



**BE1GENE**

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# 2020 NRDL Result Conference Call

December 28, 2020

# Agenda and Speakers

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|---|---------------------|
| <b>1. Welcome</b>                           | <b>Howard Liang</b> |
| <b>2. Overview and Introduction</b>         | <b>John Oyler</b>   |
| <b>3. BeiGene's NRDL Outcome and Impact</b> | <b>Xiaobin Wu</b>   |
| <b>4. Summary and Conclusions</b>           | <b>John Oyler</b>   |
| <b>5. Q&amp;A</b>                           | <b>All</b>          |

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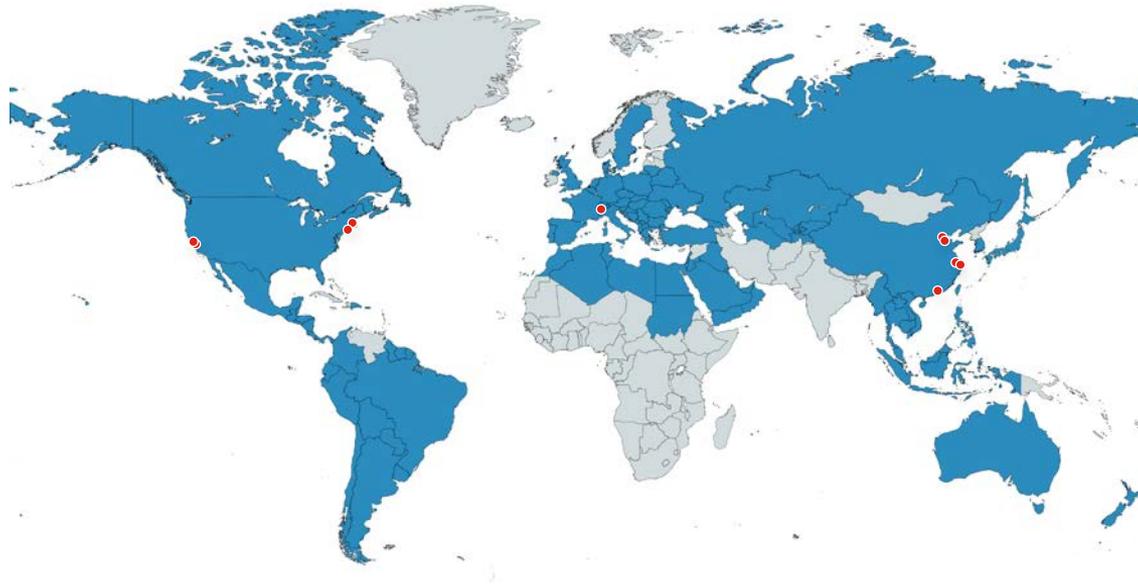
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# BeiGene's Impactful 10<sup>th</sup> Year and Upcoming Milestones

4	5	3	9	8	25+		4	7	4	12
Preclinical Assets Advanced into Clinic	Trials Enrolled	Phase 3 Data Readouts	NDA Filings	Approvals or Launches	Assets Added Through Collaborations	Organizational Progress	Early Data Readouts	Potential Phase 3* Readouts and Potential Filings	Potential NDA Filings or Regulatory Discussion	Up to - Commercial Portfolio
Past 15 Months (From 4Q19 – YTD)							Expected Milestones Over Next 12 Months			
<b>Global</b> BGB-10188 Pi3k-5i BGB-A445 anti OX40 BGB-3245 B-RAFi BGB-11417 Bcl-2i	Tisle 1L HCC BRUKINSA MZL Tisle 2/3L NSCLC Tisle 2L ESCC Pami Breast cancer	BRUKINSA HTH in WM	BRUKINSA WM (EU) BRUKINSA WM (Canada) BRUKINSA MCL (Israel)	BRUKINSA R/R MCL	     	Biologics manufacturing in process validation & expanded  Amgen transitional activities progressing  Substantial expansion of management ranks and their teams	OX40 and tisle +OX40 Bcl-2i, and BRUKINSA + Bcl-2i Tisle + sitra Data TIGIT, and Tisle + TIGIT	BRUKINSA 1L CLL/SLL BRUKINSA R/R MZL BRUKINSA HTH CLL/SLL Tisle 2L ESCC  Tisle 1L NPC Tisle dMMR / MSI-H Pami Plt-sensitive OC	Tisle 2/3L HCC BRUKINSA WM (USA)  SYLVANT Castleman Pami OC Maintenance	  tislelizumab pamiparib  XGEVA (denosumab)  Kyprolis (carfilzomib)  BLINCYTO (binetumab)  Abraxane <sup>1</sup> (nanoparticle albumin-bound paclitaxel)  Vidaza (azacitidine for injection)  Revlimid (tenatolimod) QARZIBA (dinutuximab beta)  sylvant (dolutegravir) BAT1706
<b>China</b>		Tisle 1L Sq NSCLC Tisle 1L Nsq NSCLC Tisle 2L/3L NSCLC	Tisle 1L Sq NSCLC Tisle 1L Nsq NSCLC Tisle 2/3L HCC BRUKINSA WM Pami 3L gBRCA+ OC QARZIBA neuroblastoma	Tisle cHL Tisle UC BRUKINSA R/R MCL BRUKINSA R/R CLL/SLL XGEVA GCTB XGEVA SRE BLINCYTO ALL						

1. As announced previously, the NMPA suspended the importation, sales and use of ABRAXANE® (nanoparticle albumin-bound paclitaxel) in China supplied to BeiGene by Celgene Corporation, a Bristol Myers Squibb (BMS) company. \* Phase 3 or registration enabling trials. MCL: Mantle Cell Lymphoma; CLL/SLL: Chronic Lymphocytic Leukemia/Small Cell Lymphoma; GC/GEJ: Gastric Cancer/Gastroesophageal Junction; HCC: Hepatocellular Carcinoma; MM: Multiple Myeloma; OC: Ovarian Cancer; RCC: Renal Cell Carcinoma; WM: Waldenström's Macroglobulinemia; cHL: Classical Hodgkin's Lymphoma; ESCC: Esophageal Squamous-Cell Carcinoma; GC: Gastric Cancer; MSI-H or dMMR: Microsatellite Instability High or Deficient Mismatch Repair; NDA: New Drug Application; NSCLC: Non-Small Cell Lung Cancer; R/R: Relapsed / Refractory.

# BeiGene's Mission to Provide Greater Access to Patients



- Countries and regions BeiGene is marketing or intends to provide therapeutics
- BeiGene office

- NRDL inclusion enables access to much broader patient population in China
- China's large commercial base and running China-inclusive clinical trials result in reduced per-patient development costs
- This enables accessible pricing in turn allowing broader distribution in underserved new markets
- Internally developed BRUKINSA is approved in 2 countries, filed in 12 countries and regions with 6 of the 12 accepted
- Collectively, BeiGene could provide access to patients in over 60 countries and regions

# BeiGene Successfully Obtained NRDL Listings

- Drugs approved by August 17, 2020 eligible for negotiation
  - previously prior year-end cut-off
- All three BeiGene drugs in negotiation included, for all eligible indications
  - tislelizumab: R/R cHL<sup>1</sup> and R/R UC<sup>2</sup>
  - BRUKINSA: R/R CLL/SLL<sup>3</sup> and R/R MCL<sup>4</sup>
  - XGEVA: GCTB<sup>5</sup>
- Significant victory in making innovative medicines accessible in the fight against cancer

1. Approved for patients with classical Hodgkin's lymphoma who have received at least two prior therapies<sup>a</sup>.

2. Approved for the treatment of patients with previously treated locally advanced or metastatic urothelial carcinoma (bladder cancer)<sup>a</sup>.

3. Approved for adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior therapy<sup>a</sup>, and

4, for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy<sup>a</sup>.

5. Part of Amgen BeiGene collaboration. Approved for the treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity<sup>a</sup>.

a. This indication is approved under conditional approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

# National Reimbursement Drug List of China

- Basic Medical Insurance covers >95% of Chinese patients
- Drugs listed in NRDL have been covered since 2000
- Innovative medicines have been covered via negotiation since 2016
- Coverage of drugs in China is label based
- Drug co-pay of 5%-50% depends on economics of each city/province
- Patients can elect to use an unlisted drug and self-pay

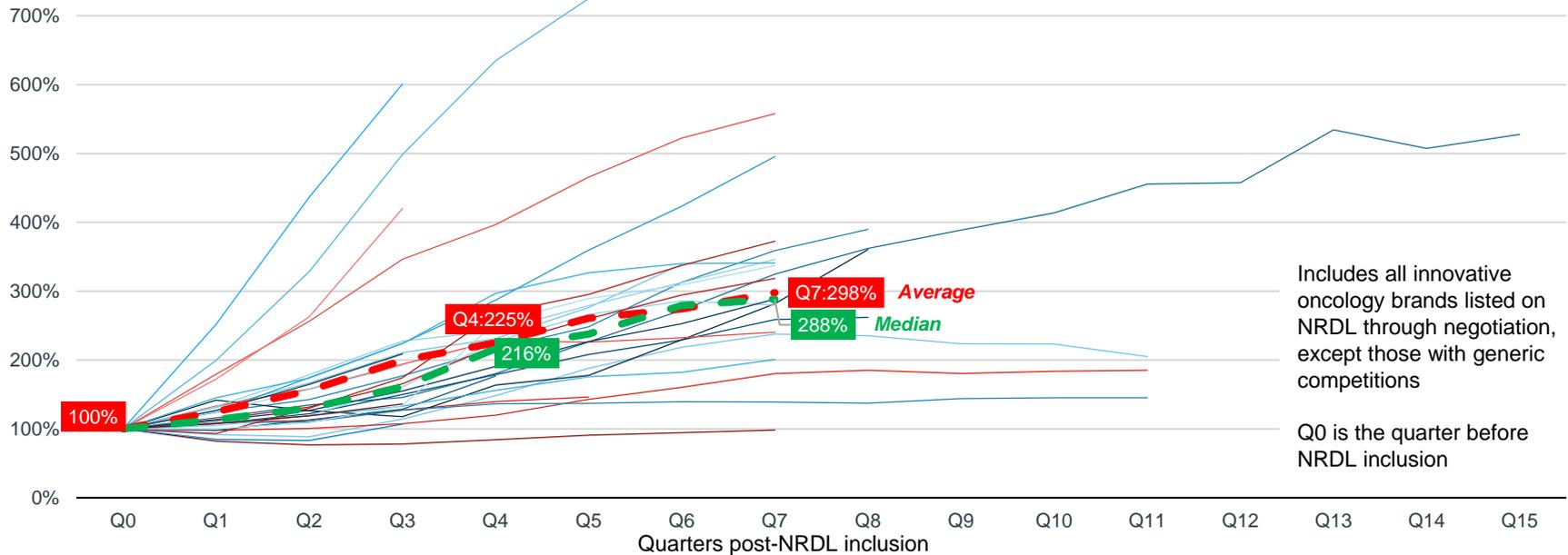
# NRDL Class of 2020

## Only BeiGene and two local PD-1's made this year's list

- 758 drugs were submitted to NHTA
- After 3 rounds of elimination 162 went into final negotiation
- 119 drugs were added to this year's list
- Within oncology:
  - PD-(L)1's: Only BeiGene and two local companies were added this year
    - tislelizumab (R/R cHL, R/R UC)
    - camrelizumab (R/R HCC, R/R ESCC, 1L nsq NSCLC, R/R cHL)
    - toripalimab (melanoma)
    - sintilimab (R/R cHL, added last year)
    - MNCs approved but not on NRDL (Keytruda, Opdivo, Imfinzi, Tecentriq)
  - BTK Class: BRUKINSA is the only newly listed BTK inhibitor
    - zanubrutinib (R/R MCL, R/R CLL/SLL)
    - ibrutinib (R/R MCL, R/R CLL/SLL, 1L CLL/SLL, R/R WM)
  - RANKL: Amgen and BeiGene's XGEVA added

# NRDL Inclusion Historically Has Led to Significant Growth of Oncology Product Sales

NRDL Negotiated Oncology Brand Performance, as Percentage of Annual Sales Value Before NRDL

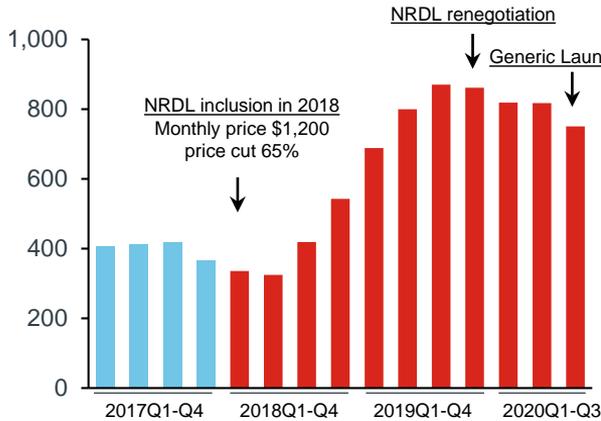


Note: Analyses of NRDL included all innovative oncology brands that entered NRDL through negotiation, including 2, 10, 14, and 6 brands in 2016, 2017, 2018, and 2019, respectively, except 4 brands which had generic competition at the time of inclusion; data points are trailing four quarters of sales. Source: NRDL; BeiGene Analysis

# Post-NRDL Oncology Cases Illustrate Large Sales Increase Driven by Volume

## Herceptin

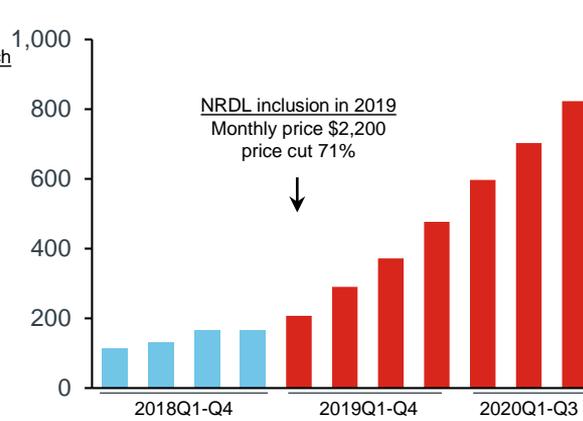
Trailing previous 4Q sales  
Unit: mn USD



- Achieved peak trailing of 4Q sales of \$870mn by 2019Q3
- Illustrating volume potential in China

## Tagrisso

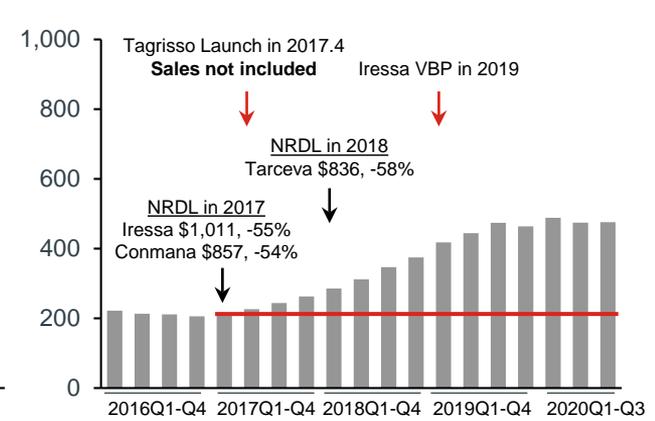
Trailing previous 4Q sales  
Unit: mn USD



- Achieved trailing of 4Q sales of \$820mn by 2020Q3, two years after launch, seven Qs post NRDL
- Illustrating volume potential and willingness to pay for quality

## 1<sup>st</sup> Generation EGFR Inhibitors

Trailing previous 4Q sales  
Unit: mn USD



- Total sales of 1<sup>st</sup> generation EGFR originator brand doubled in two years post NRDL, despite lower prices, generic launches, Tagrisso launch, and VBP

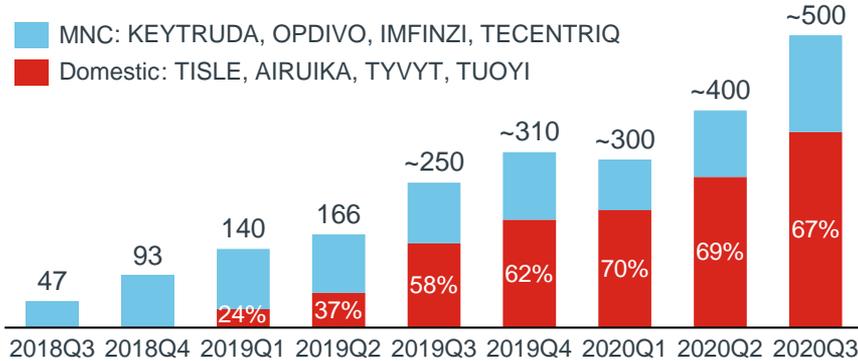
Note: Trailing four quarters, adding up the previous 4 quarters of sales; VBP = value-based purchase; 1st and 2nd Generation EGFR class include: CONMANA (Betta), IRESSA (AZ), TARCEVA (Roche), GIOTRIF (BI), VIZIMPRO (Pfizer); Source: BeiGene Analysis for China sales;

# China PD-(L)1 Market is Large and Poised for Growth

## Domestic players have approximately 2/3<sup>rd</sup> share

### China PD-(L)1 Market Growth

(Est. Sales by Quarter, in USD Mn, all brands)



2020: ~\$2bn

#### Potential Impact of NRDL on the Class

Est. Penetrated Patients (Annual, 000s)	Patient Potential (Annual, 000s)	DOT
~300	Incidence: 2,580 Mortality: 1,810	Opportunity to double based on DOT reference in the US, current China ~3 mo

- **China PD-(L)1 class sales** growing quickly despite limited reimbursement
  - Annualized run rate of approximately **\$2bn**
  - Domestic PD-1's have dominant share despite later entrance
- **Large market opportunity, annual incidence of 2.6 million** in PD-(L)1-sensitive tumors
  - NRDL inclusions could significantly **improve access, increase treatment duration**, and further **favor domestic companies**
  - None of the MNC PD(L)1 brands are included in NRDL
  - Anticipate many additional patients to benefit from NRDL listing
- **Tislelizumab included in NRDL - cHL and UC**, the only PD(L)1 listed on NRDL for UC
  - Lung and liver already filed (1L sq-NSCLC, 1L non-sq-NSCLC, 2L/3L HCC accepted on April 20, June 19 and July 1, 2020)
  - Also in late-stage development in a broad range of cancers: lung, liver, gastric, esophageal, nasopharyngeal, MSI-High cancers

Note: DOT = Duration of Therapy; PD-1 target cancer types include breast (triple negative), lung, colon rectum (MSI-h CRC), melanoma of skin, bladder, kidney, liver, stomach, lip, oral cavity, esophagus, cervix uteri, oropharynx, larynx, cHL, salivary glands, nasopharynx; US DOT reference (5.8mo – 7.8mo in median DOT) is PD(L)1 claim data analyses of a range of cancers including 2L NSCLC, 1L MCC, 2L HNSCC, 3L GC, 2L RCC, 2L CRC, 2L HCC, and ESCC; Source: Cancer Registry 2018 for China incidence and mortality; BeiGene Analyses

# Tislelizumab Is Uniquely Positioned

tislelizumab  百泽安®  
替雷利珠单抗注射液

**1** Mechanistically differentiated and Fc- $\gamma$  receptor sparing

**2** Favorable label in cHL (CR 61.5%) and only reimbursed PD-1 in bladder cancer

**3** Truly global clinical program, including:

- 16 registration-enabling clinical trials, >20 countries
- >2,000 patients outside of mainland China



Countries / regions with Tisle clinical trials

**4** Commitment to quality manufacturing

Collaboration with one of the world's leading biologics manufacturers



25 global biologics manufacturing approvals



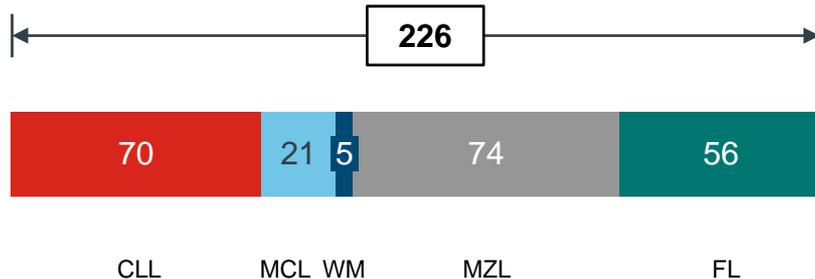
**5** Favorably positioned long term

- Two approved indications: R/R cHL, R/R UC
- Three filings: 1L squamous, 1L non-squamous lung cancer and HCC filed
- 11 other pivotal or potentially registration-enabling studies ongoing
- Compelling breadth of combinations: e.g., TIGIT, sitravatinib, etc.

# NRDL Inclusion Expected to Significantly Strengthen BRUKINSA's Position

## Dx Prevalence of Selected B-cell Lymphoma in China

(Unit 000s)  
BTKi eligible population is a subset of the prevalence below



- BTK class annualized run rate is approximately **\$200M** in China currently
- Reimbursed indications CLL/SLL and MCL constitute 70% of the BTK market potential
- Phase 3 ASPEN trial in WM **demonstrated improved safety and tolerability, and suggested improved efficacy**
- BRUKINSA also in **late-stage development in a broad range of indications:**
  - NMPA priority review for R/R WM in Nov 2020
  - R/R MZL (data presented at 2020 ASH)
  - 1L CLL/SLL (Interim analysis expected in 1H21)
  - R/R CLL/SLL (enrollment completion expected in 2020)
  - R/R FL
  - 1L MCL

# NRDL Inclusion for XGEVA, Only Product Approved for GCTB

- Strong performance in the first three months of launch
- **XGEVA was included for one indication in NRDL: GCTB**
- NRDL inclusion expected to accelerate hospital listing and improve patient affordability, which will support SRE penetration into hospitals
- NMPA approved SRE indication on November 19, 2020, not eligible for this year's reimbursement negotiation
- **SRE indication includes large patient population**, such as breast, prostate, lung cancers, and MM
- Recognition of bone health and quality of health increasing among cancer patients in China

**XGEVA**<sup>®</sup>  
(denosumab)

# Key Takeaways

- 1 All BeiGene listing negotiations successful, 3 products 5 indications
- 2 NRDL listing historically doubled sales on average in first year
- 3 Tislelizumab only PD-1 listed for bladder cancer
- 4 BRUKINSA first second-generation BTK to be NRDL listed



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**Thank You**