

Industry Report

China Pharmaceutical & Healthcare

2022 NRDL results came as no surprise

■ On Jan 18, the NHTA released the official results of the latest 2022 NRDL update, which will be effective on Mar 1, 2023

■ The NRDL outcome in line w/ our projection: ~82% success rate (121 of 147 shortlisted drugs) and ~60% of avg. price concessions

■ We reckon NRDL policy and result prove to be more predictable. Our top picks remain BeiGene (BGNE US) and Innovent (1801 HK)

NRDL results: high success rate, discount level in-line

The 2022 NRDL updates added 91 drugs (first inclusion via negotiation, excl. 30 renewals/non-exclusives) and removed 3 drugs across 23 therapeutic areas. The updated 2022 NRDL consists a total of 2,967 products (vs. 2,859 in 2021), including 1,586 (1,486) Western medicines and 1,381 (1,373) and TCM finished drugs (中成藥). Despite most of new drug prices remain confidential, we noted average price concession of 60.1% remain within the prior outcome range (~50-60% discount in 2018-2021). This reflects the NRDL results become more predictable.

PD-1/L1 price war cooling down as expected

The price war eased in PD-1 space, 1) the NHTA official said the annual treatment cost of PD-1 class are RMB30k-60k for four legacy PD-1 products, reflecting discount moderation under new rules (~10-15% price cut based on the NHTA's rule, see figure 2); 2) there is no new PD-1 products being included in the 2022 NRDL, in-line w/ our projection (see our report, [link](#)). This might because the domestic latecomers and MNC might see limited commercial opportunities from a deep price concession in exchange for potential volume ramp-up. We think Innovent is the biggest winner as it included another two major indication (1L ESCC/GC), followed by BeiGene (BGNE US) (4 new inclusion: incl. 2L sq-NSCLC, 2L ESCC, MSI-H/dMMR solid tumor and 1L NPC) and Hengrui (4 new inclusion: ≥2L NPC, 1L NPC, 1L ESCC & 1L sq-NSCLC). We noted Junshi opted out for its new available indications in 2022 NRDL. The results cement our projection that three major domestic players will continue to take over ~70% market share in 2023E and beyond.

NRDL continues to encourage innovation transformation

Newly approved drugs seized the opportunity in the NRDL updates given the high success negotiation rate: BeiGene's carfilzomib (proteasome inhibitor), HutchMed's savolitinib (c-MET), Hansoh's inebilizumab (αCD19) and Ascentage/Innovent's olverembatinib (Bcr-Abl). We believe the result also signals a much desired balance between innovation and reimbursement, and represents govt.'s continued stance of encouraging innovation transformation of the pharma/biotech industry.

Azvodine added & rare disease inclusion favourable

Anti-viral: azvodine is included w/ a price reduction of ~35% (to RMB11.58/3mg tab). The drug was approved w/ HIV/COVID-19 labels in 2021/2022. **Rare diseases:** the NHTA added 7 drugs in the NRDL (vs +7 in 2021) w/ total 59 under coverage. Worth noting, Takeda's lanadelumab for hereditary angioedema (HAE) is also included, which had a prior treatment cost of ~RMB1mn/yr. We believe favourable reimbursement measures should continue to drive the development of rare disease market. **Investment risks:** Higher-than-expected degree of price reduction in NRDL initial inclusions/ renewals, lower-than expected sales ramp-up post-NRDL inclusion etc.

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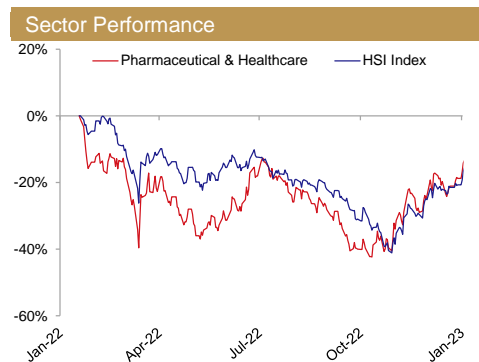
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WHAT'S NEW

2022 NRDL review

OVERWEIGHT

Previous	OVERWEIGHT
HSI (Jan 19, 2023)	21,651
HSCEI (Jan 19, 2023)	7,313



%	1m	6m	12m
Absolute return	17.5	11.6	(8.2)
Relative return	5.5	6.7	4.9

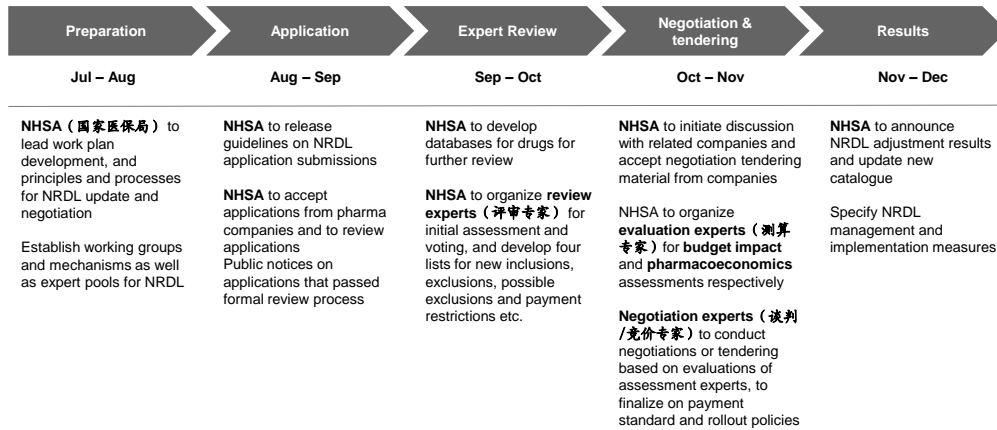
Source: Bloomberg

Related Research

1. China Pharmaceutical & Healthcare – Dental implant VBP result in-line; more VBPs ahead (OVERWEIGHT) (Jan 17, 2023)
2. China Pharmaceutical & Healthcare – The 8th national VBP preview (OVERWEIGHT) (Jan 17, 2023)
3. China Pharmaceutical & Healthcare – Biochemicals VBP result in-line, maloccl. VBP moderate (OVERWEIGHT) (Jan 6, 2023)
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5. China Pharmaceutical & Healthcare – 2023 outlook: The longest night will have an end (OVERWEIGHT) (Dec 30, 2022)
6. China Pharmaceutical & Healthcare – VBP expands into more medical device categories (OVERWEIGHT) (Dec 19, 2022)
7. China Pharmaceutical & Healthcare – ASH 2022 data readout review (OVERWEIGHT) (Dec 9, 2022)
8. China Pharmaceutical & Healthcare – Favorable stent VBP renewal results (OVERWEIGHT) (Dec 5, 2022)

Focus charts

Figure 1: NRDL listing timeline and tasks have become more predictable



Sources: NHTSA, CMS (HK), Simon-Kucher; Note: NRDL 2022 negotiation was delayed to Jan 2023 from Dec 2022

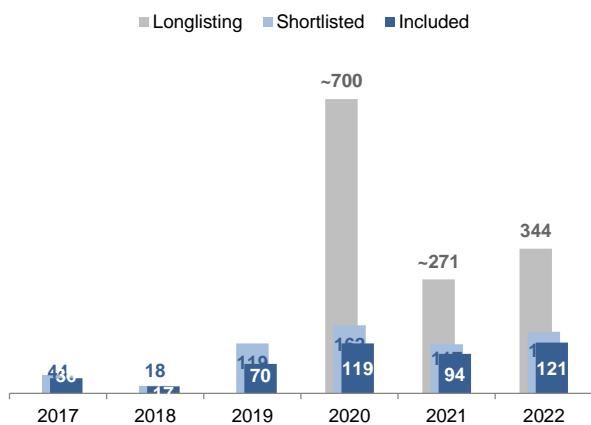
Figure 2: NRDL renewal price adjustment has become more predictable

ASP1: adjustment based on below rules, if indication coverage remains unchanged					
Ratio A: actual exp. vs. Co.'s prev. budget	Actual annual expenditure of SHI				
	<RMB0.2bn	RMB0.2-1.0bn	RMB1.0-2.0bn	RMB2.0-4.0bn	>RMB4.0bn
A ≤ 110%	No change	-2%	-4%	-6%	-10%
110% ≤ A ≤ 140%	-5%	-7%	-9%	-11%	-15%
140% < A ≤ 170%	-10%	-12%	-14%	-16%	-20%
170% < A ≤ 200%	-15%	-17%	-19%	-21%	-25%
A > 200%	Unsuitable for simple renewal, full scale renegotiation is required				

ASP2: adjustment made based on above ASP 1 and below rules, if indication coverage is expanded					
Ratio B: budget increase vs. max (prev. budget or actual exp.)	Actual annual expenditure of SHI				
	<RMB0.2bn	RMB0.2-1.0bn	RMB1.0-2.0bn	RMB2.0-4.0bn	>RMB4.0bn
B ≤ 10%	No change	-2%	-4%	-6%	-10%
10% < B ≤ 40%	-5%	-7%	-9%	-11%	-15%
40% < B ≤ 70%	-10%	-12%	-14%	-16%	-20%
70% < B ≤ 100%	-15%	-17%	-19%	-21%	-25%
B > 100%	Unsuitable for simple renewal, full scale renegotiation is required				

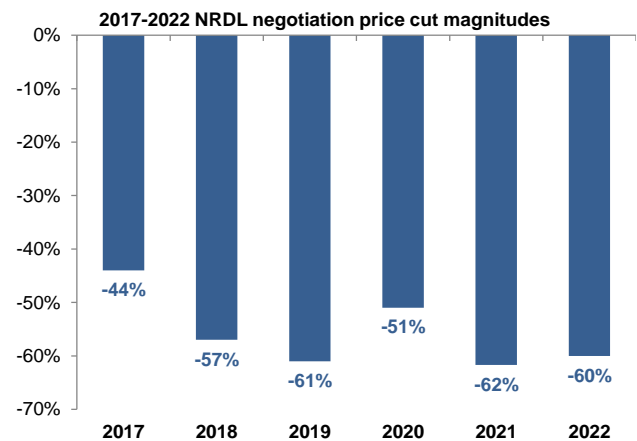
Sources: NHTSA, CMS (HK), Simon-Kucher

Figure 3: 2017-2022 NRDL negotiation inclusion outcomes



Sources: NHTSA, CMS (HK)

Figure 4: 2017-2022 NRDL negotiation price cut magnitudes



Sources: NHTSA, CMS (HK) estimates

The price war eased in PD-1 space, 1) the NHSA official said the annual treatment cost of PD-1 class are RMB30k-60k for four legacy PD-1 products, reflecting discount moderation under new rules (~10-15% price cut based on the NHSA's rule, see figure 2); 2) there is no new PD-1 products being included in the 2022 NRDL, in-line w/ our projection (see our report, [link](#)). This might be because the domestic latecomers and MNC might see limited commercial opportunities from a deep price concession in exchange for potential volume ramp-up. We think Innovent is the biggest winner as it included another two major indication (1L ESCC/GC), followed by BeiGene (BGNE US) (4 new inclusion: incl. 2L sq-NSCLC, 2L ESCC, MSI-H/dMMR solid tumor and 1L NPC) and Hengrui (4 new inclusion: ≥2L NPC, 1L NPC, 1L ESCC & 1L sq-NSCLC). We noted Junshi opted out for its new available indications in 2022 NRDL. The results cement our projection that three major domestic players will continue to take over ~70% market share in 2023E and beyond.

Figure 5: Selected PD-1/L1 products for 2022 NRDL negotiation

Molecule	Target	Company	Indications in NRDL (*Newly added to NRDL)	Indications NOT in NRDL	Act. price reduct./CMS est
Sintilimab	PD-1	Innovent	≥3L cHL; ≥1L sq/nsq-NSCLC; 1L HCC; 1L G/GEJ; 1L ESCC	n.a.	To be disclosed
Camrelizumab	PD-1	Hengrui	≥3L cHL; HCC; 1L nsq-NSCLC; ≥2L ESCC; ≥2L NPC; 1L NPC; 1L sq-NSCLC; 1L ESCC	n.a.	To be disclosed
Tislelizumab	PD-1	BeiGene	≥3L cHL; ≥2L UC; 1L sq/nsq-NSCLC; ≥2L HCC; 2/3L NSCLC; 2L ESCC; MSI-H/dMMR ST; 1L NPC	n.a.	To be disclosed
Toripalimab	PD-1	Junshi	Melanoma; ≥2L NPC; UC	1L NPC; 1L ESCC; 1L nsq-NSCLC	n.a.
Serplulimab	PD-1	Henlius	n.a.	MSI-H/dMMR ST; 1L sq- NSCLC; ES-SCLC	Opted-out
Penpulimab	PD-1	SBP/Akeso	n.a.	r/r nHL; 1L sq-NSCLC	Opted-out
Zimberelimab	PD-1	Gloria	n.a.	≥2L nHL;	Opted-out
Envafohimab	PD-L1	Alphamab	n.a.	MSI-H/dMMR ST (GC/CRC/other STs)	Opted-out
Sugemalimab	PD-L1	Pfizer/CStone	n.a.	1L sq/nsq-NSCLC (Stage IV) / 1L NSCLC (Stage III)	Opted-out
Cadonilimab	PD-1xCTLA-4	Akeso	n.a.	r/m CC	Opted-out
Pembrolizumab	PD-1	Merck	n.a.	2L melanoma; 1L sq/nsq-NSCLC; 1L NSCLC (PD-L1+); 2L ESCC; 1L HNSCC; 1L MSI-H/dMMR CRC; 1L G/GEJ	Opted-out
Nivolumab	PD-1	BMS	n.a.	1L sq/nsq-NSCLC; HNSCC (PD-L1+); 1L MPM; ≥2L G/GEJ; 1L G/GEJ; G/GEJ (adju.); 1L ESCC	Opted-out
Atezolizumab	PD-L1	Roche	n.a.	1L ES-SCLC; 1L HCC; 1L sq/nsq-NSCLC; 1L Stage II-III NSCLC (adju.)	Opted-out
Durvalumab	PD-L1	AZ	n.a.	2L Stage III NSCLC; 1L ES-SCLC	Opted-out

Sources: NHSA, News, CMS (HK)

Figure 6: Selected other major products for 2022 NRDL negotiation

Molecule	Target	Company	Indications in NRDL (*Newly added to NRDL)	Indications NOT in NRDL	Act. price reduct./CMS est
Osimertinib	EGFR (3rd Gen)	AZ	≥1L EGFRm NSCLC; Stage IB-IIIa EGFRm NSCLC	EGFRm NSCLC (adjuvant)	To be disclosed
Almonertinib	EGFR (3rd Gen)	Hansoh	NSCLC (EGFRm); 1L NSCLC (EGFRm)	n.a.	To be disclosed
Furmonertinib	EGFR (3rd Gen)	Allist	NSCLC (EGFRm); 1L NSCLC (EGFRm)	n.a.	To be disclosed
Savolitinib	c-MET	HutchMed	NSCLC (MET+ exon 14)	n.a.	To be disclosed
Ensartinib	ROS1/ALK/c-MET	Betta	≥2L ALK+ NSCLC; 1L ALK+ NSCLC	n.a.	To be disclosed
Pyrotinib	HER-2/EGFR	Hengrui	2L HER-2+ mBC	HER-2+ BC (neo adju.)	n.a.
Dalpiciclib	CDK4/6	Hengrui	HR+/HER-2- mBC	n.a.	To be disclosed
Palbociclib	CDK4/6	Pfizer	n.a.	HR+/HER-2- mBC	Opted-out
Rezvilutamide	AR antagonist	Hengrui	mHSPC	n.a.	To be disclosed
Enzalutamide	AR antagonist	Pfizer	n.a.	mHSPC	Opted-out
Ripretinib	KIT/PDGFRα	Zai Lab	GIST	n.a.	To be disclosed
Omadacycline	30S ribosomal subunit	Zai Lab	ABSSSI/CABP	n.a.	To be disclosed
Disitamab vedotin	HER2 ADC	RemeGen	2L+ HER2+ GC/GEJ; 2L HER2+ UC	n.a.	Moderate (CMS est.)
Trastuzumab emtansine	HER2 ADC	Roche	HER2- HR+ BC	n.a.	To be disclosed
Selinexor	XPO1	Antengene/ Karyopharm	n.a.	≥2L MM	Opted-out
Carfilzomib	proteasome	BeiGene/ Onyx	r/r MM	n.a.	To be disclosed
Siltuximab	IL-6	BeiGene/ EUSA	n.a.	Castleman	Opted-out
Pemigatinib	FGFR1/2/3	Innovent/ Incyte	n.a.	≥2L Cholangiocarcinoma	Opted-out
Olverembatinib	Bcr-ABL/KIT	Innovent/ Ascentage	T315Im CML	n.a.	<-5% (CMS est.)
Pralsetinib	RET	CStone/ Blueprint	n.a.	MTC; NSCLC	Opted-out
Ivosidenib	IDH1	CStone/ Servier	n.a.	IDH-1 AML	Opted-out
Avapritinib	KIT/PDGFRα	CStone/ Blueprint	n.a.	GIST (PDGFRA exon 18)	Opted-out
Duvelisib	PI3K	CSPC/ Secura	n.a.	3L FL	Opted-out
Lanadelumab	Plasma kallikrein inhib.	Takeda	HAE	n.a.	To be disclosed
Azvodine	RdRp	Genuine Bio	HIV; COVID-19	n.a.	-35%

Sources: NHSA, News, CMS (HK)

Figure 7: Selected renewal products for 2022 NRDL negotiation

Molecule	Target	Company	Indications in NRDL (*Newly added to NRDL)	Indications NOT in NRDL	Act. price reduct./CMS est
Ibrutinib	BTK	JNJ	2L MCL; CLL/SLL; WM	n.a.	To be disclosed
Olaparib	PARP	AZ	OC; tubal cancer; PPC; mCRPC	n.a.	To be disclosed
Flumatinib	Bcr-Abl	Hansoh	Ph+ CML	n.a.	-7%
TPO	Hematology	3sBio	CIT/ITP	n.a.	To be disclosed
Sanbexin	Neurology	Simcere	Acute ischemic stroke (AIS)	n.a.	-33%
NBP (injection)	Neurology	CSPC	Acute ischemic stroke (AIS)	n.a.	-16%
NBP (capsule)	Neurology	CSPC	Acute ischemic stroke (AIS)	n.a.	Unchanged

Sources: NHSA, News, CMS (HK)

Investment Ratings

Industry Rating	Definition
OVERWEIGHT	Expect sector to outperform the market over the next 12 months
NEUTRAL	Expect sector to perform in-line with the market over the next 12 months
UNDERWEIGHT	Expect sector to underperform the market over the next 12 months

Company Rating	Definition
BUY	Expect stock to generate 10%+ return over the next 12 months
HOLD	Expect stock to generate +10% to -10% over the next 12 months
SELL	Expect stock to generate loss of 10%+ over the next 12 months

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