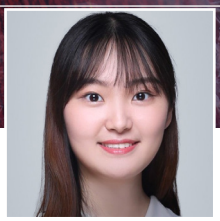
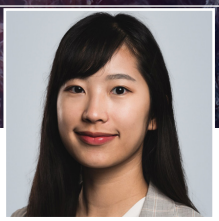
China's NRDL 2022 Update: Spotlight on Oncology

Part 2 of 3


Chloe Wang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In part 2 of the NRDL 2022 update series, PRECISIONadvisors' Chloe Wang, Katherine Leong and Cherry Moldovan discuss key trends and strategic considerations for multinational companies, with a deep dive into oncology.

Oncology continues to be a key therapy area for NRDL inclusion, where 14 new oncology products entered the NRDL for the first time this year (Table 1).

- Most of them were included via negotiations, with a considerable proportion of new entrants being domestic products.
- Ibrance was the only oncology product that went through the bidding process; after Pfizer's previous attempts to get Ibrance on the NRDL without success, loss of exclusivity this year allowed Ibrance to secure a place on the list via the new bidding process.

Product	Inclusion route	Company	Indication
Venclexta (venetoclax)	Negotiation	AbbVie	AML
Nai Li Ke (olverembatinib)	Negotiation	Ascentage/ Innovent	T315Im CML
Kyprolis (arfilzomib)	Negotiation	Amgen/ BeiGene	r/r MM
Adcetris (brentuximab)	Negotiation	Takeda	CD30+ ALCL, HL, MF
Alunbrig (brigatinib)	Negotiation	Takeda	ALK+ NSCLC
Lorbrena (lorlatinib)	Negotiation	Pfizer	ALK+ NSCLC
Orpathys (savolitinib)	Negotiation	HUTCHMED/ AZ	MET14+ NSCLC
Ariane (rezvilutamide)	Negotiation	Hengrui	HSPC
Firmagon (degarelix)	Negotiation	Ferring/ Pfizer	androgen-dependent PC
Qinlock (ripretinib)	Negotiation	Deciphera/ Zai Lab	GIST
Kadcyla (trastuzumab emtansine)	Negotiation	Roche	HER2+ BC
Ai Rui Kang (dalpiciclib)	Negotiation	Hengrui	HR+/ HER2- BC
You Ti Di (utidelone)	Negotiation	Biostar/ Luye	recurrent/metastatic BC
Ibrance (palbociclib)	Bidding	Pfizer	HR+/ HER2- BC

Table 1: Overview of New Oncology Entrants in NRDL 2022

● China as first global launch market ■ Multinational ■ Domestic[1]

PD-(L)1 inhibitors on the NRDL remain crowded with domestic products dominating the spotlight, including Innovent's Tyvyt (sintilimab), Hengrui's AiRuiKa (camrelizumab), Junshi's Tuoyi (toripalimab), and BeiGene's Baize'an (tislelizumab).

- All products except Tuoyi had successfully expanded coverage to new indications this year. With homegrown PD-(L)1s setting low price benchmark- at ~CNY 30K-50K (~USD 4.3K-7.2K) per year, it is challenging for MNCs to remain competitive on price.
- In fact, Merck, BMS, AZ and Roche did not participate in this NRDL update round for their PD-(L)1s despite being eligible. These companies have strategically decided to stay in the NRDL alternative lanes in providing patient access (eg, through commercial health insurances) which is unsurprising considering their previous failed attempts at NRDL inclusion and the increasing domestic competition.
- Interestingly, NRDL inclusion is becoming challenging even for domestic PD-(L)1s, with Henlius, Alphamab/3D and Akeso having failed to secure coverage for their PD-(L)1s this year.[2]

Another domestic player that had been highly anticipated was JW Therapeutics' Carteyva, being the only CAR-T therapy that passed the NRDL preliminary review this year.

- Currently priced at CNY 1.29M per vial, Carteyva is indicated for large B-cell lymphoma and follicular lymphoma. This homegrown product was the second NMPA-approved CAR-T in China following Yescarta by Fosun Kite.
- Carteyva passed the NRDL preliminary review for the former indication but did not secure its listing in the end, following the same fate as Yescarta's failed attempt at NRDL inclusion in 2021. Noticeably, Yescarta was priced at CNY 1.2M (~USD 173K) per vial, and Fosun Kite did not attempt for NRDL inclusion in 2022.
- Considering the NHSA's unofficial price threshold of CNY 300K per year, it may be very challenging for high-cost advanced therapy medicinal products (ATMPs) to secure broad patient access under the current inclusion process.

Considerations and Conclusions

Oncology remains a key therapeutic area for NRDL inclusion with a strong presence of domestic companies, primarily given their ability to offer greater price discounts with a more locally integrated supply chain. On the backdrop of the growing competition in the market, MNCs may consider localising their operations or enhancing collaboration with domestic manufacturers, in order to increase their capability to compete on price whilst considering the price-access balance. Beyond NRDL, MNCs should also consider the increasingly popular alternative routes to gain patient access, (eg, commercial health insurance, crowdfunding and direct-to-patient financing), particularly in areas with intense competition and domestic presence.

1 Companies headquartered in China

2 Serplulimab, envafolimab and cadonilimab, respectively

Abbreviations: ALCL, anaplastic large cell lymphoma; ALK+, anaplastic lymphoma kinase-positive; AML, acute myeloid leukemia; ATMPs, advanced therapy medicinal products; BC, breast cancer; CAR-T, chimeric antigen receptor T-cell; CNY, Chinese Yuan/renminbi; GIST, gastrointestinal stromal tumour; HER2+, human epidermal growth factor receptor 2-positive; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive; MF, myelofibrosis; MNC, multinational corporation; HL, Hodgkin lymphoma; HSPC, hormone-sensitive prostate cancer; MET14+, MET exon 14-positive; MS, multiple sclerosis; NHSA, National Healthcare Security Administration; NMPA, National Medical Products Administration; NRDL, National Reimbursement Drug List; NSCLC, non-small cell lung cancer; PC, prostate cancer; PD-1/PD-L1, programmed death receptor-1/programmed death-ligand 1; r/r MM, relapsed/refractory multiple myeloma; T315Im CML, T315I-mutated chronic myeloid leukemia.

For any questions in relation to the NRDL updates or China access more generally, please don't hesitate to **reach out to our China Centre of Excellence**:

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