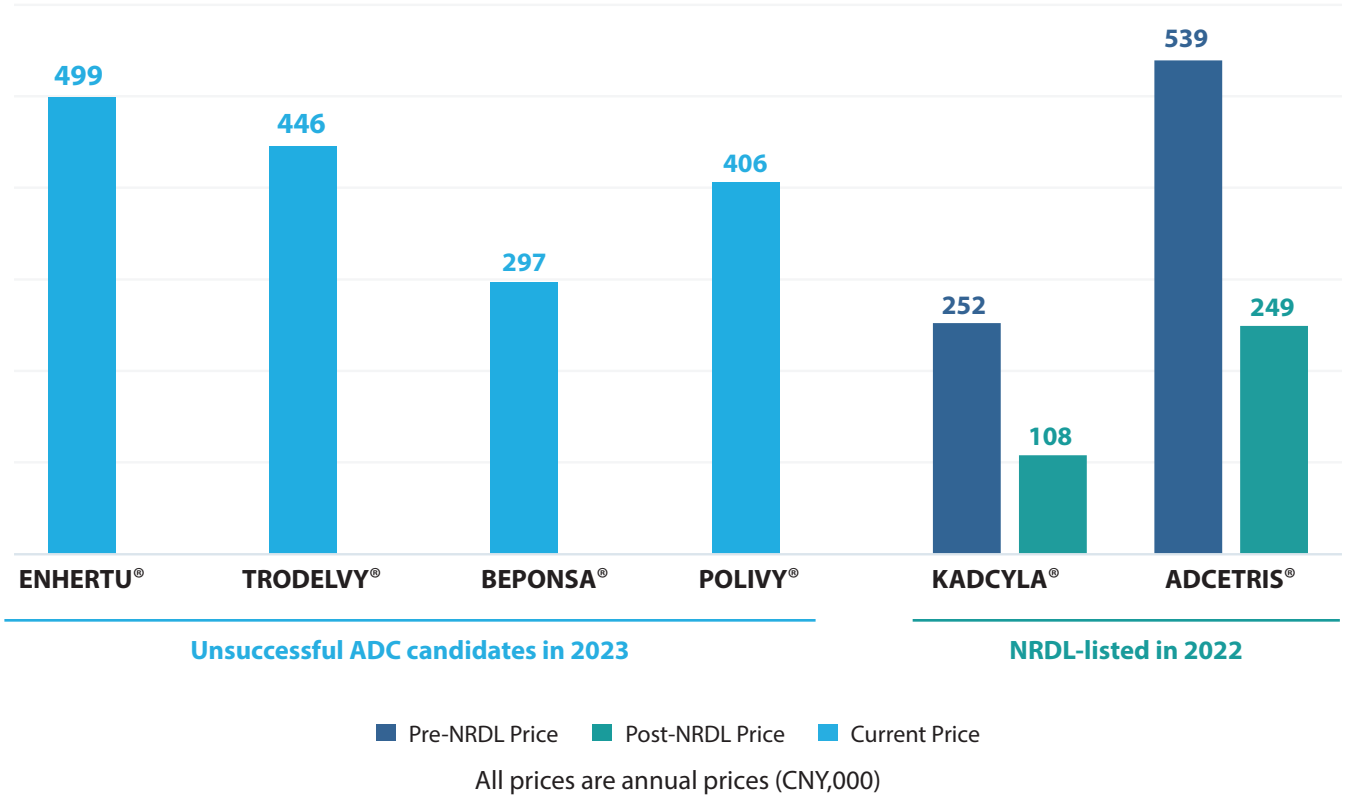


Oncology Case Studies – Unsuccessful Listings

Unsuccessful oncology listings in 2023 included some antibody-drug conjugate (ADC) drugs from MNC players as well as CAR-Ts due to perceived "high prices."

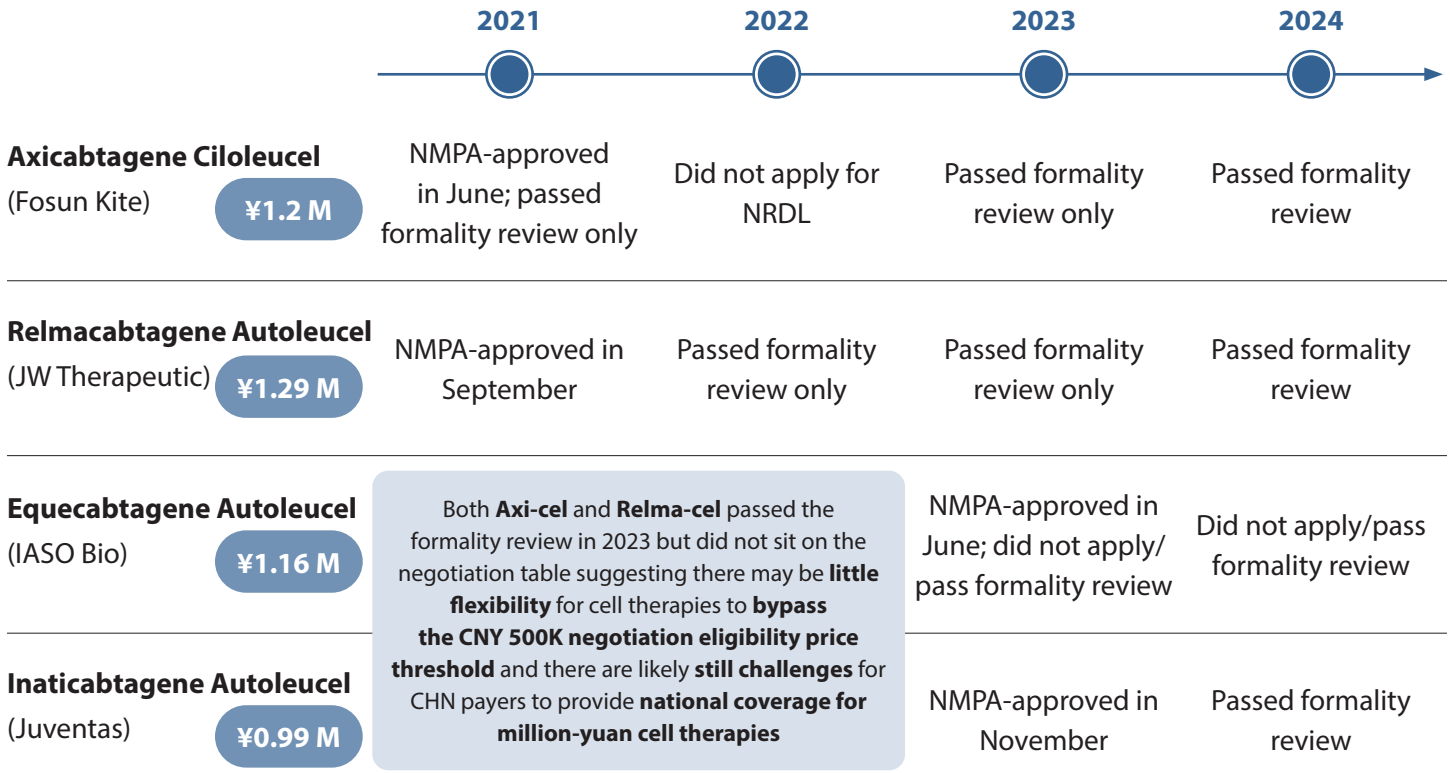
With annual prices near or above the informal NRDL price ceiling of CNY 300K, all MNC ADC applicants failed to gain NRDL listing in 2023. Considering that previous ADCs, such as KADCYLA® and ADCETRIS®, only achieved NRDL listing by reducing prices to the CNY 100-250K range, it is likely that emerging ADCs will be expected to fall within a similar pricing range. Furthermore, the anticipated entrance of domestic ADCs will increase competition, potentially reducing the urgency for payers to provide coverage for these ADCs. Interestingly, all ADCs that did not succeed in 2023 have re-submitted their NRDL assessment dossiers and are now shortlisted for the 2024 NRDL review. It will be intriguing to see how the ADC reimbursement landscape develops after the 2024 negotiations.

Figure 6. Annual Prices of Unsuccessful ADC Candidates for 2023 Update Compared to NRDL-Listed Products in 2022



After another attempt for NRDL inclusion following last year's failure, both YESCARTA® and CARTEYVA® once again failed to secure a spot in the 2023 NRDL. Although both CAR-Ts passed the formality review this year, they did not sit at the negotiation table. This suggests there may be little flexibility for cell therapies to bypass the CNY 500K negotiation eligibility price threshold and there are likely still challenges for CHN payers to provide national coverage for million-yuan cell therapies.

Figure 7. Timelines, Prices and Outcomes of Unsuccessful CAR-T Candidates for 2023 NRDL Update



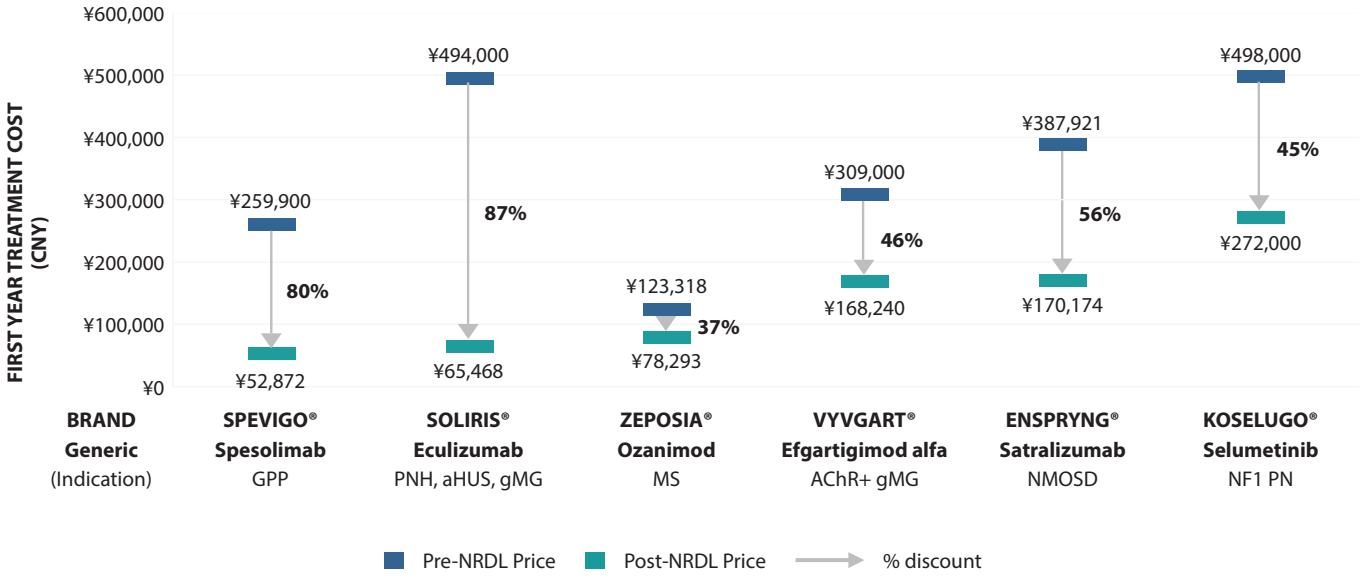
2023 NRDL Newly Negotiated MNC Oncology Rare Disease Drugs

The 2023 NRDL included the highest number of rare disease drugs in history, with 6 out of 15 manufactured by MNC players.

Growing payer focus on rare disease drugs: The 2023 NRDL included 15 rare disease drugs, a notable increase from the 6–8 drugs listed in previous years, signaling increasing NRDL focus on treatments for rare diseases. MNC contributed to 6 out of 15 total new listings, covering diseases that are both blank spaces with high unmet needs, such as generalized myasthenia gravsi (gMG) and neurofibromatosis type I plexiform neurofibromatos (NF1 PN), as well as more competitive spaces such as multiple sclerosis (MS).

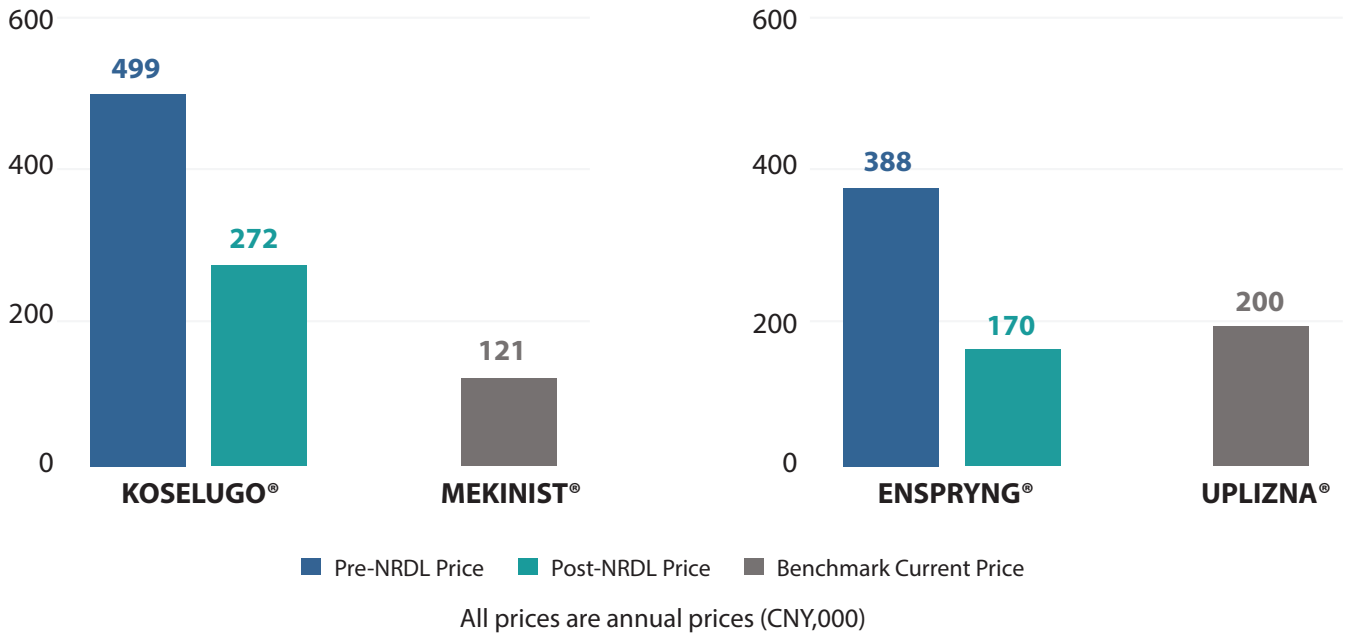
Informal price ceiling also applied to rare disease drugs: Similar to the oncology space, negotiated prices for all successfully listed MNC rare disease drugs did not exceed the informal threshold of CNY 500K pre-negotiation and CNY 300K post-negotiation. On average, rare disease drugs saw a 58.5% price cut, slightly less than the 61.7% average price reduction observed across all therapeutic areas.

Figure 8. Pre- and Post-NRDL Negotiation Prices for Listed Rare Disease Branded Drugs



Rare Disease Case Studies – Successful Listings

Figure 9. Successful NRDL listing of Rare Disease Drugs Case Studies: KOSELUGO® and ENSPRYNG®



All prices are annual prices (CNY,000)

Similar to oncology drugs, rare disease candidates were evaluated based on the NRDL value rating to determine pricing level compared to benchmarks.

KOSELUGO® was included as the first treatment indicated for NF1 PN, addressing a significant unmet need in this space. It showed durable tumor shrinkage, with an objective response rate of 68% and a PFS of 86%, as well as substantial quality of life improvements, with the pain reduction in 84% of patients. Although there is no formal pricing benchmark for KOSELUGO, it achieved significant premium vs. its reference drug, MEKINIST®, the only treatment with the same MoA (i.e., MEK inhibitor) listed in NRDL but indicated for multiple myeloma and metastatic NSCLC.

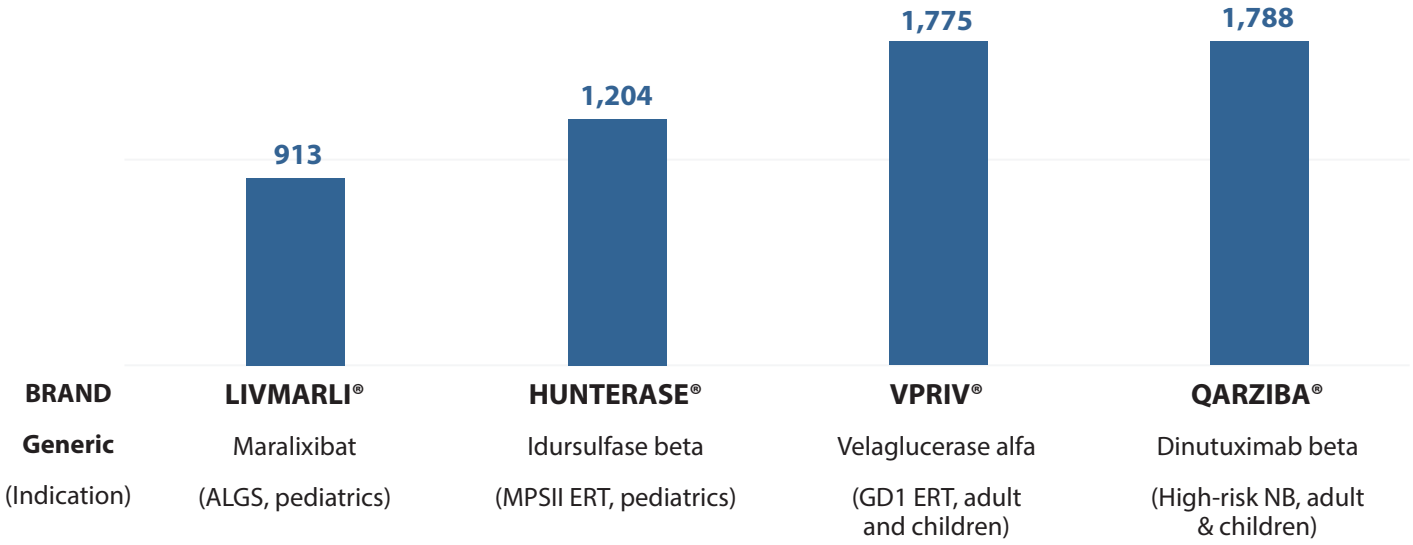
On the other hand, ENSPRYNG faced direct competition from UPLINZA®, which is already included in the NRDL. Despite ENSPRYNG offering better safety and a more convenient administration route, its efficacy was seen as slightly inferior to UPLINZA. Consequently, ENSPRYNG was deemed "equivalent" and negotiated at a 15% lower price than UPLINZA.

Based on the learnings from KOSELUGO and ENSPRYNG, value ratings may aid in determining the level of premiums or discounts a drug can achieve compared to its direct competitors or pricing benchmarks during negotiations. "Breakthrough" drugs are typically assigned higher value, making them more likely to secure a significant premium over benchmarks, while "equivalent" drugs are less likely to exceed the prices set by their benchmarks within the NRDL.

Rare Disease Case Studies – Unsuccessful Listings

Among rare disease products that were unsuccessful in securing an NRDL listing, most have drug prices that significantly exceed the informal price ceilings.

Figure 10. Pre-NRDL Current Prices of Unsuccessful Rare Disease Candidates



All prices are annual prices (CNY,000)

Four MNC rare disease drugs passed the formality review this year but failed to achieve NRDL listing, likely due to their inability to meet the informal price thresholds of CNY 500K for negotiation eligibility and CNY 300K for NRDL inclusion.

While disease burden, unmet needs and clinical benefits are crucial in the NRDL assessment, they alone are not sufficient to ensure successful inclusion. Payers also prioritize the sustainability of the healthcare budget, making them less flexible in adjusting the informal pricing thresholds (below CNY 500K pre-NRDL and below CNY 300K after negotiations).

What Have We Learned and What Do We Expect in the 2024 NRDL?

With the 2024 NRDL approaching, manufacturers can apply key lessons from 2023 to the upcoming updates. A notable change is the introduction of a new assessment framework. Historically, there has been limited transparency in the clinical value assessments for NRDL listings. However, as the value rating system matures, it is expected to offer a more objective measure for Chinese payers to assess and communicate product value, akin to the G-BA added benefit ratings in Germany and ASMR ratings in France. Despite this development, its influence on pricing remains uncertain, as current NRDL pricing negotiations are still heavily influenced by budget impact and annual price ceiling considerations.

Additionally, with policy shifts favoring innovative therapies, the 2024 NRDL is expected to continue prioritizing innovative treatments, including rare disease drugs. Products with breakthrough status launched in white space therapeutic areas are likely to have the greatest advantages in value assessment and price negotiations. However, overcoming the informal annual price thresholds may still pose a challenge.

Authors

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Wenting Zhang has over ten years of healthcare consulting experience. She has extensive experience across numerous therapy areas including oncology, immunology, neurology, cardiovascular diseases and rare (orphan) diseases.

She has in-depth knowledge of the global pharmaceutical markets including USA, EU and APAC, with a strong focus on China, particularly in pricing and reimbursement. As an expert of Trinity's Asia Pacific Center of Excellence, Wenting is leading the client engagements in this region as well as driving the development of thought leadership to share insights.

Wenting has a PhD in pharmacology from the University of Cambridge, U.K. Outside work, she enjoys spending time with family, traveling, swimming and dancing.

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