McKinsey&Company

Building Bridges to Innovation

Shanghai, November 14-15, 2017

Over the last 3 years, we have helped to frame and understand this fundamental transition period for the industry

2014 BioCentury BayHelix Summit

1. *Framing the possibilities – Bridges to innovation*
2. *Managing today – driving growth of mature brands*
3. *Bridging to tomorrow's innovation*

2015 BioCentury BayHelix Summit

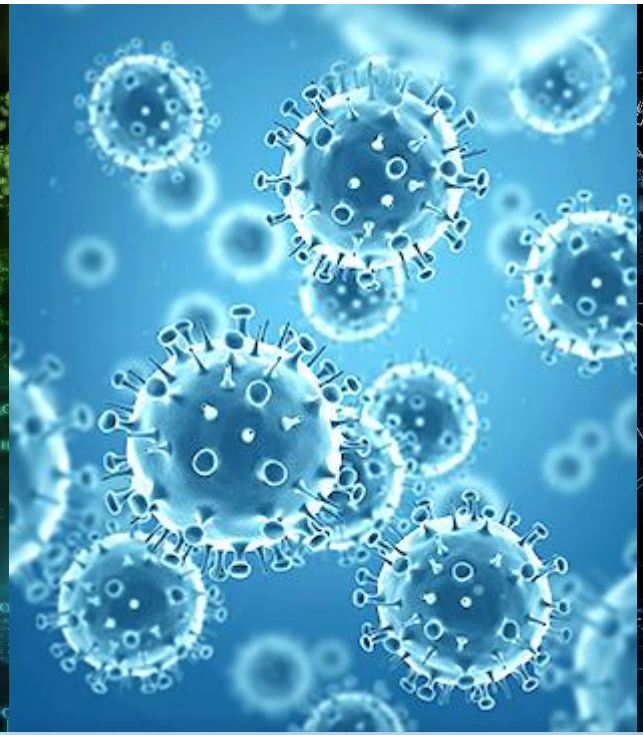
1. *2015 in the mirror*
2. *Decoding the big slowdown*
3. *Assessing progress on innovation*

2016 BioCentury BayHelix Summit

1. *Innovation in China – taking stock of progress*
2. *Driving growth in a BioPharma market in transition*
3. *MedTech in China – Coming of age*

Building on this, three key topics to explore

2017 in the mirror

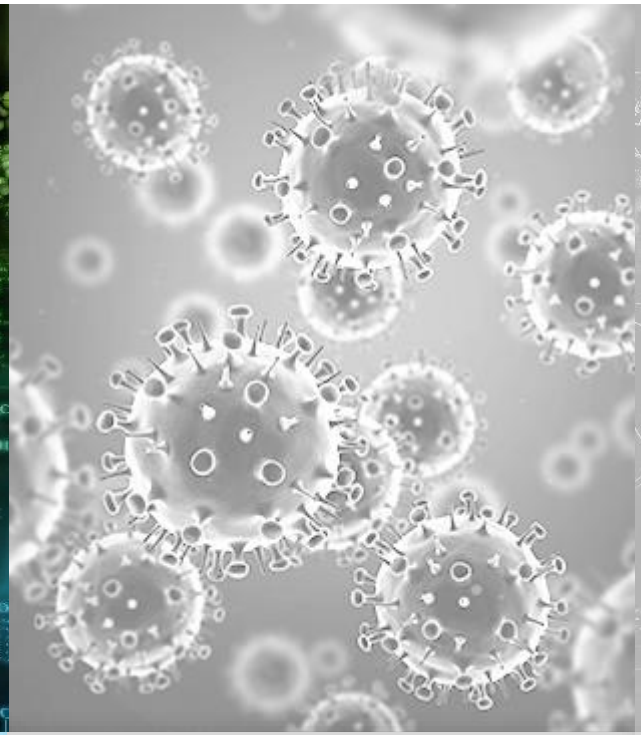


Rise of China-based bio-pharma innovation

Launch success imperative in the new era

Building on this, three key topics to explore

2017 in the mirror



Rise of China-based bio-pharma innovation

Launch success imperative in the new era

2017 in the mirror – 9 significant themes shaping the market evolution

1 Economic recovery and political stability...for now

2 China as an emerging leader in globalization

3 Setting the stage for AI and big data

4 Big Bang at CFDA

5 Making strides towards improving patient access

6 Rubber meets the road on GQCE

7 Turning the corner on remote healthcare

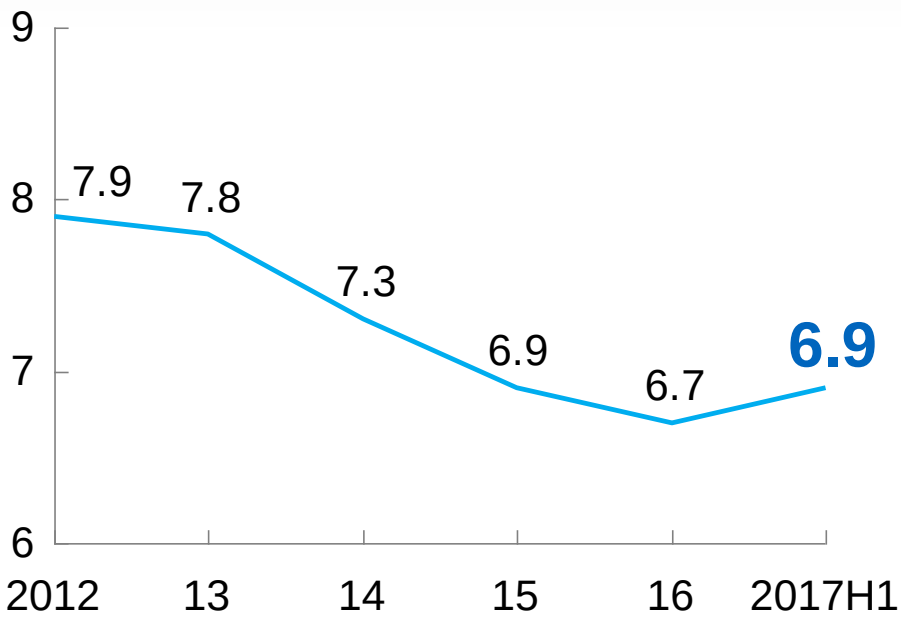
8 The rise of China biotech

9 China healthcare going global

1 Economic recovery and political stability

Signs of China economic recovery

China GDP YoY growth rate, %



China GDP, RMB trillions

54	59	64	69	74	38

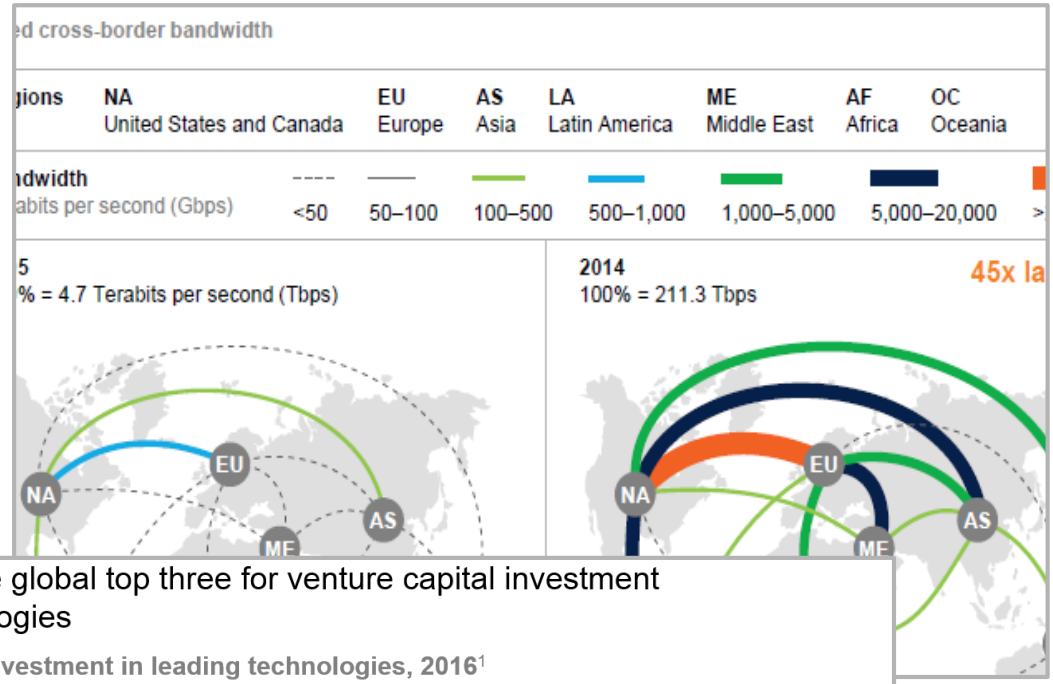
19th Party Congress brings focus on priority agenda

19th Party Congress reinforces **"Healthy China 2030" aspiration**

- Deepen **healthcare system reform**
- Encourage **drug** and **medical device innovation**
- Improve **primary care** and **GP system**

SOURCE: National bureau of statistics of China; Press search; McKinsey analysis

2 China as an emerging leader in globalization



China is in the global top three for venture capital investment in key technologies

Venture capital investment in leading technologies, 2016[1]
$ million

Fintech		Virtual reality		Autonomous driving	
China	7,158	United States	1,437	United States	582
United States	5,437	China	1,312	China	357
United Kingdom	1,793	Japan	166	Japan	268
Germany	668	United Kingdom	73	Australia	264
Japan	493	France	20	United Kingdom	142
Wearables		**Education technology**		**Robotics and drones**	
United States	1,724	United States	1,282	United States	728
China	992	China	681	China	227
Germany	170	Japan	217	Japan	129
Canada	134	United Kingdom	163	Singapore	96
United Kingdom	95	India	145	Canada	59
3D printing		**Big data**		**AI and machine learning**	
United States	602	United States	6,065	United States	3,782
China	221	United Kingdom	1,673	United Kingdom	1,222
Germany	182	China	942	China	900

SOURCE: McKinsey Global Institute

3 Setting the stage for AI and big data

Recent policies promoting AI and big data

State Council published **Action Plan to Promote Big Data Development,** [2015] No.50

- State Council issued **guideline to promote the development of Healthcare Big Data,** [2016] No.47
- Goals for 2020
  - Create unified and interconnected public health information platform
  - Build 100 regional clinical data centers across the country

Sep. 2015 — *June 2016* — *July 2017*

- State Council issued **guideline on developing artificial intelligence (AI)**, [2017] No.35, setting the goal of becoming a global innovation center by 2030
- Key areas for **healthcare** include data mining, smart medical devices, wearable device, etc.…

AI/ Big data powered healthcare services

AI

- DXY developed an AI-assisted lupus diagnostic system
- Baidu Medical Brain developed an AI robot Melody to help physicians with diagnosis
- Watson collaborating with Baheal Pharm in oncology space
- HYHY using AI-assisted diagnostic system to support digital medical imaging and tumor radiotherapy

Big data

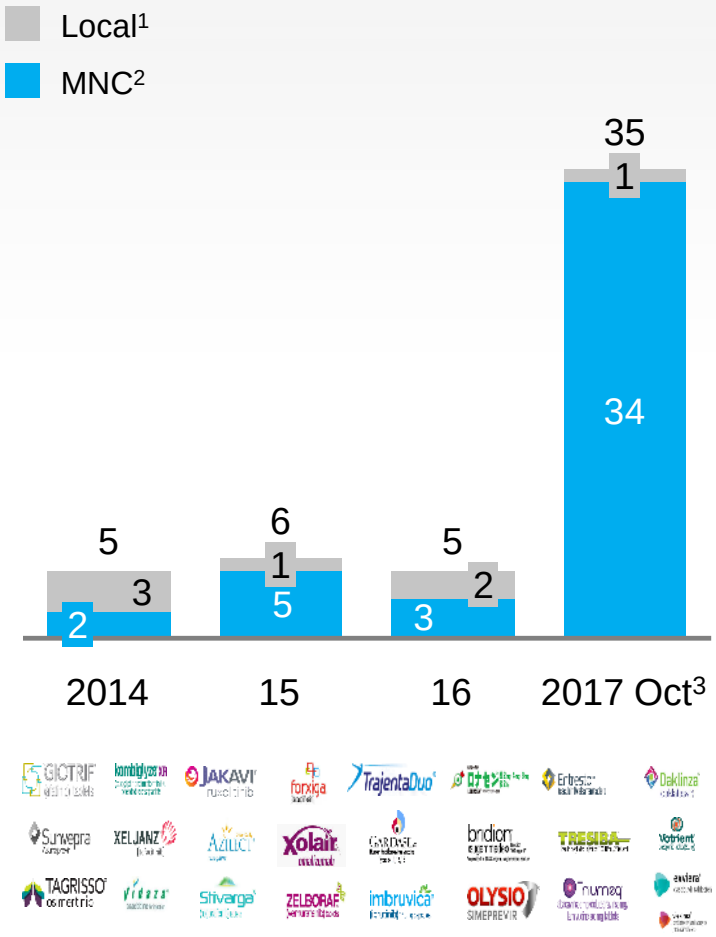
- Ping An Healthcare developed health risk prediction and healthcare big data analytics
- Chinese State-owned Enterprises formed a Healthcare Big Data Company to build national and regional big data cloud centers
- Emerging oncology big data providers (e.g., LinkDoc)

SOURCE: Press search; McKinsey analysis

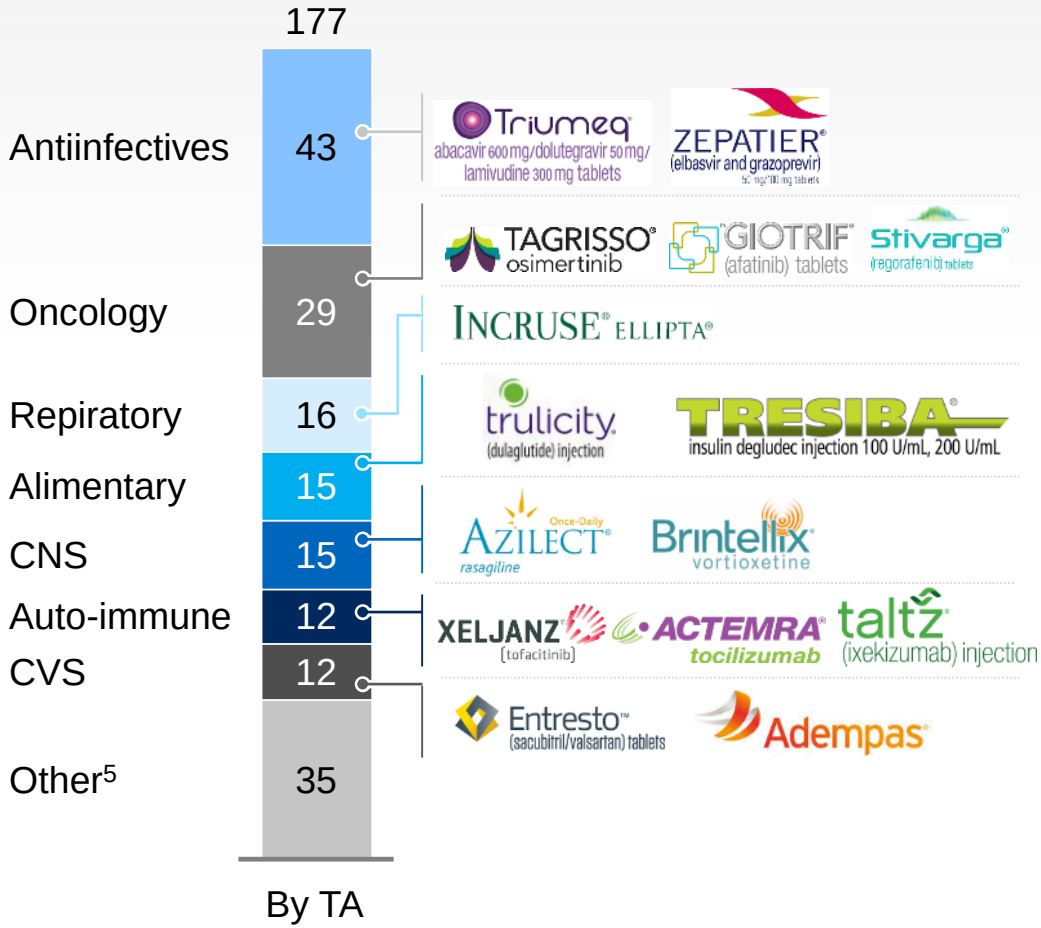
4 Big Bang at CFDA

SELECTED EXAMPLES

Tsunami of new launches starting in 2017



No. of molecules granted priority review by TA[4]



1 Defined as new launch (Chem 1.1, Bio-1) by registration year
2 Defined as originators with first recorded commercial launch year based on RDPAC data
3 According to registration record as of Oct 26th, 2017
4 As of Oct 26th, 2017
5 Other TAs include blood, sensor organ, dermatology, genital, etc.
SOURCE: CDE; team analysis

5 Making strides toward improving patient access

- NRDL update added ~340 drugs in 2017
- 36 innovative drugs completed national reimbursement negotiation
- MoHRSS released draft document to explore NRDL dynamic update

- 24 provinces announced local implementation plans for negotiation results as of October 2017

- BMS rolled out outcome-based insurance for HCV therapy (Daklinza+ Sunvepra)
- AstraZeneca launched pay-by-installment program for NSCLC patients treated with Tagrisso

SOURCE: Literature search; McKinsey analysis

6 Rubber meets the road on GQCE

Reimbursement payment standard pilots initiated

- In February 2017, Fujian released a local version of **reimbursement payment standard (RPS)**, set **by molecule name**
- **Translates into significant price pressure for off-patent originators**[1] (RPS set at 1.5X generics' maximum retail price or 70% of its own MRP)
- Continued **central government support of Fujian model**

Drugs expected to pass QCE soon (examples)

Company	Drug name	QCE qualification progress
药友制药 YAOPHARMA	Alfacalcidol	CFDA review in progress
湖南洞庭药业股份有限公司 HUNAN DONGTING PHARMACEUTICAL CO.,LTD.	Amitriptyline	CFDA review in progress
SALUBRIS PHARMACEUTICALS 信立泰药业	Clopidogrel Calcium Tablets	CFDA review in progress
京新药业 JINGXIN PHARMACEUTICAL	Rosuvastatin Calcium	CFDA review in progress
青峰医药集团	Entecavir Dispersible Tablets	CFDA review in progress
扬子江药业集团 YANGTZE RIVER PHARMACEUTICAL GROUP	Enalapril maleate tablets	BE test completed, on-sites inspection also completed
聯邦制藥 UNITED LABORATORIES	Amoxicillin	BE test completed, on-sites inspection also completed
dezhan 德展健康 Dezhan Healthcare	Atorvastatin Calcium Tablets	BE test completed
SALUBRIS PHARMACEUTICALS 信立泰药业	Pitavastatin Calcium Tablets	BE test completed

1 Exceptional 80% reimbursement for drugs treating 7 classes of special diseases (i.e. diabetes, hypertension, hyperlipidemia etc.)

SOURCE: Press search; team analysis

7 Expansion of BMI coverage helping to turn the corner on remote healthcare

Policy	Highlights
Sichuan and Guizhou pilot incorporating **telemedicine** into BMI coverage	▪ **199 public hospitals** in Guizhou were **connected with telemedicine system** by 2016 ▪ All BMI schemes eligible for reimbursement, up to **90% reimbursed** for 1-hour consultation
Yinchuan approved **17 Internet medical service providers**, and **piloted BMI with Good Doctor**	▪ Patients can get **reimbursed online** directly for consultation ▪ **UEBMI: 50% reimbursable**, 8 RMB/time/day, annual cap 120 RMB ▪ **URBMI: 40% reimbursable**, 5 RMB/time/day, annual cap 50 RMB
Ningbo **approved BMI status to NeuSoft Cloud Hospitals** XIKANG 熙康 | 云医院	▪ **Pilot** BMI payment **in 3 districts** in Ningbo before **end of 2017** ▪ **Full roll-out** of BMI payment in cloud hospitals **in 2018**

SOURCE: Press search; team analysis

8 The rise of China biotech

SELECTED EXAMPLES

Attracting more capital

2x

Growth of VC investment in China healthcare in 2017

IPO

$2.8 Bn

Combined value of all China biotech IPOs in past 12 months[1]

Expanding pipeline

~800

innovative molecules in pipeline (pre-clinical to Phase III)

70-80

# of Phase-III molecules

anlotinib	brivanib	BGB-3111	HMS-5552
BGB-A317	savolitinib	pyrotinib	ensartinib
SHR-1210	IBI-308	Danoprevir	famitinib
Ravidasvir	Fruquintinib	Sulfatinib	KW-136

Licensing-in

- Bremelanotide → FOSUNPHARMA
- Zevtera → 华润九新
- omadacycline → zai Lab
- HL161 & HL036 → HARBOUR BIOMED
- MIV-802 → 歌礼中国 ASCLETIS
- Liafensine → Denovo Biopharma
- VGX-3100 → ApolloBio
- Olamkicept → 天境生物

Licensing-out

- PD-1 asset → ARCUS BIOSCIENCES
- An I-O asset → pieris

JV

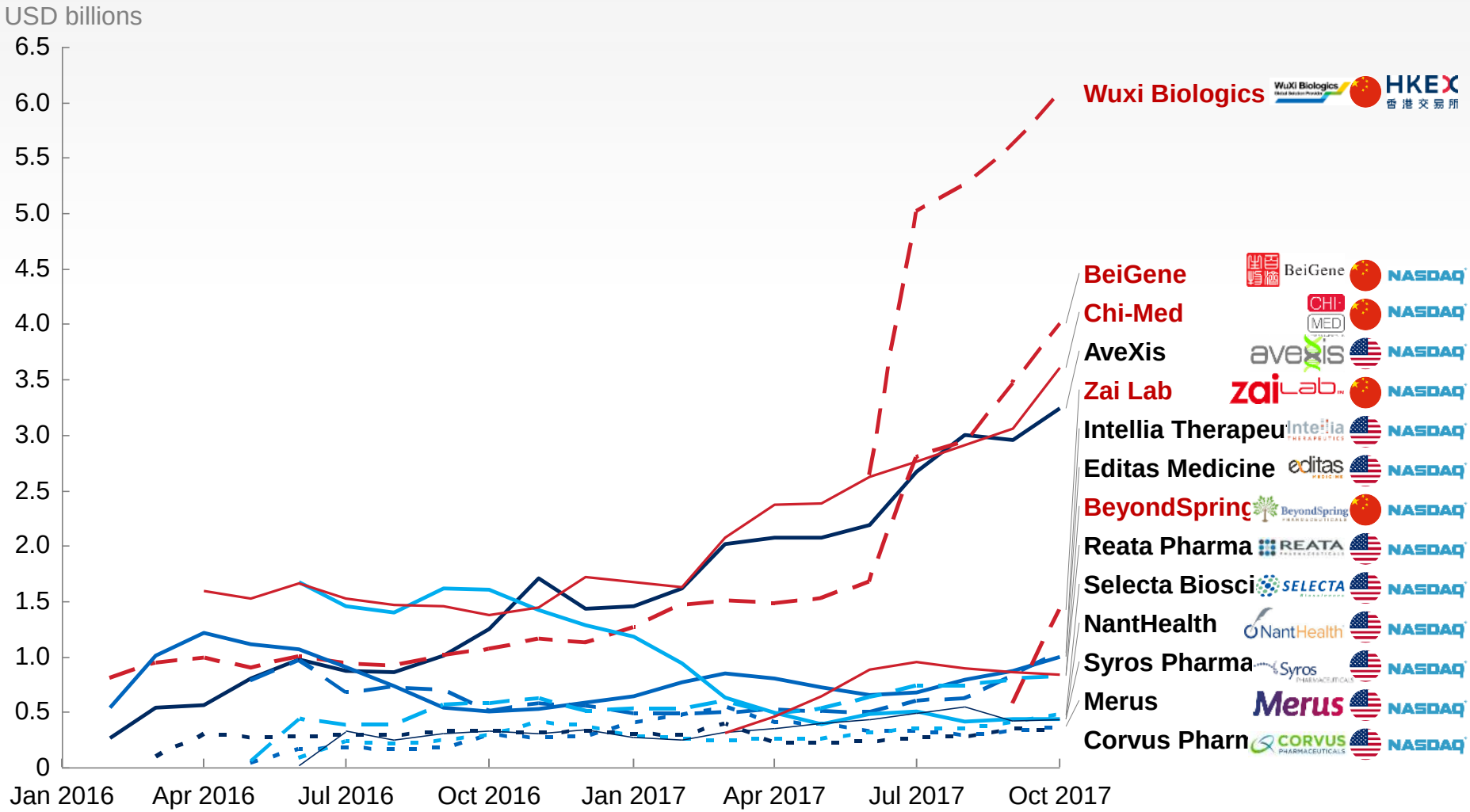
- FOSUNPHARMA + Kite Pharma
- 九芝堂 + TRIMEDICINE
- G-CON MANUFACTURING
- Shenzhen Royal Asset ement + Prometic

1 Including IPOs in Nasdaq, HKEX (Hong Kong Stock Exchange), SZSE (Shenzhen Stock Exchange) and SSE (Shanghai Stock Exchange)

SOURCE: Wind; Pharmaprojects; McKinsey analysis

8 Market valuation of China biotechs outperform peers reflecting lofty expectations

Monthly average mkt. cap since IPO for top 10 biopharma companies in 2016[1] by net proceeds at IPO, + Chi-Med, Wuxi Biologics, Zai Lab and BeyondSpring



1 Ranked by www.genengnews.com

SOURCE: Capital IQ; team analysis

9 China healthcare going global

Outbound M&A in 2017

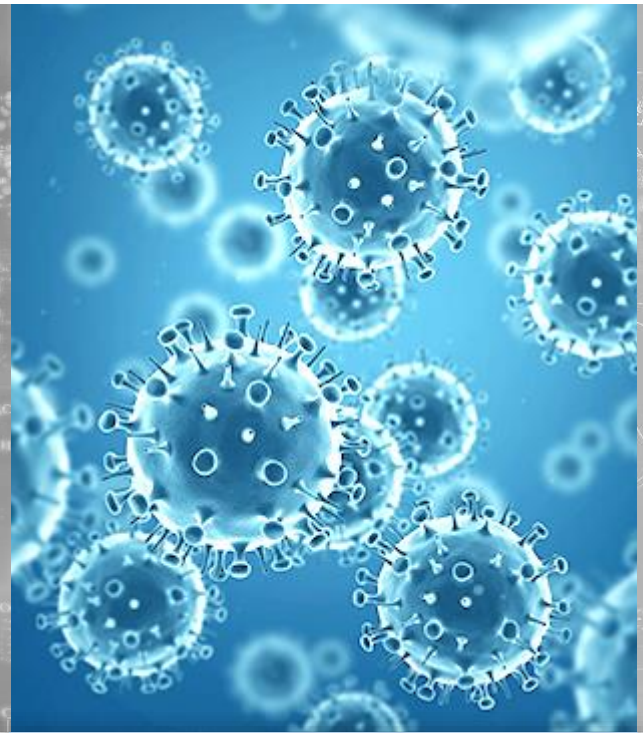
SELECTED DEALS

	Target	Acquirer	Target country	Deal date	Deal value USD, Mn
BioPharma	GLAND PHARMA LIMITED	FOSUN PHARMA 复星医药	India	Sep	1090
	Dendreon	SANPOWER	US	Jun	820
	TRC	人福医药集团股份公司 HUMANWELL HEALTHCARE GROUP CO., LTD.	US	Jun	605
	BioVision BioVision Incorporated	NKY	US	Jun	290
	Impax	FOSUN PHARMA 复星医药	US	Aug	66
	Xcovery	BETTA PHARMACEUTICALS 贝达药业	US	Apr	20
Healthcare Services	ICON CANCER CARE	PAGODA INVESTMENT	Australia	May	768[1]
	CLÍNICA BAVIERA	EYE 爱尔眼科	Spain	Apr	177
	pulsehealth	LUYE PHARMA 绿叶制药	Australia	May	120

1 China's Pagoda present in the AUD 1 Bn investment led by QIC, Pagoda's share not disclosed

SOURCE: GBI; press search; team analysis

Building on this, three key topics to explore



2017 in the mirror

Rise of China-based biopharma innovation

Launch success imperative in the new era

Beginning of a new era – latest on China-based biopharma innovation

1

Deepening CFDA reform – what's ahead?

2

What is the broader momentum of China-based biopharma innovation?

3

How should Multinationals and Chinese biotechs embrace the new innovation environment ?

Deepening CFDA reform – what's ahead?

After addressing critical gaps over the past two years, the CFDA reform has entered an exciting new phase of development

NOT EXHAUSTIVE

Phase I: 2015-2017
Addressing critical gaps

Phase II: Q4'2017 onwards
Pave the way for integration with global

	Phase I: 2015-2017	Phase II: Q4'2017 onwards
Review accele-ration	▪ Reduction of application backlog ▪ Review timeline acceleration ▪ Granting of priority review	▪ **Further strengthen review transparency** ▪ **Streamline and implement scientific review system** (e.g., 60-day CTA review)
Quality	▪ QCE for generics ▪ Clinical trial data inspection	▪ Develop Chinese version of **"Orange Book"**
Encourage innovation	▪ Market Authorization Holder (MAH) pilot ▪ "International new" definition	▪ **Full MAH roll-out** ▪ **Patent linkage** and compensation ▪ **Deepen data protection**
Integration with global	▪ Encouragement of participation in IMCT ▪ Joined ICH in June 2017	▪ **Encourage early phase trials** and simultaneous development ▪ **Translate ICH guidelines** at scale
Capability building	▪ Expansion of reviewer team	▪ **Further strengthen leadership in regulatory science** (e.g., recruit from leading regulatory agencies)

> The reform started in 2015 has gone beyond drug review and approval to **the reform of the entire medicines regulatory system.** The ultimate goal of the reform is to **integrate with global**
>
> **– Bi Jingquan, CFDA Director**

SOURCE: CFDA; press search; team analysis

Phase I: CFDA reform has made significant progress over the past two years, aiming to create an "innovation-fostering" regulatory environment

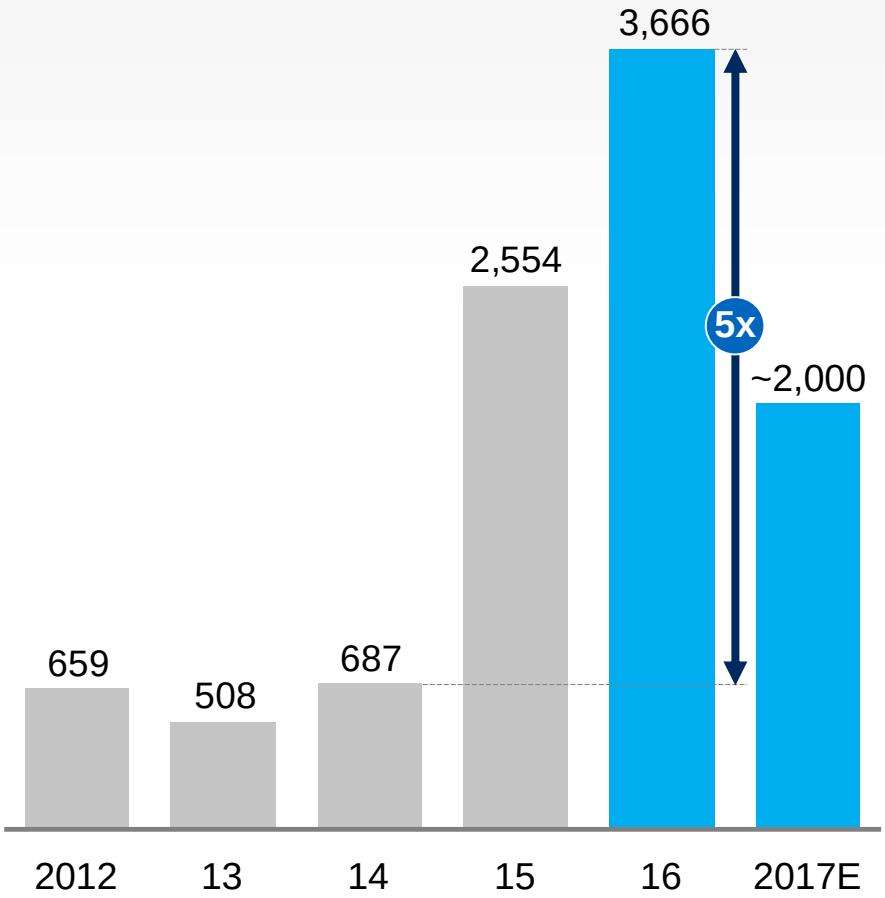
Key themes	Major progress in past two years
Provide transparent and scientific review	▪ Established formalized process to **encourage consultative interactions** between applicants and CDE[1] ▪ Established **advisory committee** to provide scientific inputs on related topics (similar to FDA)
Achieve faster review	▪ Queue time and overall review timeline shortened, (e.g., Chem-IDL-CTA reduced to ~20 months by end 2016 from ~34 months in 2015) ▪ **Backlog reduced** from 21K in 2015 **to <4K** by Oct 2017 ▪ **Priority review: 59 CTA and 58 NDA approvals** ▪ CDE reviewers capacity X3, from 200 to 600
Encourage innovation	▪ **Pilot market authorization holder (MAH) launched** in 10 provinces ▪ Encouragement of **local clinical trial centers to participate in IMCT** and allow eligible trial data to be used in NDA ▪ **Removal of GCP certification** to allow more sites to participate in clinical trials
Enhance drug quality	▪ **Conducted clinical trial self-inspection and systematic site inspections**, with 313 site inspections completed ▪ **Recruited 600+ inspectors** to enhance GXP inspections ▪ **Quality Consistency Evaluation (QCE) of generic drugs** being implemented

1 Issued Administrative Measures for the Communication on Drug R&D and Technical Review (Interim)

SOURCE: CFDA; press search; team analysis

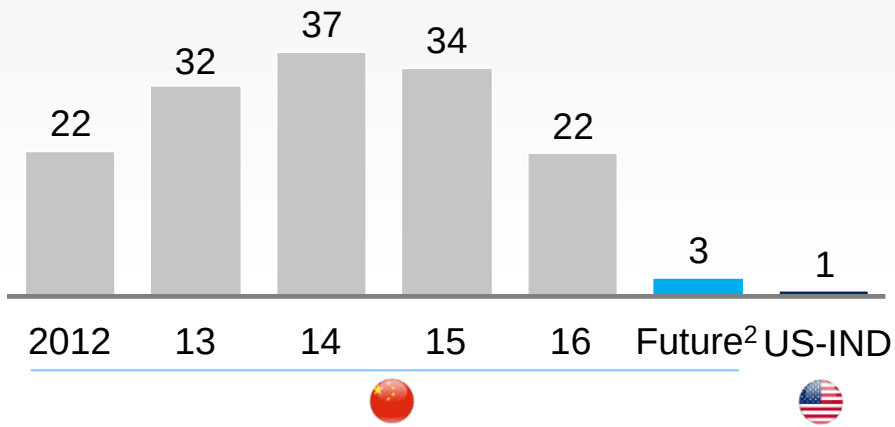
Phase I: The reform has led to visible impact in shortening review timelines, however with room to further improve

CTA approval[1]

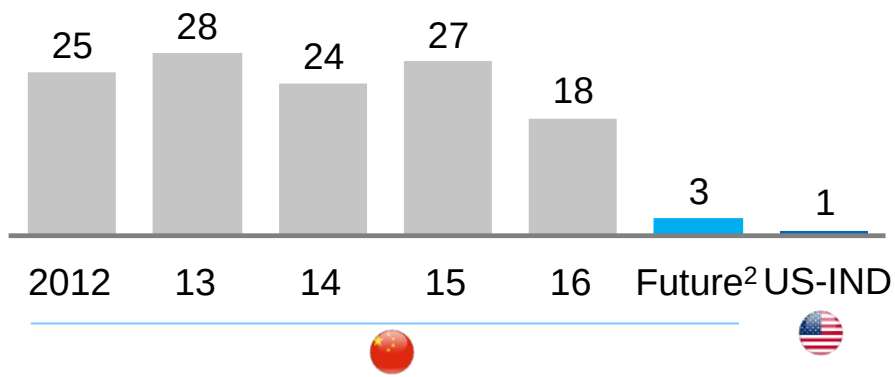


Review timeline

Chem IDL-CTA, Months



Bio IDL-CTA, Months

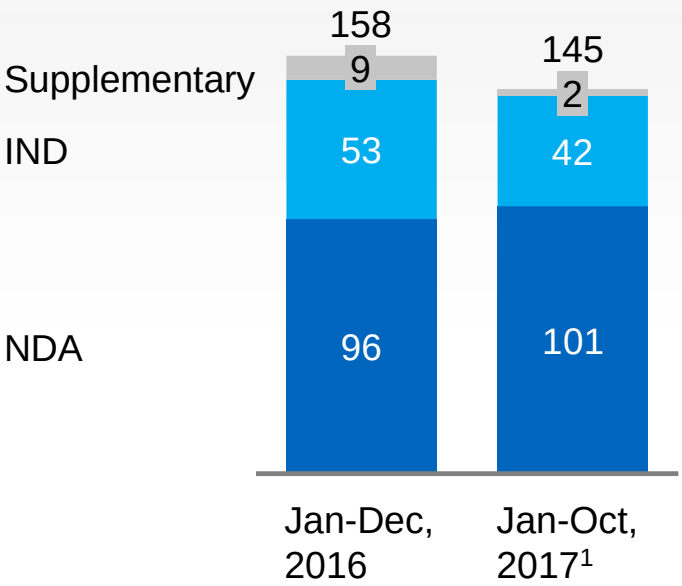


1 Including IND and confirmatory study, the number includes all clinical trial applications, and each molecule may be linked to multiple clinical trial applications
2 Recent Oct, 8Th State Council Opinions and CFDA new draft Drug Registration Regulation suggest future 60-workding day for CTA review timeline, but specific implantation timeline is still unclear

SOURCE: CFDA; GBI; RDPAC; team analysis

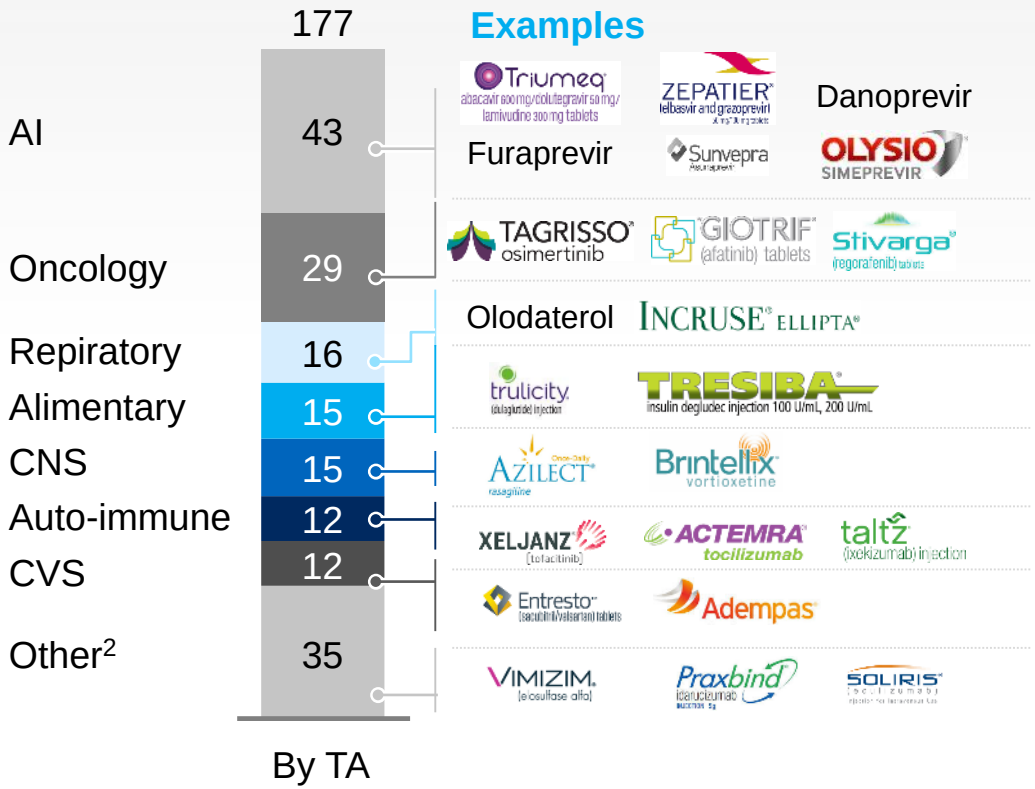
Phase I: Priority review status granted to both MNC and local assets

No. of applications with priority review



23 batches of applications granted priority review status since January 2016, linked to a total of 177 molecules

Molecules with priority review by TA



- Priority review becoming one of **CFDA's key levers to accelerate** drug review process
- **Anti-infective and oncology** are the two major TAs granted priority review

1 As of Oct 27th, 2017
2 Other TAs include blood, sensor organ, dermatology, genital, etc.

SOURCE: CDE; team analysis

Phase I: In June 2017, CFDA joined ICH as a regulatory member after years of progressive efforts

CFDA's journey to join ICH

2010 — Issued ICH common technical document (CTD) guidelines

2012 — Issued safety report guidelined using ICH Periodic Safety Update Reports for Marketed Drugs (PSUR)

2015 — Issued stem cell development guidelines based on ICH Guidelines for Viral Safety Evaluation of Biotechnology Products Derived from Cell lines of Human or Animal

2017 — In March, filed application to join ICH

2017 — On June 19th, ICH officially announced that CFDA was approved as a new regulatory member

> Joining ICH will effectively improve the innovation capability and global competitiveness of Chinese pharmaceutical industry
>
> **– Yuan Lin, Director of International Cooperation Division, CFDA**

- In recent years, **China FDA** has been actively engaging with ICH by **contributing to the development and revision of ICH guidelines**
- CFDA has transformed and referenced **20+ ICH guidelines**
- Potential for more harmonization of CFDA's regulations with ICH, including:
  - **E17** guidelines for **MRCT** (to be published soon)
  - **Q1** guidelines for **API stability** requirements,
  - **Q7A** guidelines for **API plant GMP** inspections
  - **E6** guidelines for **GCP** requirements

SOURCE: ICH, CFDA, PharmAsia, and McKinsey analysis

Phase II: Central government's recent milestone opinions[1] laid out measures[2] to further foster biopharma innovation

NON-EXHAUSTIVE

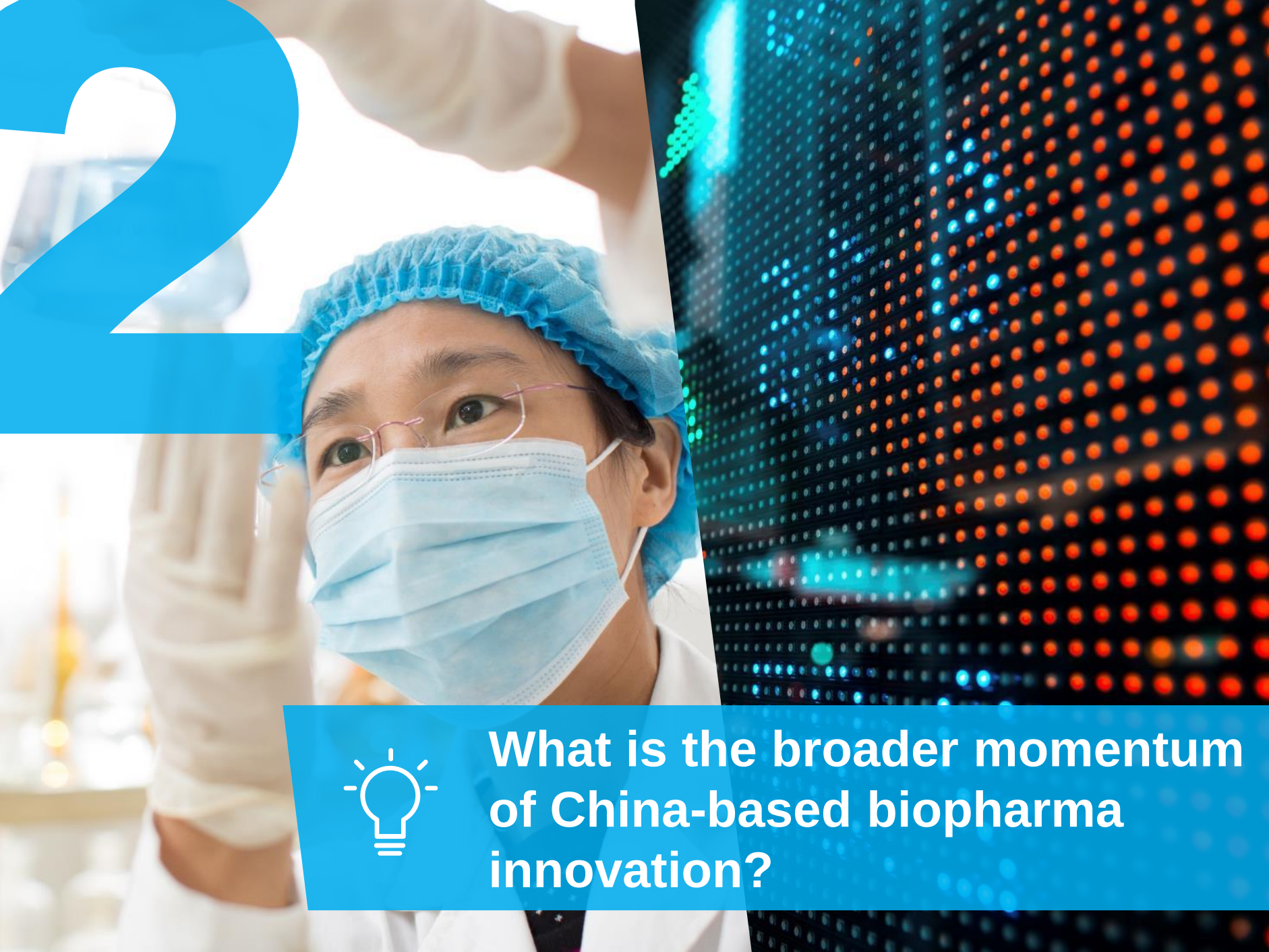
中共中央办公厅 国务院办公厅印发《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》

Office of CPC Central Committee/State Council opinions on "Deepening the Reform of the Drug and Medical Device Review and Approval System to Promote Innovation", released on Oct 8th, 2017 (No. 42 [2017])

Streamline regulatory process	▪ **Notification-based CTA review** ▪ Allow **central IRB mechanism** ▪ Streamline the review and approval process for **human genetic materials** ▪ Removal of quality test as a time limitation barrier
Science-based review	▪ Conditionally allow **overseas trial data** in support of drug registration in China ▪ **Potential conditional approvals** based on early/mid-stage clinical data ▪ **Expanded use of drugs** in clinical trial stage for potential indication expansion ▪ **Rare disease list and patient registry** to be established, potential to apply for **trial waivers** or reduction of trial sample size
Promote clinical research capability	▪ **Remove GCP accreditation of trial sites**, and encourage clinical research ▪ Carry out **in-process inspections of GxP** to ensure drug quality and safety
Better IP and data protection	▪ Establish a **Chinese version Orange Book** ▪ Establish the **patent linkage system** ▪ Grant **data protection period** to certain types of drugs (innovative, pediatric or rare disease)
Reward for innovation	▪ **Move towards dynamic NRDL revision** ▪ Pilot regional **preferable public hospital procurement policies** for innovative drugs ▪ Drug patent **compensation-period mechanism** for drugs with delayed launch

1 Offices of State Council/CPC Central Committee Opinions on Deepening the Reform of Review and Approval System and Encouraging Innovation of Drugs and Medical Devices (Oct 8th, 2017); 2 Detailed regulation need further finalization and release; e.g.: New draft of Drug Registration Regulation was released for comments on Oct 23rd, 2017

SOURCE: State Council; General Office of the CPC Central Committee; CFDA; press search; team analysis



2

What is the broader momentum of China-based biopharma innovation?

Beginning of a new era – China biopharma innovation continues to accelerate, reaching new "highs" both in scale and quality

NON-EXHAUSTIVE

Expanding pipeline

110

# of innovative[1] assets entering clinical development in 2017

China biotech getting ready for global stage

34

# of licensing deals[2]

Attracting more capital

2x

VC investment in China healthcare in 2017 (vs. 2016)

41

# of innovative assets developed globally by Chinese companies

4

# of cross boarder out-licensing deals

>$2.8Bn

Total funding raised through IPO by China biotechs over past 12 months

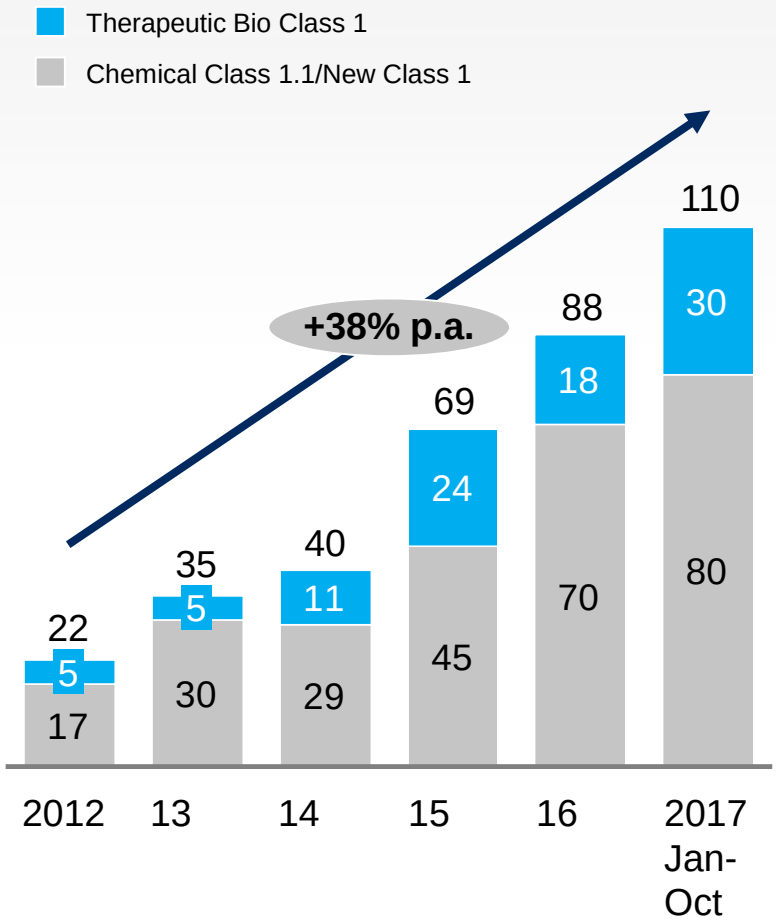
1 Chem class-1 and Therapeutic bio class-1 assets approved for CTA from Nov 1st,2016- Oct 18th, 2017
2 Including China to global, China from global and China to China deals
3 Counting Wuxi Biologics, BeiGene, Zai Lab, Chi-med, Betta Pharma, BeyondSpring, Kanghong

SOURCE: Press search; team analysis

More innovative compounds are entering the pipeline in China

ESTIMATION

Number of Chem new Class 1[1] and Biologics Class 1 molecules approved for clinical trials



Number of compounds in active development[2]

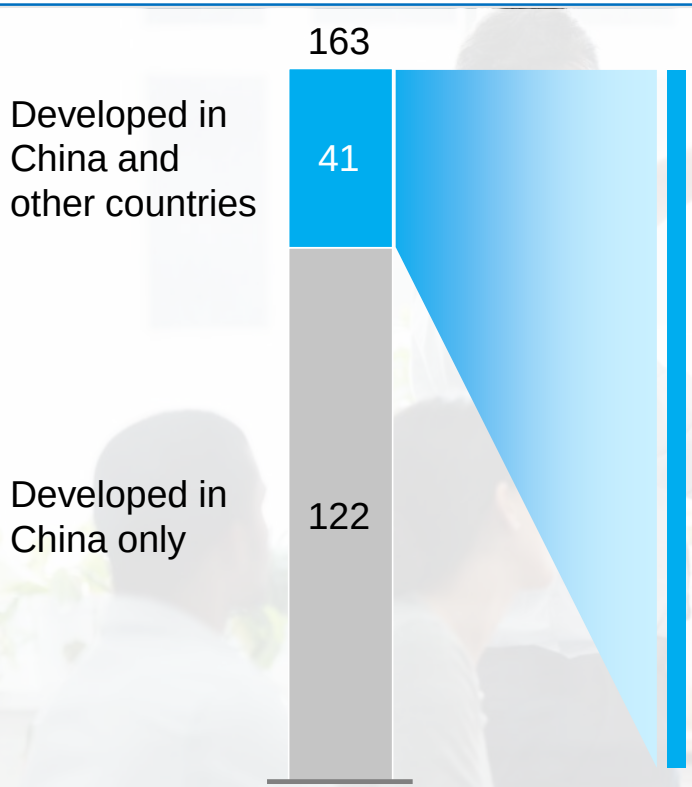
1 Chem-1.1 (old class); 2 As documented in Pharmaprojects, number of chemical compounds developed by both MNCs and domestic manufacturers in pre-clinical and clinical phases I-III in China in a given year; 3 Includes compounds undergoing registration approval

Sources: CDE Annual Report on Drug Review and Approval 2016; GBI; Pharmaprojects; team analysis

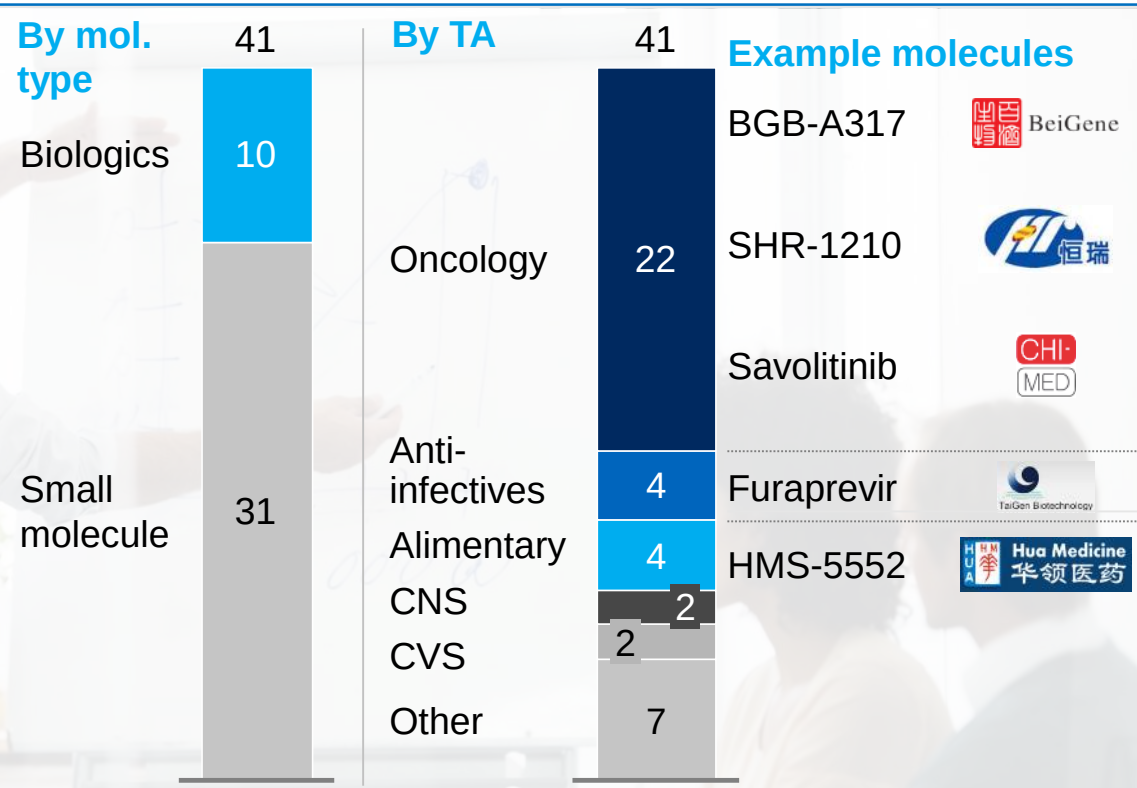
Chinese companies are increasingly developing innovative assets beyond China; an indication of their global aspirations

NON-EXHAUSTIVE

Phase II/III innovative assets developed by Chinese companies[1]



Breakdown of molecules developed by Chinese companies in multiple countries



- Chinese companies are conducting **trials for ~1/4th of their innovative assets beyond China**
- **Oncology is the hottest TA** with both innovative biotech and established pharmacos participating, followed by anti-infectives and alimentary

1 Company headquarters located in China, data based on estimation in Pharmaprojects as of Oct. 9th, 2017

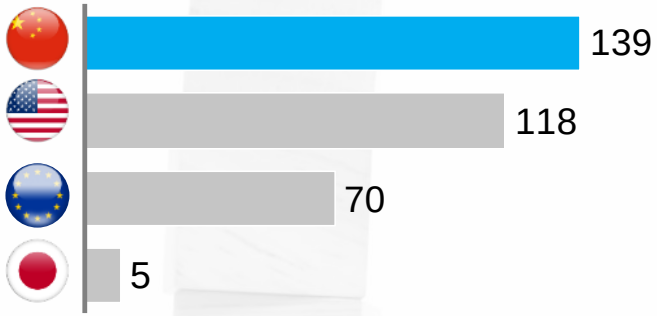
SOURCE: GBI; Pharmaprojects; press search; team analysis

CAR-T is a prime example of Chinese biotechs actively investing in new modalities

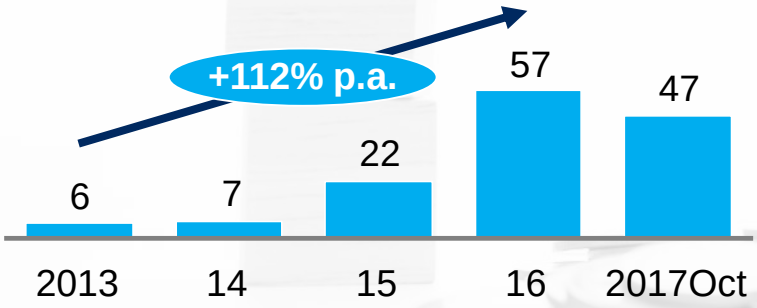
NOT EXHAUSTIVE

China is rapidly emerging as a hotspot for CAR-T clinical research

of on-going trials by country[1]



Rapid uptake in China in recent years[2]



Some China CAR-T clinical research have shown promising early results

Agent	Company	Disease	Results
LCAR-B38M CAR-T	Nanjing Legend / GenScript	Multiple myeloma	▪ ORR: 100% ▪ CR: 73%
CD19 CAR-T	吉凯基因	Acute lymphoblastic leukemia	▪ CR: 85%
CD19 CAR-T	斯丹赛生物技术	B-cell leukemia	▪ CR: 90%
CD30 CAR-T	CBMG	CD30+ NHL	▪ Overall DCR: 71% ▪ ORR: 29%

- Current clinical research efforts by Chinese companies and institutes are **primarily non-registrational**
- How Chinese industry players could innovate in **manufacturing and commercialization/access** approaches remains to be seen

1 Number of clinical trials by searching “CAR” or “CAR-T“ or “Chimeric antigen receptor” cell therapy in ClinicalTrials.gov by Oct, 27th, 2017; trials counted if including the specific country
2 # of CAR-T trials started in the year
3 Nanjing Legend Biotech is a subsidiary of GenScript

SOURCE: ClinicalTrials.gov; GBI; expert interviews; press search; team analysis

China companies continue to actively leverage cross boarder deals to enrich pipeline and gain access to additional capital

NOT EXHAUSTIVE

Breakdown of major licensing deals in the past year by asset sources

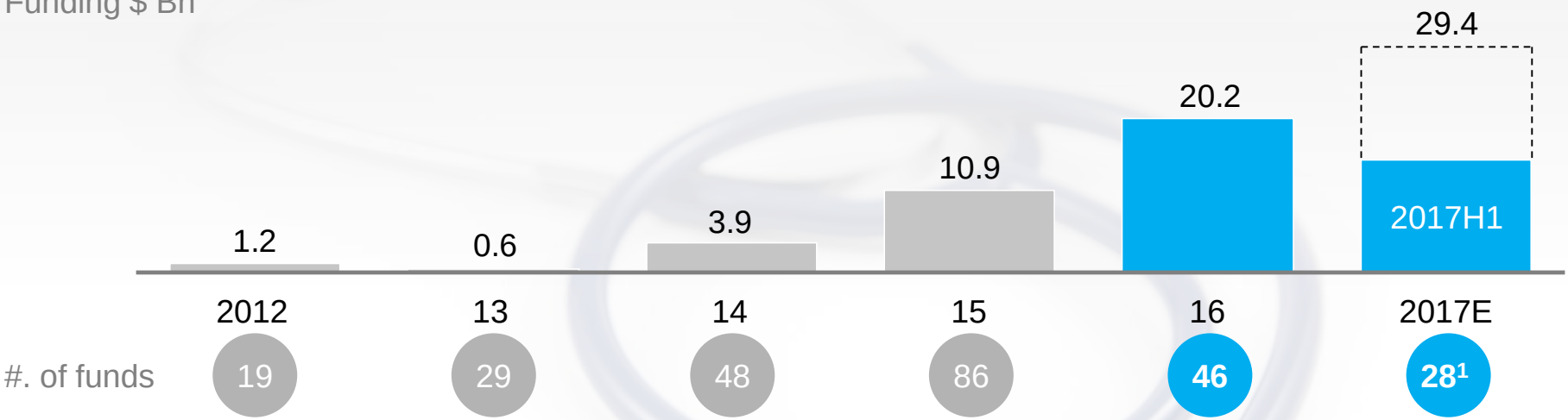
- Cross-board collaboration becoming one of the **key sources of China innovative pipelines**
- **China companies start to export innovation**, though not yet reaching the scale of in-licensing

SOURCE: Press search; McKinsey analysis

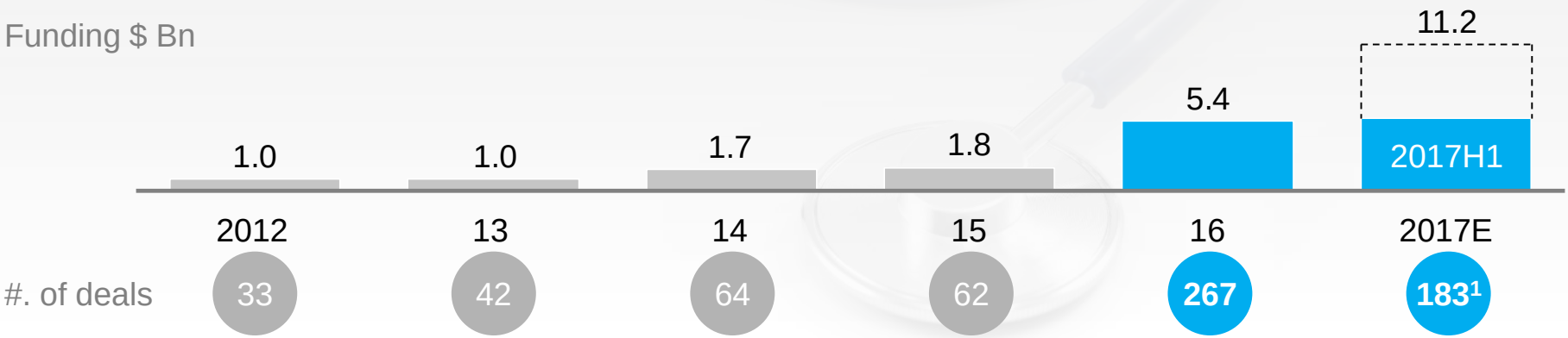
Private capital flow into healthcare sector continues to surge

USD billions

Healthcare VC/PE funds raised nearly doubled in 2016 to $20Bn and could reach $30Bn in 2017



VC investment in China healthcare tripled in 2016 and on track for new record in 2017



1 Number in 2017H1

SOURCE: ChinaBio 2017 Report; team analysis

2017 was a banner year for new healthcare PE/VC funds – some notable examples

2016.11 — Long Hill Capital raised **$125M**, with focus on healthcare and consumer health in China

2016.11 — Green Pine Venture establishes healthcare venture with **$150m fund**

2017.05 — Lyfe Capital closes **second healthcare fund at $420m**

2017.05 — Frontline BioVentures-WuXi Healthcare create joint venture with **$800m fund**

2017.08 — Lilly Asia Ventures closes its **4th healthcare fund at $450M**

2017.08 — Quan Capital born out of Zai Venture fund and raised **$150m inaugural fund**

2017.09 — OrbiMed launches **$550M** Asia Private Equity fund

2017.09 — Eight Roads launches China-dedicated healthcare fund with **$250M**

SOURCE: Company websites; press search

Looking ahead – what could the China drug innovation ecosystem look like in 2025?

	Investment	R&D	Reward for innovation	R&D expert survey (n=45)
Broad bridge	▪ **Double-digit growth of funding invested** ▪ **3-5 IPOs** each year	▪ **Benefit of reform** starts to "pay off" ▪ **Catch up** in small molecules and biologics; **lead** in select new modality ▪ **5-10 global blockbusters** launched each year	▪ **Dynamic update of NRDL** becomes the norm ▪ PHI becomes a meaningful segment enabled by healthcare big data analytics	28
Narrow bridge	▪ Investment becomes more **cautious and selective,** with steady growth ▪ **1-2 IPOs** each year	▪ **Reform continues to deepen** with some challenges in select area (e.g., clinical) ▪ **1-2 global blockbusters** launched each year	▪ **Meaningful but patchy reward** for innovation granted (e.g., in select regions and/or for priority diseases)	17
Broken bridge	▪ **Bubbles burst** and investment momentum dries up	▪ **Reform stagnant** due to systematic bottlenecks and challenges in implementation ▪ No globally meaningful asset launched	▪ Public insurance remains **heavily constrained** ▪ Self-pay and private insurance becomes major viable segment	0

SOURCE: McKinsey China Biopharma Innovation 2025 Survey; McKinsey analysis

Four key areas require concerted efforts and government support to enable continued momentum in China biopharma innovation

Drive effective and timely implementation of CFDA policies

- **Focused efforts required across ministries** to implement newly issued regulatory policy with speed & rigor
- **Systematic capability building initiative needed** to rapidly strengthen both technical and non-technical capabilities of CFDA staff

Strengthen clinical trial capability and infrastructure

- **Provide better incentives and stronger site supporting mechanisms** to motivate hospitals and PIs in clinical research
- **Strengthen quality mindset** to ensure GCP compliance and sound clinical data
- Build solid **infrastructure for early stage trials**

Accelerate talent development in critical areas

- **Attract and develop "experienced drug developers"** able to drive robust clinical strategy and steer end-to-end development process
- **Address talent gap in other critical areas** (e.g., project management to lead cross-functional development teams)

Properly reward innovation

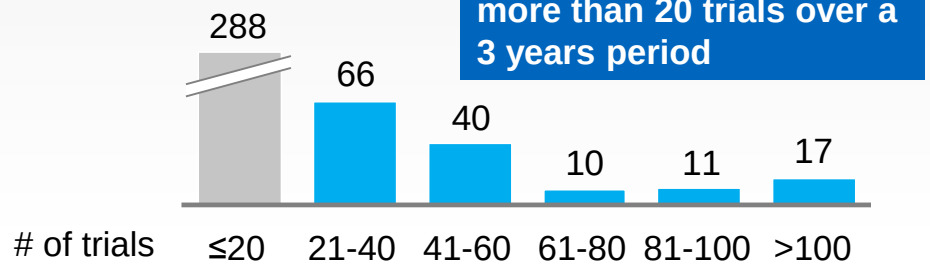
- Accelerate reimbursement of innovative drugs with proven clinical benefit and value (e.g., **timely and frequent update of NRDL/PRDL**)
- **Instill evidence-based methodology** and provide transparency on assessment criteria

Urgent need to develop more high-quality trial sites to handle rising demand for clinical trials

GCP sites with extensive trial experience are still rare in China today

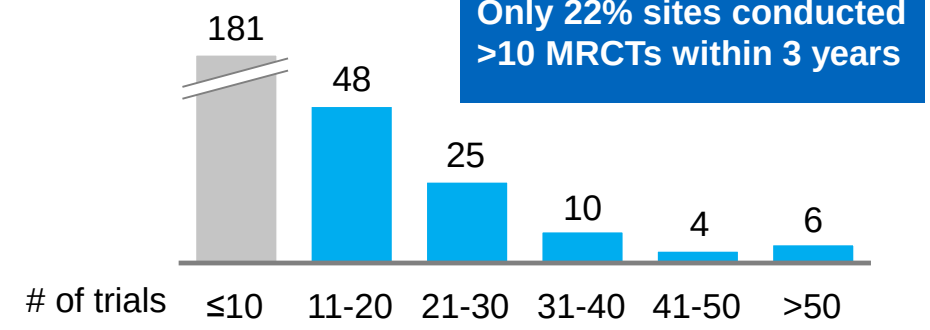
Number of trials conducted by GCP site[3], 2014-2016

of site, N = 432



Number of MRCTs conducted by GCP site[3], 2014-2016

of site, N = 274



Potential root causes

Top down design

- **Under investment** in clinical research by government
- Clinical research often **not a high priority** of academic medical center

Incentive

- **Lack of incentive** for physicians and hospital chief to conduct clinical research
- **No clear career path** for clinical researchers

Capability

- Some PIs lacking experience in clinical trial design
- **High turnover of CRAs**

Supporting system

- **Lack of experienced research supporting team** including CRC, data scientist, QA, etc...
- Capability building program tailored to clinical research in need of strengthening, both in medical schools and academic medical

The State Council Oct-8th Opinions laid out future directions to improve clinical research capability and encourage clinical research in hospitals by introducing relevant evaluation requirements and incentives

1 As of 2016, accumulated number of first-time-certified sites for drug clinical trials, not excluding organizations not recertified after expiration date
2 As of June 2017, two additional batches of first-time-certified organizations for drug clinical trials announced on May 15 and May 19 respectively
3 Including trails of all phases

SOURCE: Annual report on drug review and approval 2012-2016; chinadrugtrials.org.cn; CFDA; GBI; team analysis

How should MNCs and Chinese biotechs embrace the new innovation environment ?

Shorter approval lags observed for some drugs, but variations remain

Innovative drugs approved by CFDA in 2017 by TA[1] and by launch lag years

1 As of Oct 26th, 2017
2 Other TAs include blood, sensor organ, dermatology, genital, etc.

SOURCE: CDE; GBI; team analysis

Launch lags lead to challenges in delivering patient care at scale: Hep C market example

Hep C is a major public health issue in China…

- 0.6-0.9% prevalence rate
- 3X number of patients in the US
- ~470K[1] liver cancer cases a year
- >2,000 liver transplants a year
- Social stigma for virus carriers

…several approvals in recent months, finally putting solutions for patients within reach

- 4 oral DAA therapies approved in 2017
- Highly effective treatment for 90%+ of patients

Bristol-Myers Squibb — Daklinza (daclatasvir) — Sunvepra Asunaprevir

abbvie — viekira pak™ ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets

GILEAD — SOVALDI SOFOSBUVIR 400 mg TABLETS

西安杨森 xian janssen — OLYSIO SIMEPREVIR

… yet a cautionary tale for innovation-focused companies

- Chinese patients have been waiting for approvals for 4+ years and have high awareness of treatment options efficacy, including that of Gx
- Imported Indian Gx, not approved, have treated many warehoused patients prior to launches by MNCs, potentially limiting the opportunity for uptake

1 2015 estimates, Cancer Journal for Clinicians

Source: Expert interview, literature search

Both multinational and China biopharmacos have new opportunities to accelerate development and registration in China in light of reform

ILLUSTRATIVE

NOT EXHAUSTIVE

Early development → **Late development**

IND — POC — NDA

1 **Conduct early phase trials in China**
– e.g., China participating global phase I is allowed

2
- **Clinical trial waiver or reduced sample size[1]** for rare diseases or diseases with critical needs
- **Conditional approval eligible for therapies addressing** critical clinical needs

3 **Expanded use[2]** of development-stage assets in trial sites
– Safety data potentially applicable for registration

4
- **China joining global phase III IMCT** (i.e., simultaneous development)
- Potentially using **global IMCT data** to file **China NDA[2],** upon **demonstrating consistent profile** in Chinese patients

5 **Apply for priority review for assets in categories defined by CFDA**

- Pending further clarification (e.g., upon release of updated *Drug Registration Regulation* and other relevant regulations)
- Company will need to assess relevance and feasibility of new opportunities against each asset

1 Eligible upon application and negotiation with CFDA/CDE
2 State Council/CPC Central committee policy released high-level endorsement, but details remain unclear which would be expected in the next year. This is eligible for therapies that potentially treat patients with a disease that currently lack comparable or satisfactory option
SOURCE: Offices of State Council/CPC Central Committee Opinions on Deepening the Reform of Review and Approval System and Encouraging Innovation of Drugs and Medical Devices; CFDA; press search; team analysis

Overall MNC pharmacos remain committed to China innovation

China market, already 2nd largest, continues to be an important growth engine

Global R&D shifting towards more externally oriented models

Improving China regulatory environment brings new opportunities

- **Overall, MNCs' commitment to China remain strong**
- **However, MNCs are adapting their China R&D approach**
  - **a** **Research – divergent approaches – some accessing China innovation via external means, others keeping in-house centers**
  - **b** **Clinical development: coherent strategy and working model to capture new opportunities in light of CFDA reform**

MNCs are taking diverse approaches in research

SELECTED CASE EXAMPLES

Nov 2016
Kicked off construction of $126 million Research & Early Development Centre in Shanghai

Jun 2016
Opened $1 billion R&D campus in Shanghai focusing on disease areas with high unmet needs in China

Sep 2017
Invested in academic collaboration with China Academy of Science

> Novartis builds where the talent is, China produces far more science & engineering PhDs than anywhere else in the world
>
> ***– Joe Jimenez, CEO of Novartis***

Aug 2017
Closure of Shanghai CNS Research center

Sep 2017
Closure of China Research center

> In medicine, you need to stay focused. You have to commit to one direction and make it happen
>
> ***– GM of GSK R&D China***

SOURCE: Literature search; Team analysis

To capitalize on the regulatory reform, MNCs are beefing up key development capabilities

Strategic moves to build capabilities and accelerate development

Case examples

AstraZeneca — TAGRISSO™ osimertinib

Tagrisso significantly reduced China launch lag with early involvement of China, and proactive engagement of KOLs and CDE

SANOFI — Wuhan Union Hospital

Sanofi formed strategic partnership with Wuhan Union Hospital to build capability in translational medicine and clinical research

Innovent 信达生物制药 — Lilly

Eli Lilly expanded strategic collaboration with Innovent to co-develop 6 biologics

SOURCE: Literature search; Expert interviews; Team analysis

China biotech companies in search of a winning formula?

What can we learn from successful global biotechs?

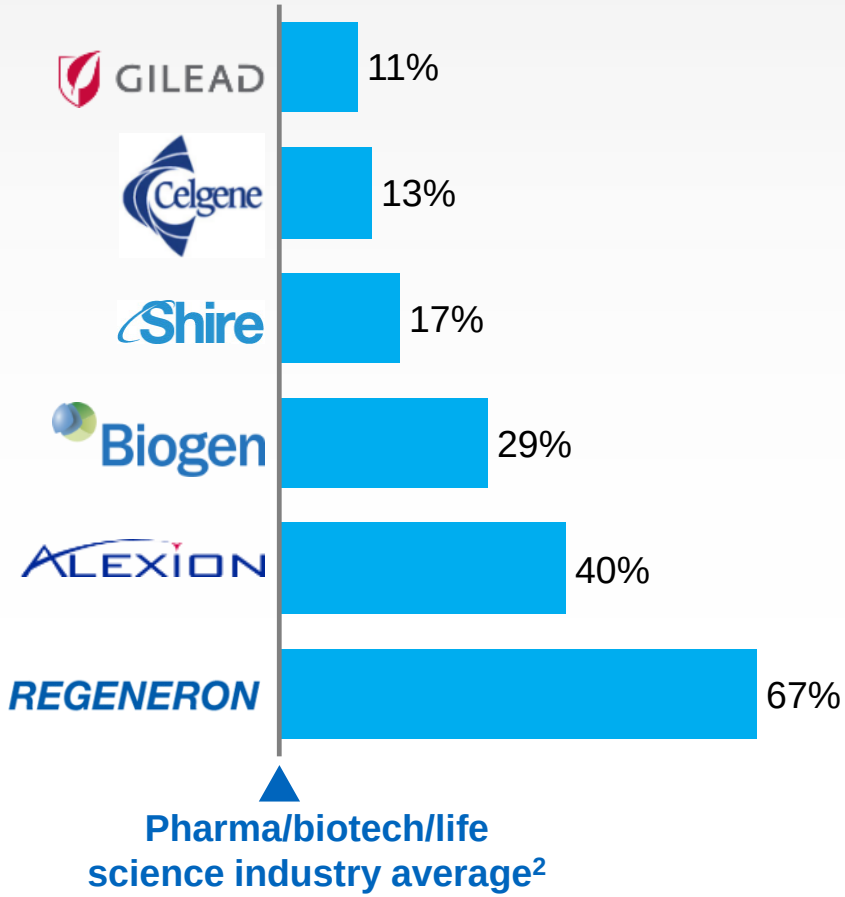
What are areas of strength and unique offerings of China?

What are key considerations for China biotechs?

What can we learn from the the success and failures of global biotechs?

Successful western biotechs have outperformed pharma industry

Excess TRS return over industry index[1]



However, failure is common

(~90% of trials fails and biotechs lack the scale to hedge risks)

Bind therapeutics filed for bankruptcy after a decade of efforts pursuing nanoparticle cancer treatment with ~$100M funding raised

Dendreon placed bet on one product (Provenge) which failed to due to limited benefit against high price. Company filed for bankruptcy in 2014

Satori shut down with failure in Alzheimer's drug, after raising $40Mn

Altair Therapeutics dissolved after failure of its phase II trials, 4 years after spinning off from ISIS

1 MSCI defined Global Pharmaceutical Index
2 2007-17 average at 8.8%

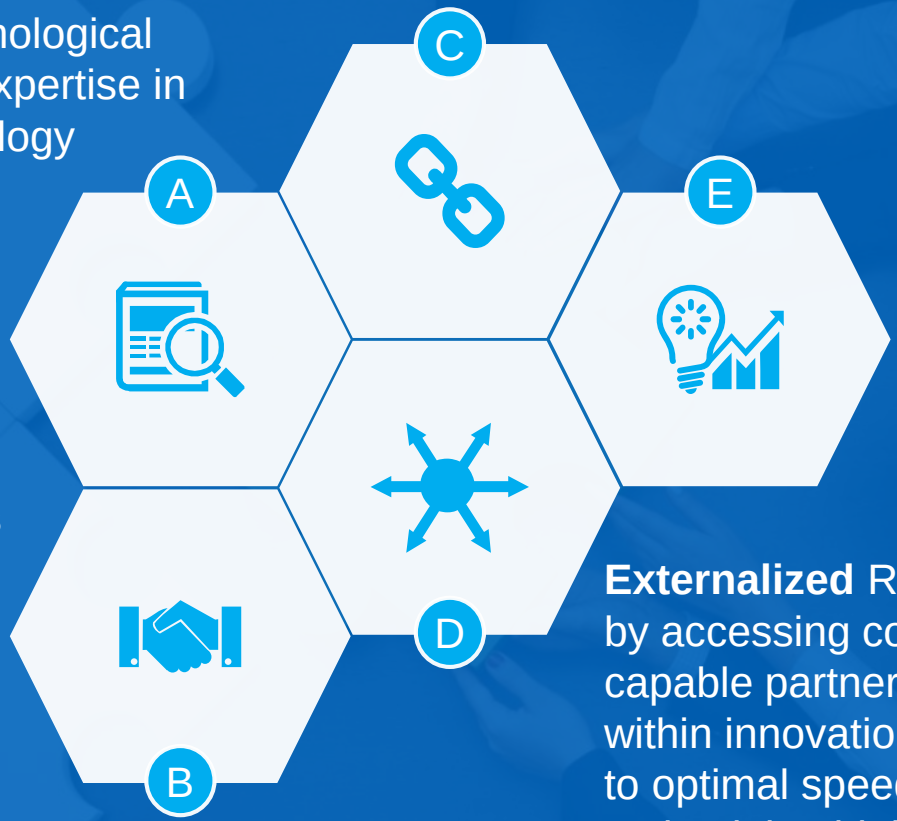
SOURCE: Datastream; McKinsey analysis

Beyond having winning products, successful western biotechs and pharmacos often excel on five dimensions

Robust development strategy and trial design (e.g., generate evidence to "fail early", clear patient stratification, adaptive trial design)

GILEAD IONIS REGENERON MERCK

Focused portfolio rooted in distinctive science/technological insight (e.g., scientific expertise in MoA/pathway or technology platform)



Smart financing that balances between accelerating asset/tech progression and maintaining operating discipline

KuDOs

Leverage partnerships to strategically bolster portfolio and/or as "vote of confidence" to asset/technology from established players

ONYX PHARMACEUTICALS Celgene ACTELION

Externalized R&D operating model by accessing core competencies of capable partners (e.g., CRO/CMO) within innovation ecosystem, leading to optimal speed, efficiency while maintaining high quality

VELOCITY pharmaceutical development

SOURCE: Expert interviews, team analysis

A Highly focused portfolio: technology platform and therapeutic area focus example

Platform-focused

REGENERON
VELOCIMMUNE
EYLEA
Praluent
KEVZARA

Two platforms of **antibody technologies**: Trap Fusion Proteins, and Fully Human Monoclonal Antibodies, launched 6 drugs and developing 18 pipeline assets

IONIS PHARMACEUTICALS
SPINRAZA (nusinersen)

RNA-targeted drug discovery and development, called the **Antisense platform**, across more than 5 therapeutic areas and >30 assets in pipeline

TA - focused

Biogen
AVONEX (interferon beta-1a)
fampyra 10 mg
plegridy
Tecfidera
TYSABRI (natalizumab)
Zinbryta

Building on early success of initial focus on **multiple sclerosis**, expanding to other CNS diseases

Shire
BEBULIN
[Factor IX Complex]
Nanofiltered and Vapor Heated

Exclusive focus on **rare diseases** utilizing specific protein engineering platforms; established strategic partnership to bring novel technical solutions in areas outside of technical expertise

GILEAD
Viread
SOVALDI
HARVONI
EPCLUSA

Concentrated on **anti-viral** drugs for Hep C, Hep B, HIV, expanding to liver diseases, cancer and respiratory diseases

VERTEX
ORKAMBI
kalydeco

A leading player in the **Cystic Fibrosis** market: successful inline products and concentrating pipeline effort to Cystic Fibrosis

B Strategic partnerships for asset-sourcing or BD-testing with large pharma

Actelion developed assets handed down by Roche, licensed Tracleer in 1998 and launched in 2001, with an IPO in 2000

Celgene followed “String of Pearls” strategy in immuno-oncology via smart early stage deals and collaborations with 30+ partners

Onyx Formed global oncology partnership with Bayer to co-develop and co-promote sorafenib and related drugs

China biopharma companies could tap into several areas of strength and unique offerings of China…

NOT EXHAUSTIVE

Areas of strength and unique offerings of China

- **Strong government commitment** to “Healthy China” and fostering innovation
- **Abundant financing**, including government funding and VC/PE
- **Growing pool of talent** with continued inflow of overseas returnees
- **“End-to-end” capabilities** in place for both small and large molecules (e.g., access to leading CROs and CMOs, support from established industry parks and incubators)
- **Sizable patient population** enables accelerated patient recruitment for clinical studies
- **Potential to explore creative, ecosystem-based business model**, taking advantage of broader innovation momentum **in other sectors** (e.g., digital, e-commerce, AI)

SOURCE: Expert interviews; team analysis

…while being mindful of “watch outs”

“Join the chase for hot target” - over 50 players on PD(L)-1 today…eventually only few with clear differentiation will win

“Me-too is a safer bet” - majority of current pipelines are me-too/me-better. Key is to win the efficacy battle (best-in-class) or differentiate with smart access strategy

“Good science will sell” - risk of underestimating competitive intensity, lacking unique insights into customer and payor needs, and under-investing in building launch engine

Under-deliver relative to market expectation – heated investment in healthcare drives up valuation without grounded view of asset’s true potential

China biopharma companies should build distinctiveness in six areas

Build on learnings from successful global biotechs

Leverage areas of strength and unique offerings of China

Focus on getting portfolio strategy right, identifying sweet spot for your company (e.g., me better vs. first-in-class, China specific diseases). Be equally clear on what NOT to do

Adopt an agile model that capitalizes on innovation ecosystem at China speed (i.e., tapping into CRO, CRMO, seasoned advisors etc.)

Master the "art of partnership" to bolster portfolio or gain "vote of confidence" (e.g., technology license-in, early input from BD partners)

Take advantage of access to capital to accelerate pace of scaling up and/or experiment new models of innovation that improve odds of success

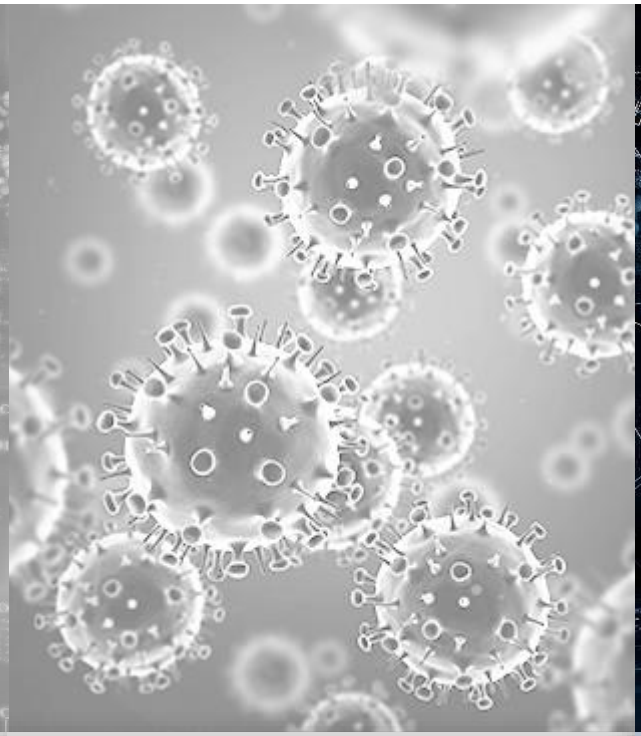
Win big on talent – attract top talent worldwide for critical positions, and invest energy to develop talent in both technical savviness and leadership skills/mindset

Leverage capabilities from other sectors (e.g., to create diagnostic solutions, pinpoint patient stratification, or accelerate patient recruitment)

SOURCE: Expert interviews; team analysis

Building on this, three key topics to explore

2017 in the mirror



Rise of China-based bio-pharma innovation

Launch success imperative in the new era

Key questions

What is the overall context for access to pharma innovation in China?

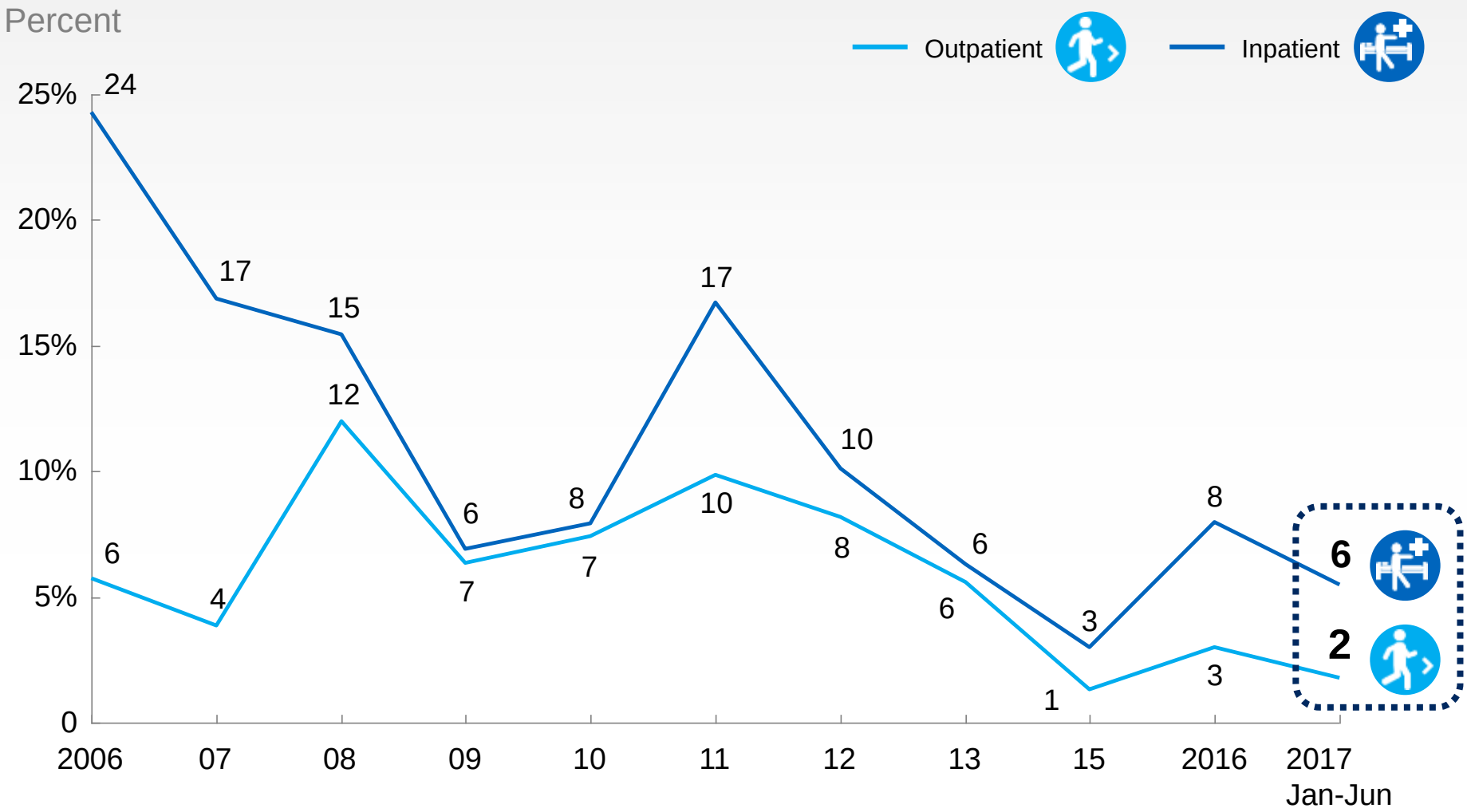
What are the key trends shaping the launch environment?

What are the key success factors for launch in this new era?

What is the overall context for access to pharma innovation in China?

Patient flow growth remains in mid to low single digits

Patient flow[1]-YOY growth



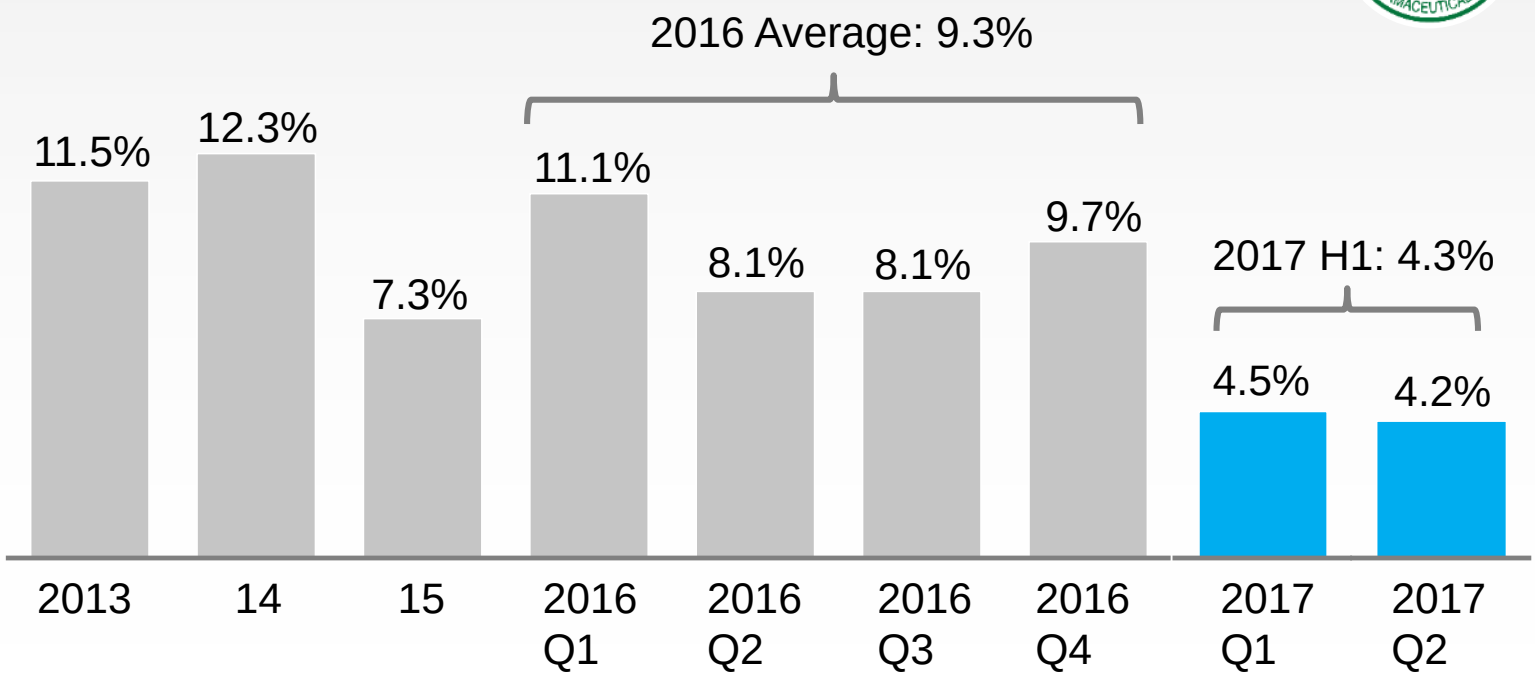
1 Include hospitals and grassroots facilities

SOURCE: NHFPC

After a recovery in 2016, market growth in large hospitals remains under pressure

YoY sales growth of CPA sampled Class III/II hospitals[1], 2013-17 Q2

Percent



Outpatient[2] YOY growth

Percent

2013	14	15	2016 Q1	2016 Q2	2016 Q3	2016 Q4	2017 Q1	2017 Q2
8.2%	5.6%	1.2%	8.2%	4.3%	4.3%	9.3%	2.1%	3.6%

1 712 sampled hospitals, including 477 Class III hospitals, 235 Class II hospitals
2 Only include hospitals

SOURCE: Chinese Pharmaceutical Association (CPA); NHFPC

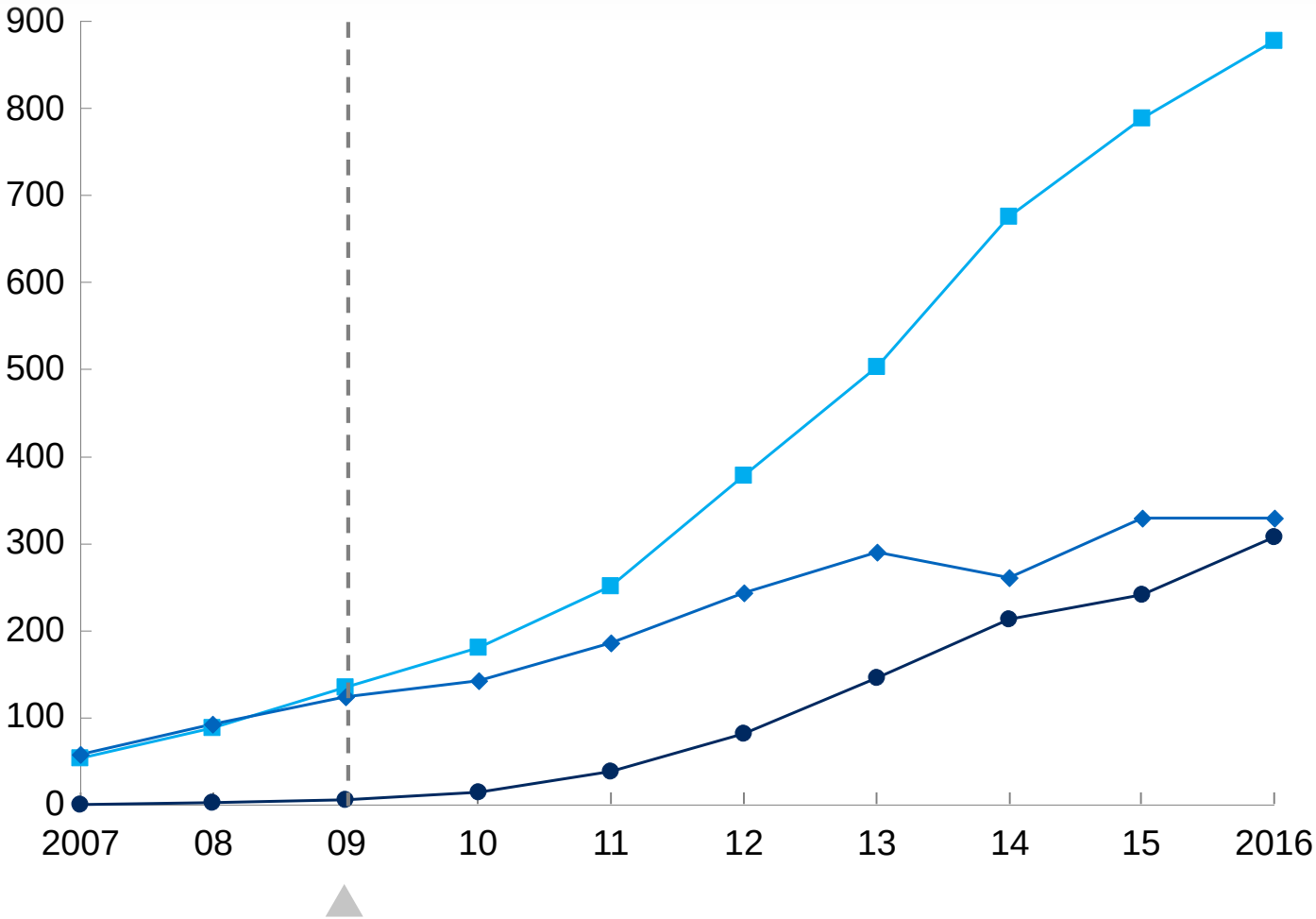
However, 2017 has turned out to be another strong year for many MNC pharmacos

	2017 H1 vs. 2016 H1 Percent	2016 H1 vs. 2015 H1 Percent	Company quotes
Bayer	19%	11%	Bayer is now 'the number one multi-national company' in China in growth terms
Pfizer	15%	10%	When we look at China, we remain very bullish, and our performance there has been very strong
SANOFI	13%	15%	Positive performance in China reflected both the solid underlying growth in our Pharmaceuticals business and the end of local market disruption in Vaccines
AstraZeneca	8%	11%	China is becoming economically more developed, it's growing and becoming richer, regions of China that could not afford medicines before are progressively able to

SOURCE: Industry association; company financial reports; investor calls; literature search

Historically, reimbursement listing is a key driver to accelerate growth of innovative products

Sales (ex-mf) before and post 2009 NRDL listing, Mn USD

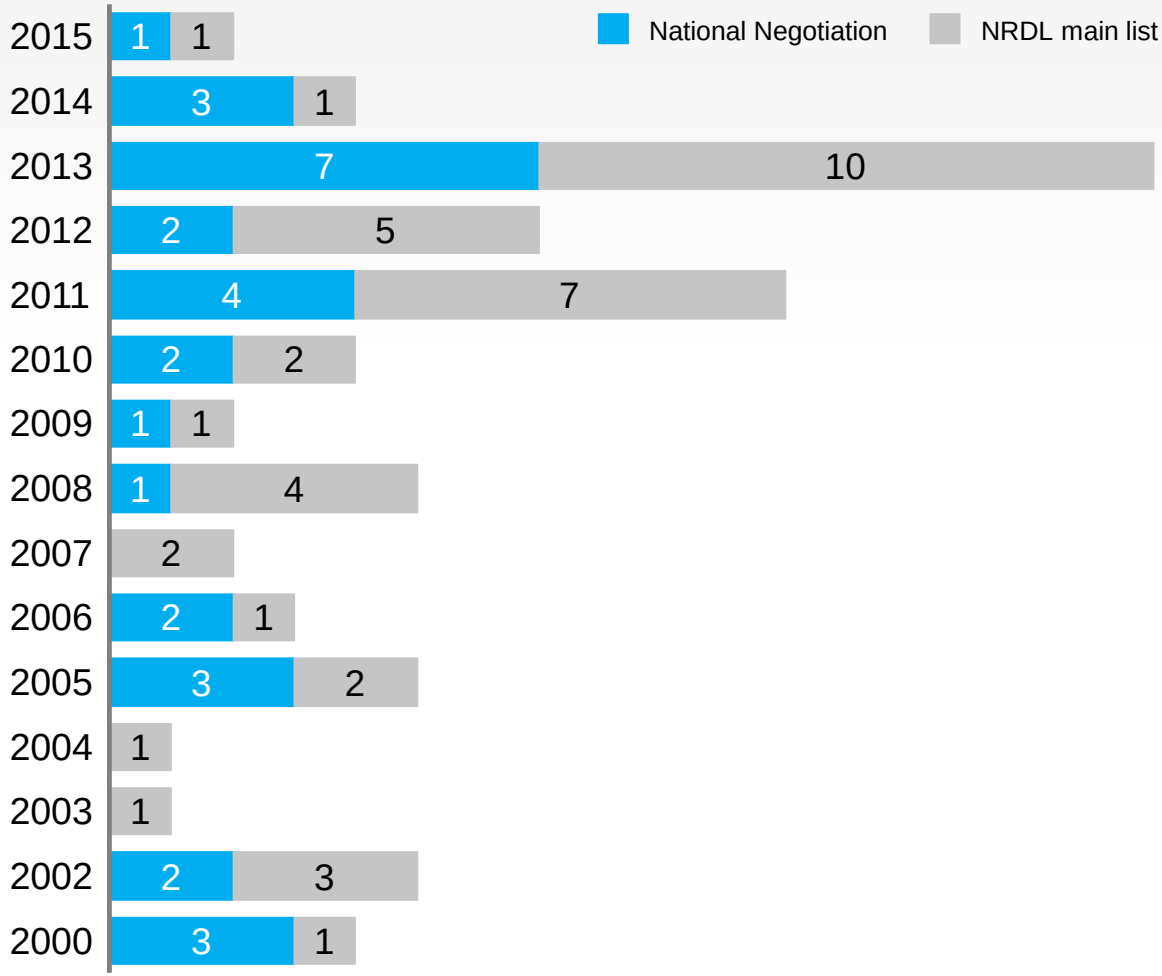


SOURCE: RDPAC, GBI, McKinsey Analysis

2017 NRDL update will therefore give a boost to innovative medicines

New molecules or new MOA added to 2017 NRDL

(by drug registration year, total = 73), number of drugs



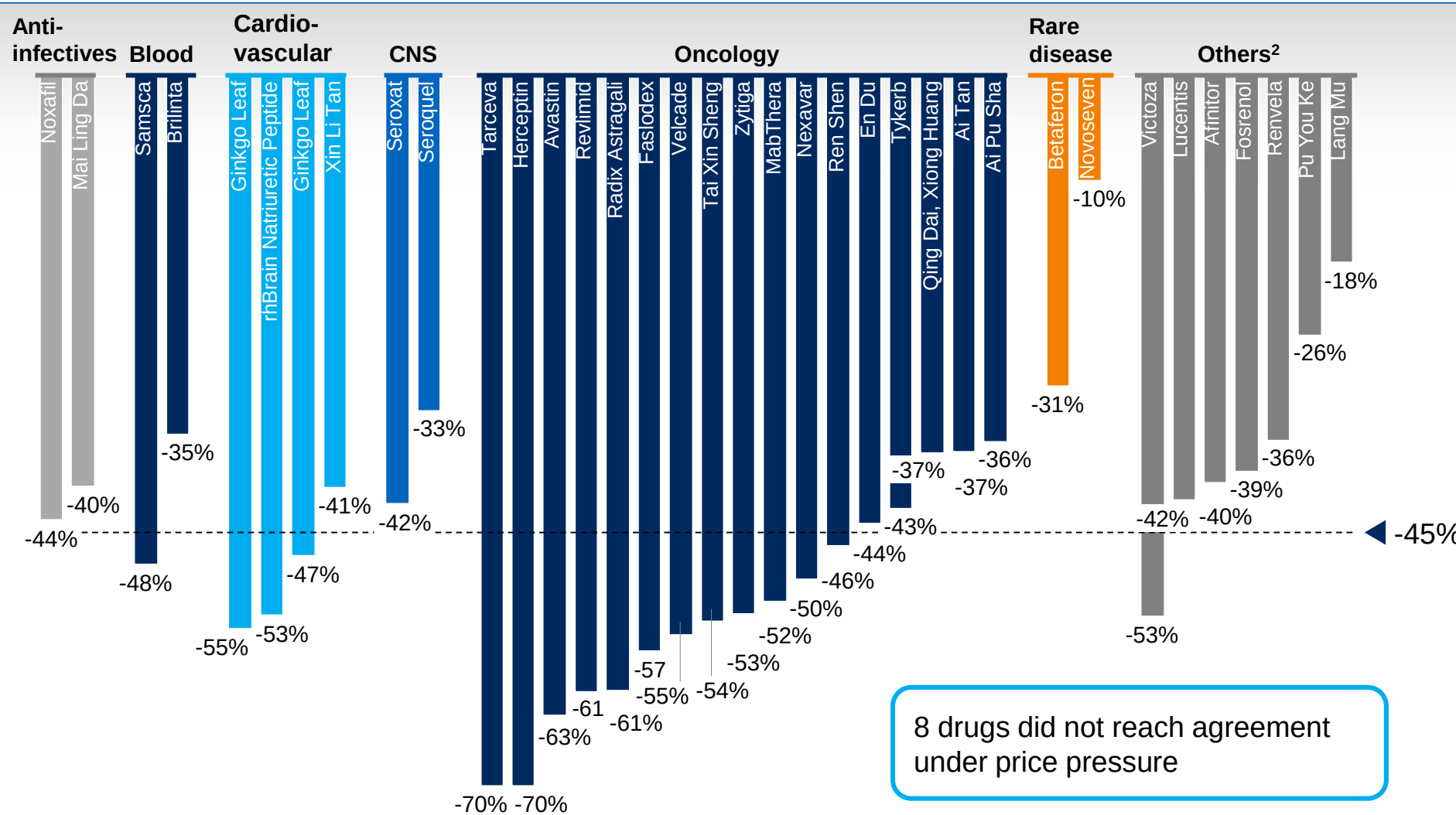
Brand examples

Zytiga (abiraterone acetate)
Corlanor (ivabradine) tablets
西达本胺片
甲磺酸阿帕替尼片 Apatinib Mesylate Tablets
康柏西普眼用注射液
Revlimid (lenalidomide)
BRILINTA ticagrelor tablets
BeneFix
LUCENTIS RANIBIZUMAB
艾瑞昔布片 Imrecoxib Tablets
AVASTIN bevacizumab
LYRICA PREGABALIN
Rebif
Januvia (sitagliptin)
尼妥珠单抗注射液
Viread
ARCOXIA (ETORICOXIBE), MSD
艾普拉唑肠溶片
Tarceva erlotinib
Nexavar (sorafenib) tablets
VELCADE
益赛普
IRESSA gefitinib
Vessel Due F
Herceptin trastuzumab
Gleevec (imatinib mesylate)
MabThera Rituximab
Simulect

SOURCE: Literature search; McKinsey analysis

NRDL negotiations came with substantial price-cuts, real impact on volume to be seen

Price-cut level[1] for the 36 drugs that entered 2017 NRDL via negotiation

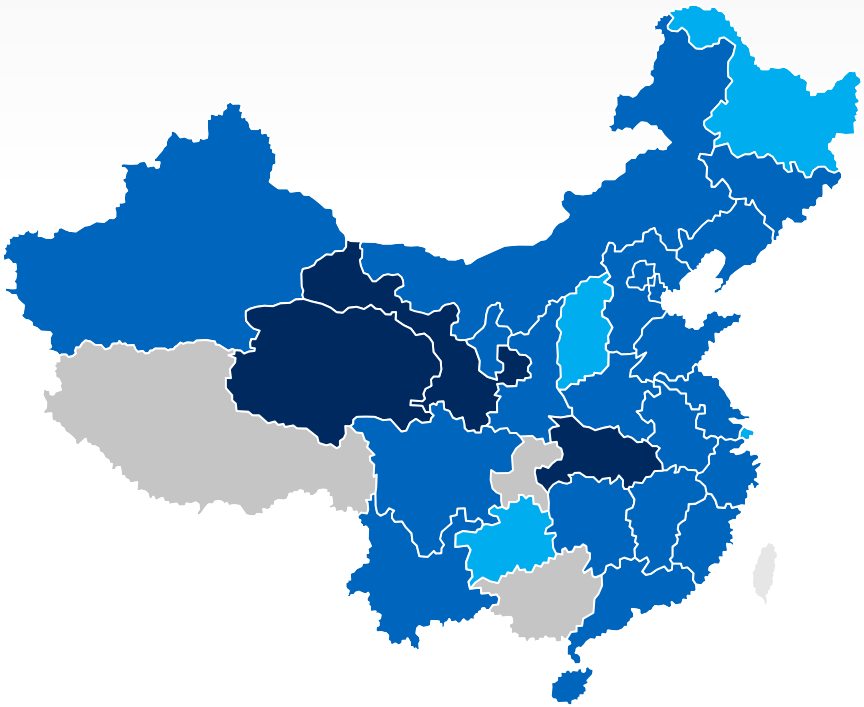


1 Not considering PAP; 2 Others include ophthalmology, diabetes, gastropathy, immunology drugs, etc.

SOURCE: Press search; McKinsey analysis

Provincial implementation for NRDL is still very much a work in progress, with 24 provinces having announced coverage for the 36 negotiation drugs

AS OF OCTOBER 2017



"Front runners" (3)

- Hubei, Gansu, Qinghai
- Already published PRDL
- PRDL includes 2017 NRDL drugs, 36 negotiated drugs, and other drugs added at provincial level

"Quick followers" (21)

- E.g., Beijing, Shandong, Fujian
- Follow NRDL while compiling local RDL
- PRDL includes 2017 NRDL drugs, 36 negotiated drugs, and 2010-11 PRDL drugs not listed in 2017 NRDL[1]

"Later comers" (4)

- E.g., Shanghai, Shanxi, Guizhou
- In the process of PRDL development. 2017 NRDL not in implementation yet
- Considering adding drugs in list B, esp. 2010-11 PRDL drugs not listed in 2017 NRDL

"Laggers" (3)

- E.g., Chongqing, Guangxi
- PRDL plan has not been announced yet

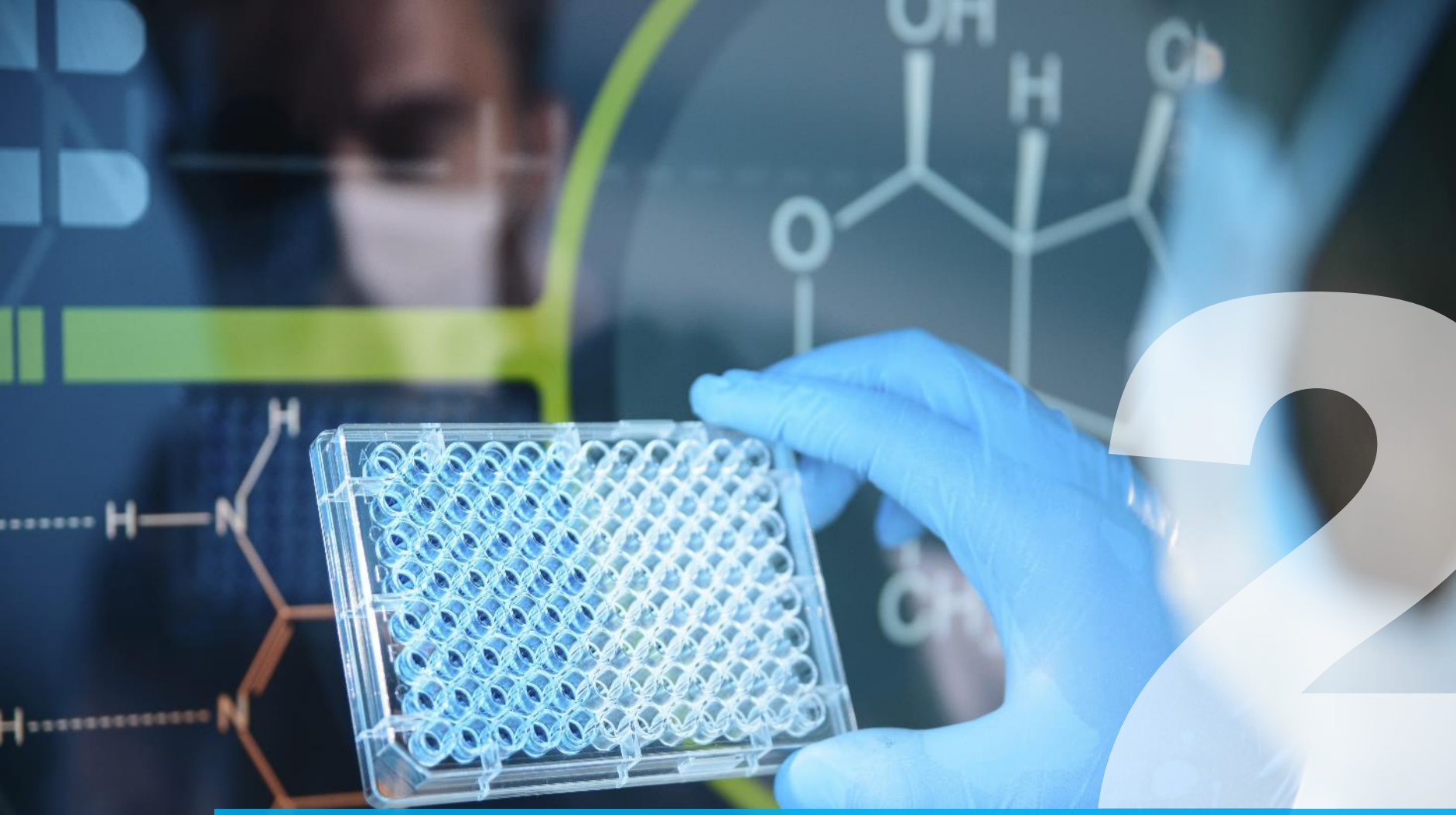
1 Except for Fujian which has released first batch of PRDL added drugs, and Ningxia which has submitted PRDL adjustment to MoHRSS

SOURCE: Press search; McKinsey analysis

Post national negotiation, what should we expect next for pricing and reimbursement framework of China?

	Potential directions	Likelihood
Reimburse-ment	▪ **Dynamic reimbursement negotiation** upon manufacturer application	Medium
	▪ **Transparent and evidence-based assessment** prior to reimbursement negotiations	High
	▪ **Provincial level negotiation** for products that do not participate or fail to reach agreement on the national level	High
Payment Mechanism	▪ Payment mechanism moving from a fee-for-service model to **comprehensive payment mechanism**	High
	▪ **Separate reimbursement funding** for **innovative medicines**	Medium
	▪ Continuous policy support for **PHI development**	High
Hospital Access	▪ Innovative medicines successfully negotiated with reimbursement authorities **directly accepted by the provincial procurement platform**	High
	▪ **Restrictions removed** on listing caps for innovative medicines, drug revenue percentage, etc.	Medium
	▪ **Expanded dispensing channels for reimbursed products** via independent pharmacies, etc.	Medium

SOURCE: McKinsey analysis



2

What are the key trends shaping the launch environment?

More and more pharmacos tailor their pipeline for China considering acute local patients' need

Company → Product

Notable new product launches in the past 3 years

GILEAD

Breakthrough improvement in efficacy for **prevalent HCV population**

Daklinza (daclatasvir)
Sovaldi® Sunvepra®
viekirax® (ombitasvir/ paritaprevir/ ritonavir tablets)
exviera® (dasabuvir tablets)

BAYER
ACTELION

Only treatment choice for **Chinese rare disease patients**

Adempas® (riociguat)
zavesca® (miglustat)

First to market 3rd generation TKI addressing unmet needs of lung cancer patients

TAGRISSO® osimertinib

西安杨森 xian janssen

Addressing unmet needs for **increasing prostate cancer incidence**

Zytiga® (abiraterone acetate)

MSD
gsk

First to market preventive treatment for **cervical cancer**

GARDASIL®
Cervarix

Tsunami of new product launches expected in next few years

NOT EXHAUSTIVE

OUTSIDE-IN PERSPECTIVE

# of molecules expected to launch in 2018-20

Logos: Therapeutic areas (example products)

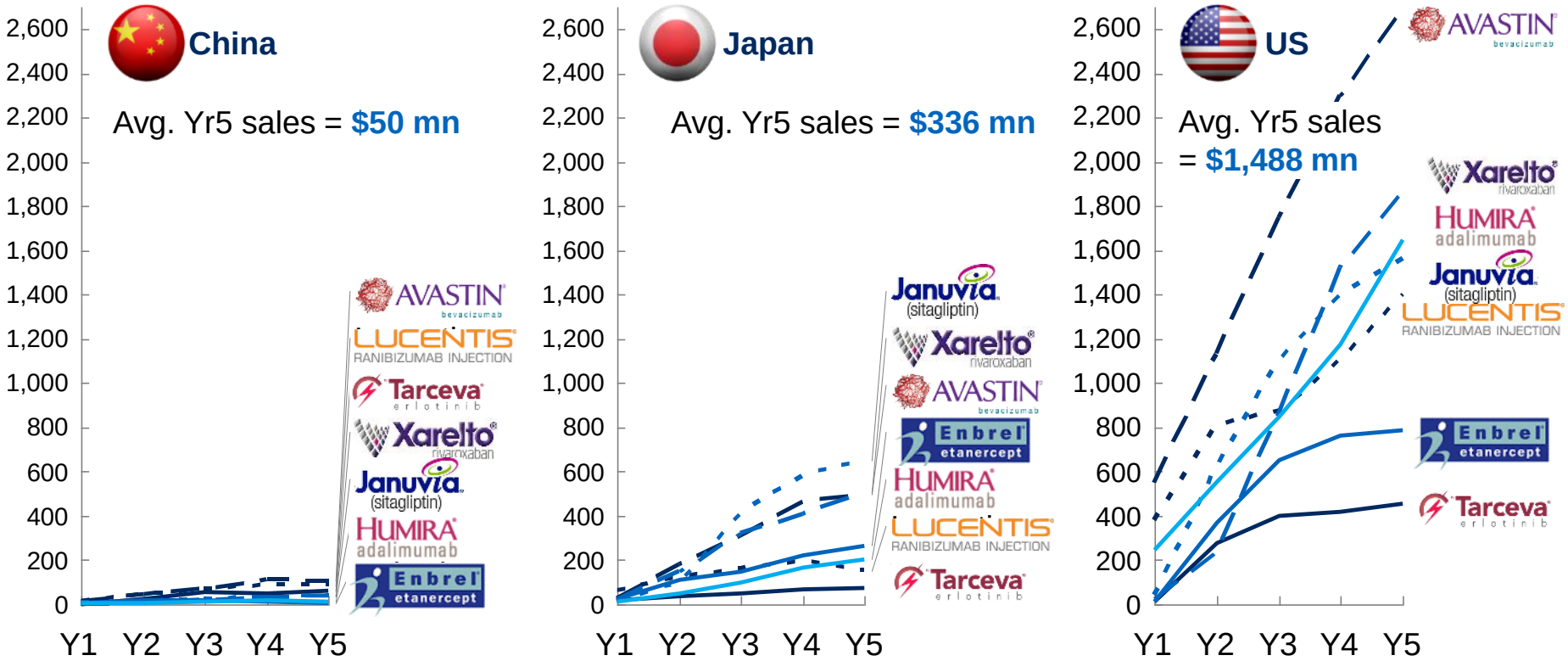
1: Molecule name

SOURCE: DXY Insight; GBI Source

Historically, launch in China have underperformed relative to potential and developed markets

Sales growth of example drugs in local market after launch

Mn USD[1]



Average year 5 sales of selected innovative drugs: Japan = ~**6x** of China, US = ~**30x** of China

Taking into consideration population and epidemiology, "underperformance" is even more striking

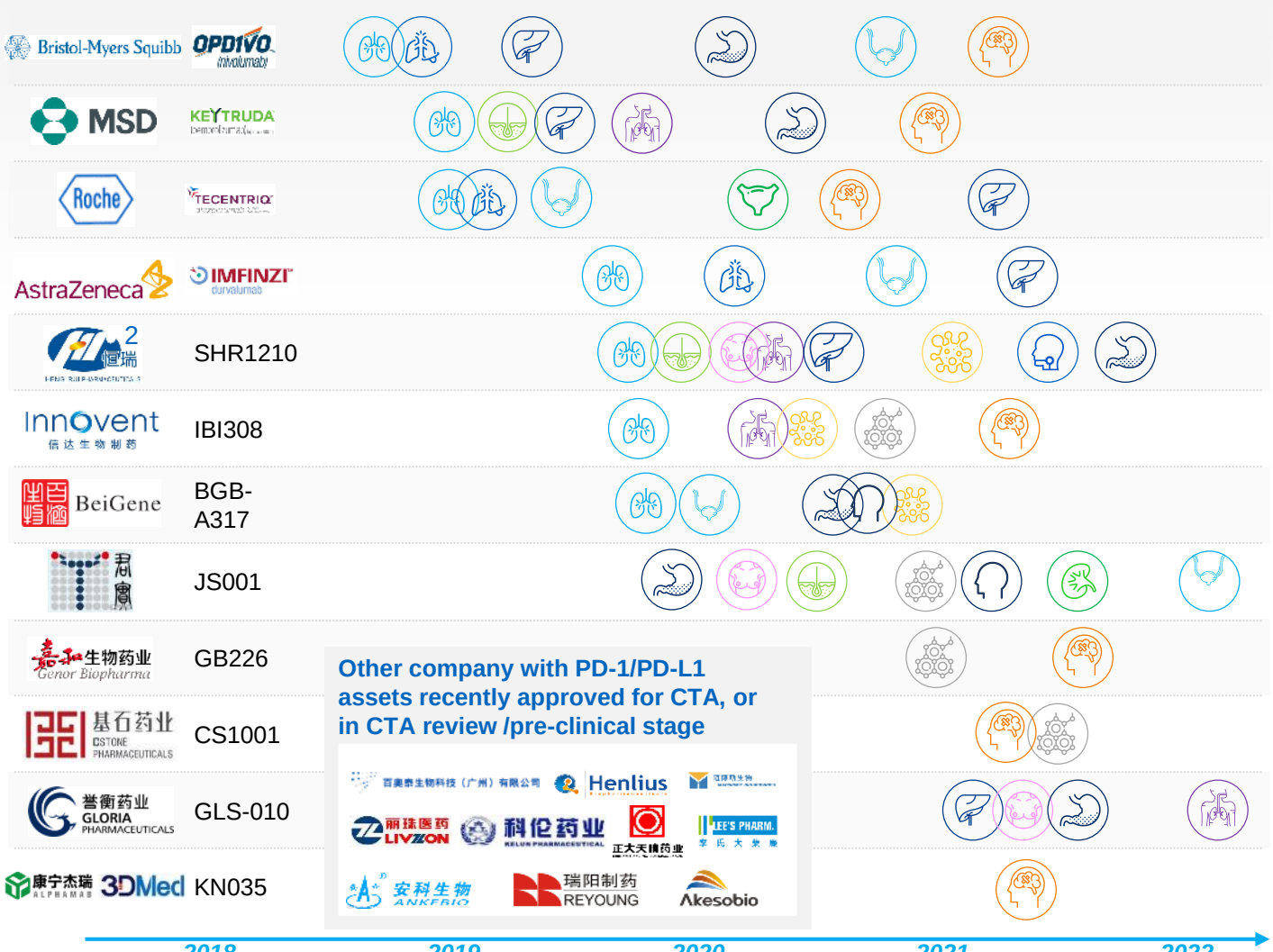
1 USD/RMB=6.6; USD/JPY=113.9

SOURCE: EvaluatePharma; Company reports; Prospectus; Testa Marketing; Fuji Keizai; WHO (2014); Industry association; McKinsey analysis

New launches will face hyper-competition: PD-1/PD-L1 example

NOT EXHAUSTIVE
OUTSIDE-IN ESTIMATION

Estimation of PD-1/PD-L1 launch time and indications[1]

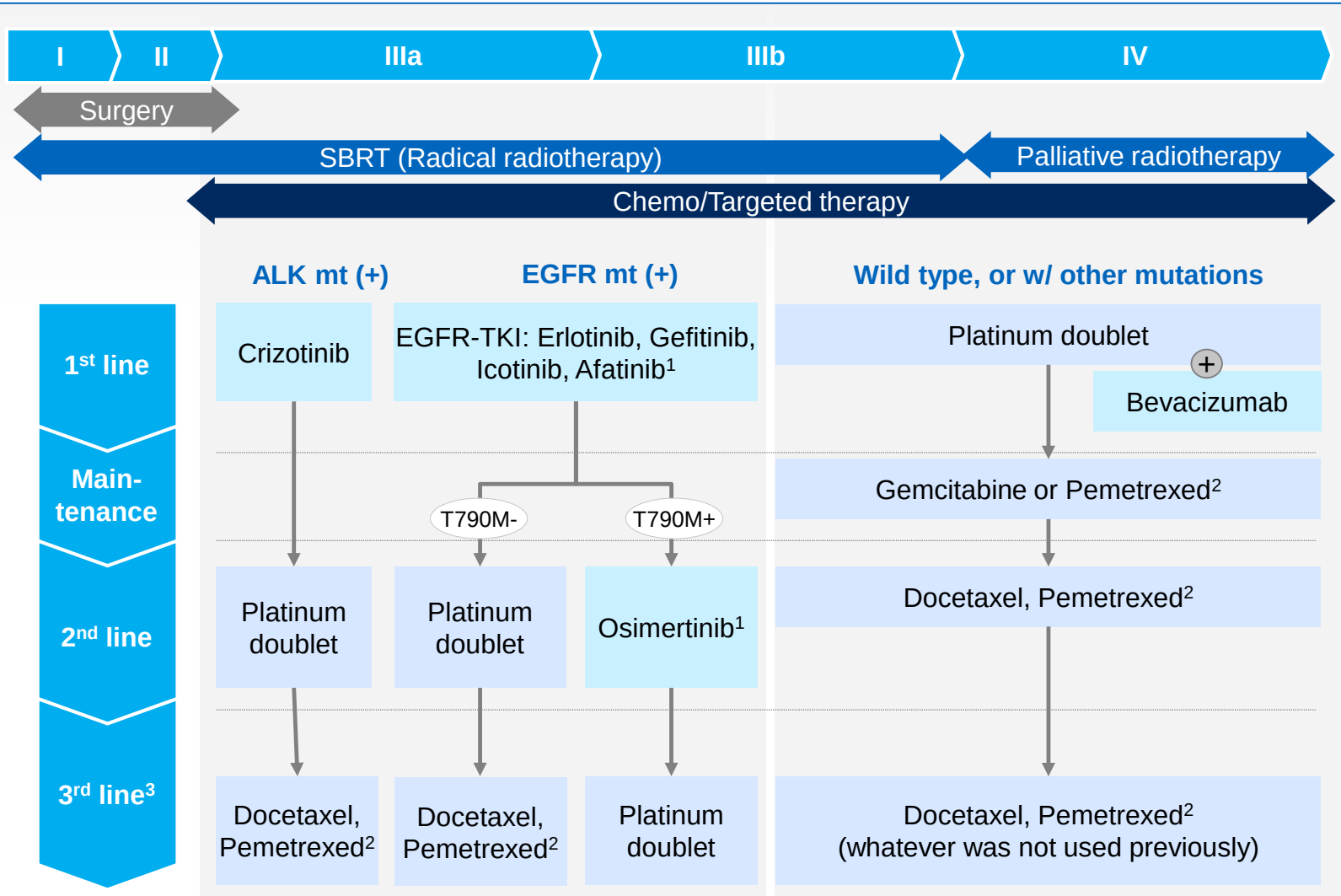


1 Showing selected assets that are approved for CTA by Nov 13th, 2017; do not include combo therapies; launch timeline is estimated based on current development status and assumption of development success of all indications currently in trials; indication information from clinicaltrials.gov, Chinadrugtrials and press search; 2 SHR-1316 (PD-L1 mAb) approved for clinical trials in China on Sep.14th, 2017

SOURCE: GBI; Clinicaltrials.gov; Chinadrugtrials.org; press search; team analysis

Taking NSCLC as an example, the driver mutation based segmentation results in a complex treatment paradigm in China today

NSCLC EXAMPLE

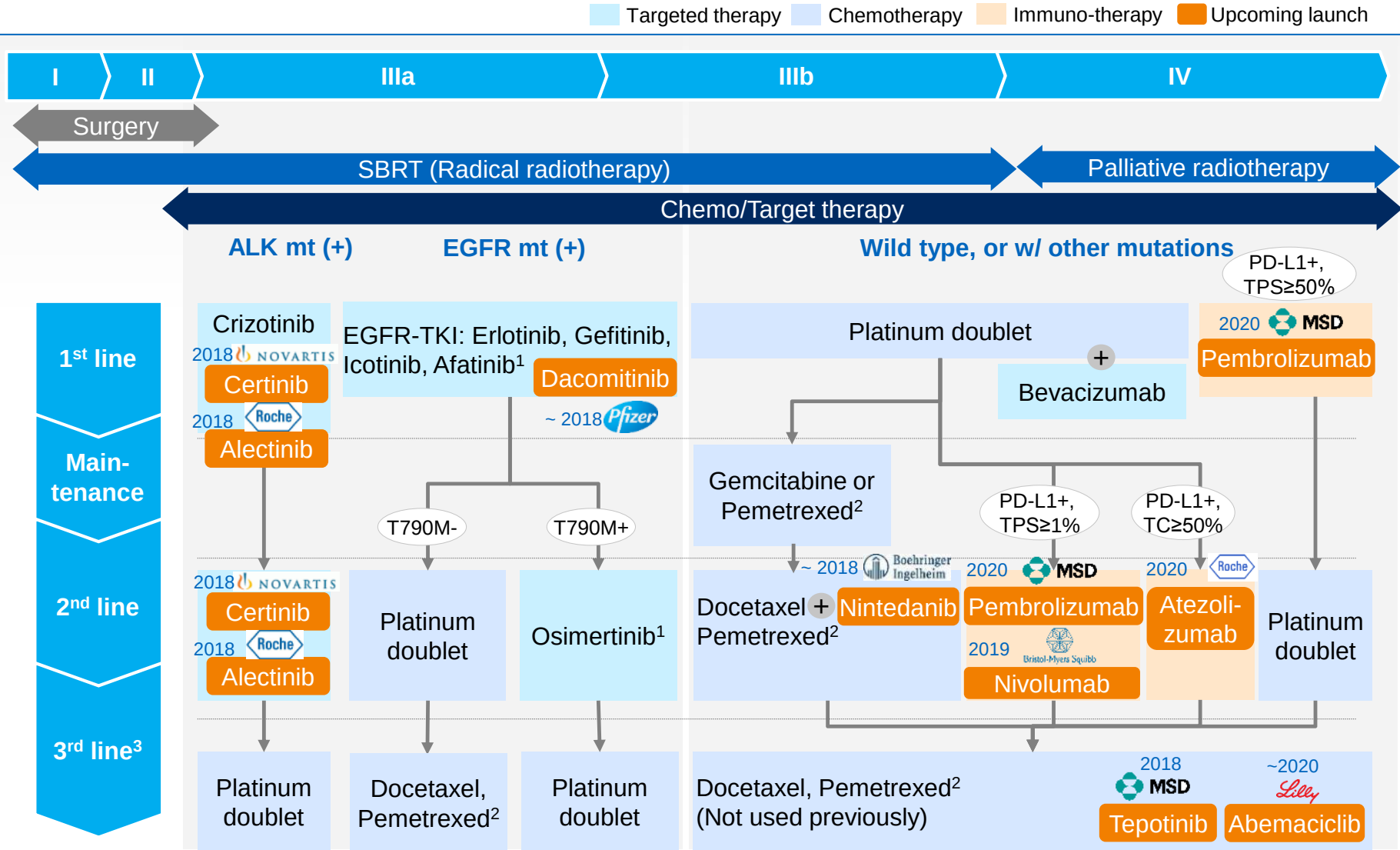


1 not yet included in latest official Guidelines (2015 edition), but has been launched earlier in 2017 2 Mostly for use in squamous NSCLC
3 Currently there is no standard treatment/guideline

SOURCE: Expert interview; team analysis

With plenty of upcoming new drugs, treatment paradigm is expected to be even more complex in the future

NSCLC EXAMPLE



1 not yet included in latest official Guidelines (2015 edition), but has been launched earlier in 2017
2 Mostly for use in squamous NSCLC
3 Currently there is no standard treatment/guideline

SOURCE: Expert interview; team analysis

Physician daily interactions and engagement needs will be more sophisticated and diversified

More **efficient and effective communication with patients** (e.g., quality communication on explaining treatment options, available PAP programs)

More effective **clinical decision making** (e.g., AI-enabled clinical decision support providing customized treatment choice guidance)

Continued learning from **platforms integrating multiple sources** (e.g., academic, social media, physician peers, pharmacos)

Real-time engagement with peers to share **challenges and learnings in real clinical practices**

Enhanced integration and linkage **with other industry players** (e.g., link patients to integrated care programs, DTP pharmacies)

Physicians leverage broader set of information channels, while having to manage a tighter schedule

Variety of information channel

HCP

- E-newsletter
- Virtual congresses / peer-to-peer events
- Virtual IITs interaction/AD boards
- Web portal
- Apps
- MRs (medical representatives)
- Med Info hub
- MSL “on demand” eMSL / Digital MSL
- KOL Webcast participation
- People networks/On-line communities
- Trial managers
- MSLs

Number of days spent per week on different activities[1]

1 DAY — Rest

1 DAY — Teaching, research, admin

5 DAYS — Patient care

1 McKinsey DXY physician survey 2017

“Death of sales reps”? Increasing constraints on sales and physician interactions call for innovative engagement approaches

Government pushing for restrictions of sales reps’ promotional activities …

2017 Feb

State Council [Doc. 13]
Set up a registration system for sales reps

2017 May

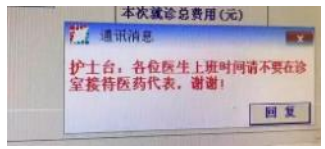
State Council [Doc. 57]
CFDA to lead drafting administrative measures for sales rep registration by 2017 Dec

2017 Oct

State Council document
To further clarify the roles of sales rep and prohibit drug sales, and TRx information collection activities

…with enforcement at hospital level

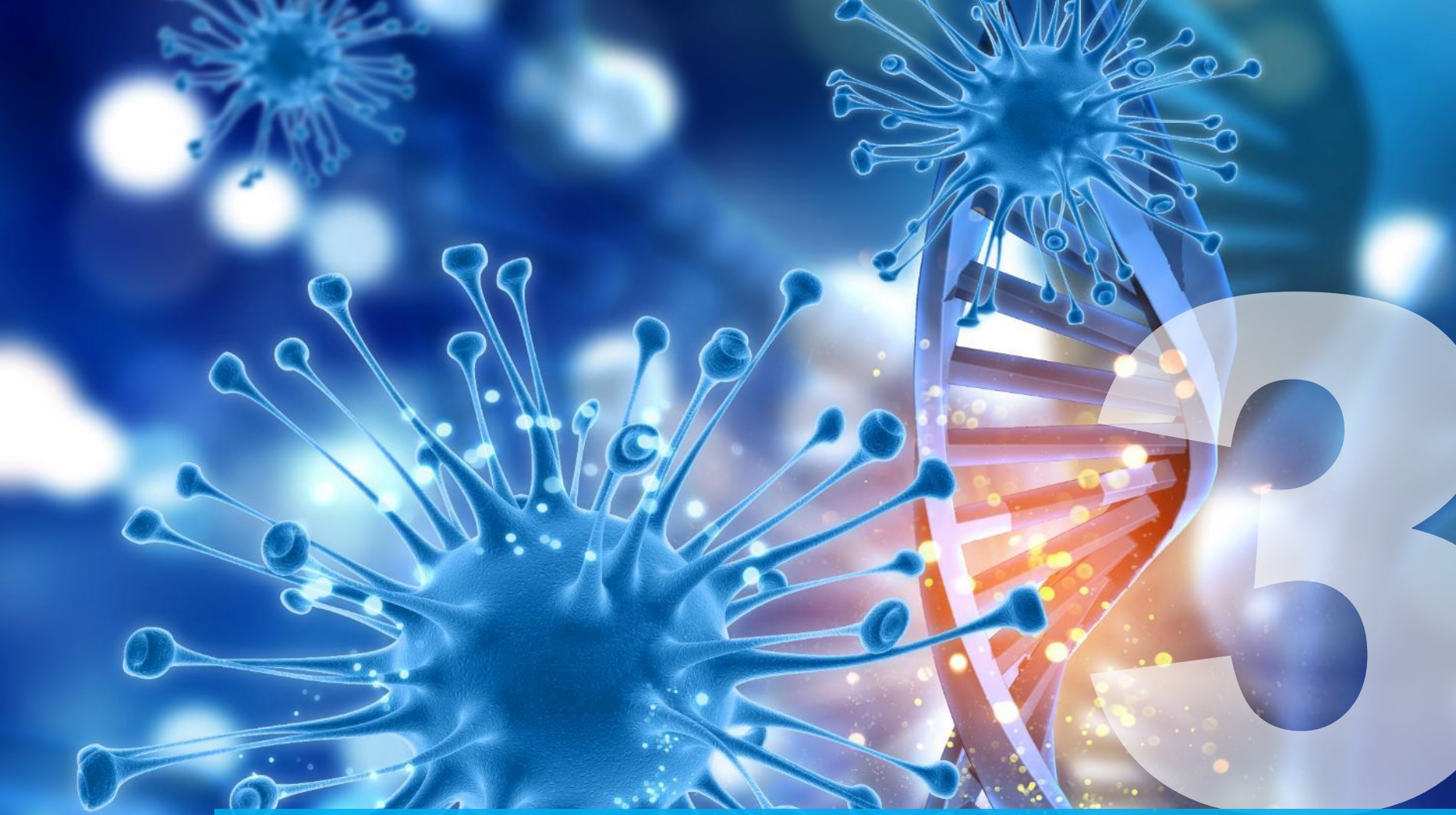
Sales rep face recognition system in Shanghai No.10 People's Hospital



Pop-up reminder in IT system to remind physicians of appropriate engagement with sales rep

> With all the government policy, we can only visit physicians at a set time, set place and with everything on record. We may not need to go to hospitals anymore, but need to find other ways to engage physicians
>
> **– Sales representative**

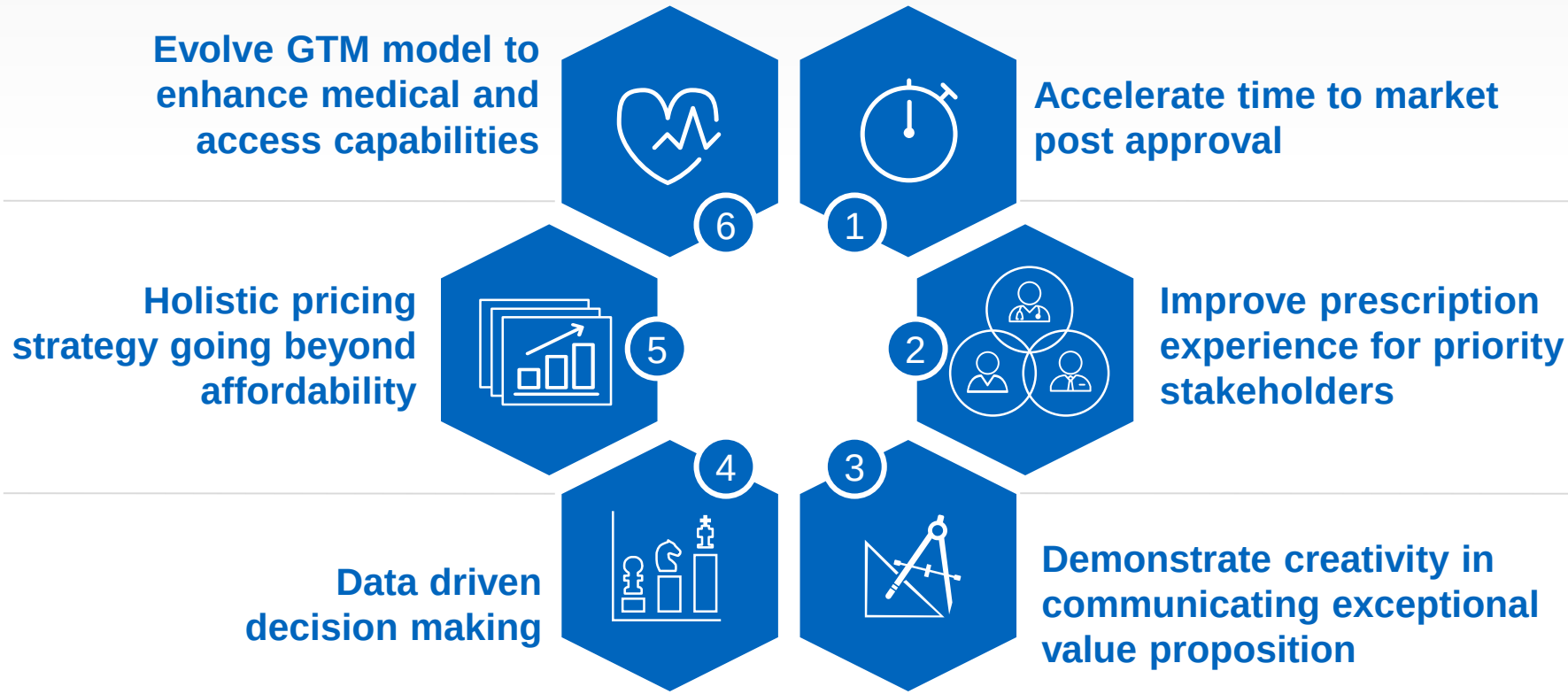
SOURCE: Press search; team analysis



3

What are the key success factors for launch in this new era?

Learning from pharmacos to drive launch excellence in the new hyper-competition era



1 Speed to market: recent launches are able to significantly accelerate time to market post CFDA approval

In the past …

CFDA approval

~6-12 months

Commercial launch

Today …

TAGRISSO® osimertinib

Approved on 22/03/2017 → ***~25 days*** → **Available in market by mid-April**

Entresto™ (sacubitril/valsartan) tablets 24/26mg · 49/51mg · 97/103mg

Approved on 26/07/2017 → ***55 days*** → **First prescription on 19/09/2017**

imbruvica® (ibrutinib) 140mg capsules

Approved on 24/08/2017 → ***74 days*** → **Commercial launch on 06/11/2017**

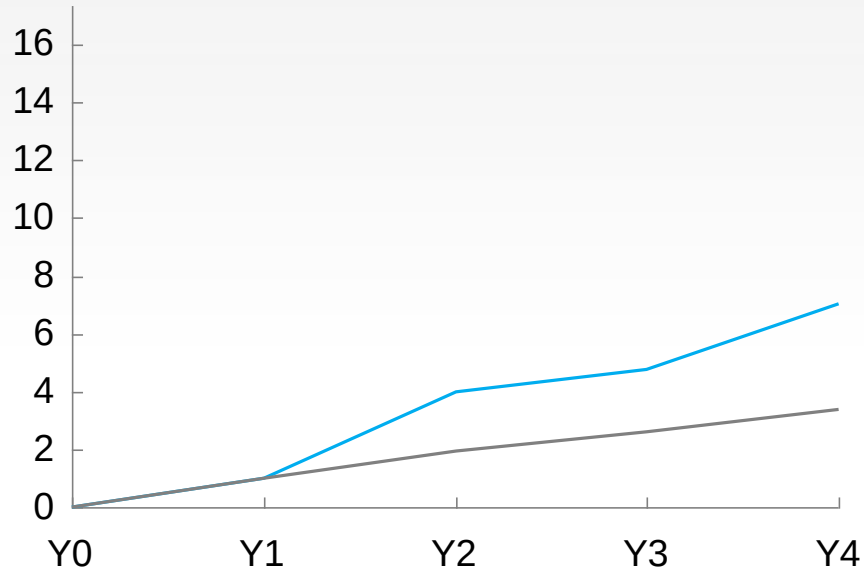
SOURCE: GBI Database; Literature search; McKinsey analysis

2 Improve experience for priority stakeholders: significantly better performance observed in hospitals that were clinical trial sites

Clinical trial hospital[4] — Non-clinical trial hospital

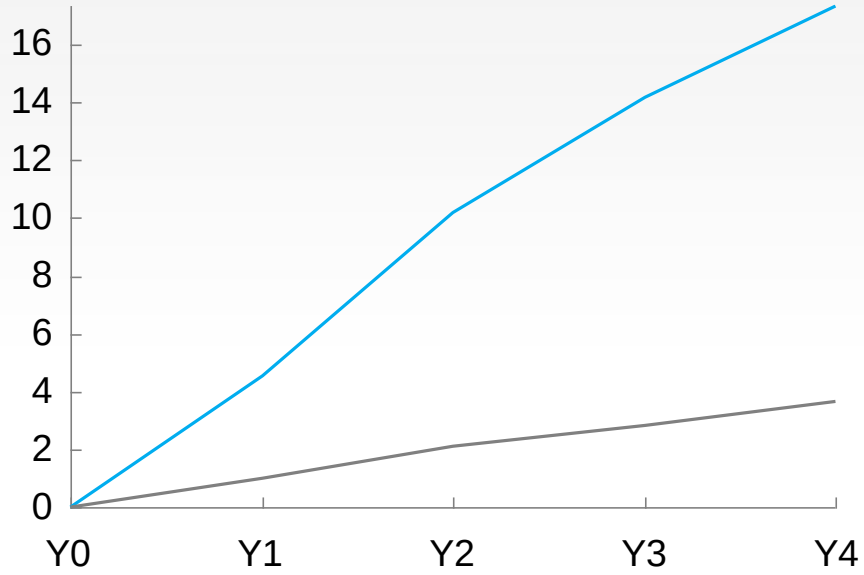
Primary care/chronic disease drugs post-launch performance[1]

Index[3]



Specialty care drugs post-launch performance[2]

Index[3]



- Physician participation in trials has **boosted their confidence in adopting the new therapy post launch**, especially for specialty care drugs
- Physicians/medical institutions with previous experience in clinical trials will **likely become the frontrunners in adopting the new therapy**

1 Based on data from 5 primary care/chronic disease drugs average sales in clinical trial hospitals and non-clinical trial hospitals
2 Based on data from 6 specialty care drugs average sales in clinical trial hospitals and non-clinical trial hospitals
3 Assume non-clinical hospital sales at year 1 (Y1) is 1, relative sales at different years are plotted
4 Clinical trial hospitals were identified based on clinical trials published on www.chinadrugtrials.org.cn, which included all hospitals involved throughout phase 1-3

SOURCE: Chinese Pharmaceutical Association; McKinsey analysis

3 Exceptional value proposition through outcome commitment: BMS introduced China's first outcome-based insurance for HCV patients

The insurance product (肝愈保) required collaboration by 4 parties…

BMS

- Manufacturer of Daklinza(®) and Sunvepra(®)

Shanghai Pharma

- Manage patients on its platform for benefit program, "Meditrust health"
- Pay a premium of 800 RMB for patients
- Provide value-added services, e.g., physician consultation, disease management

Huatai Insurance

- Refund RMB 30,000 for patients who fail to achieve treatment endpoints

KingMed Diagnostics

- Provide testing and diagnosis reports

…and was introduced for HCV patients who take Daklinza(®) + Sunvepra(®)

百立泽® 盐酸达拉他韦片60mg　速维普® 阿舒瑞韦软胶囊100mg

Eligibility

- HCV genotype 1b (diagnosis report needed)
- NS5A non-resistance (diagnosis reports needed)
- Prescribed with Daklinza + Sunvepra by physicians (prescription records needed)

Enrollment process

- Follow the official WeChat account "愈见小甘"
- Register and pay for a membership fee of 9.9 RMB
- Upload relevant reports on application and proof of compliance periodically (medication package, medical records, fapiao, etc.)

Claim process

- File the claim if endpoint is not achieved after 24 weeks of treatment and 12 weeks of follow-up (9 months in total)
- Get paid for RMB 30,000, 50% of total cost [1]

1 Treatment cost is 57,810 RMB for 24 weeks of Daklinza + Sunvepra

SOURCE: Literature research; McKinsey analysis

4 Data driving decision making: a leading global pharmaco leveraged CRM data analytics to optimize marketing campaigns in the field

EXAMPLE

Context

- **"More is more" mindset in marketing organization**
- **Belief in sales organization that "reps know best"** and deliver against brand strategy given adequate training
- Lack of aligned view on where to find efficiency and effectiveness across marketing and sales

How CRM analytics were used

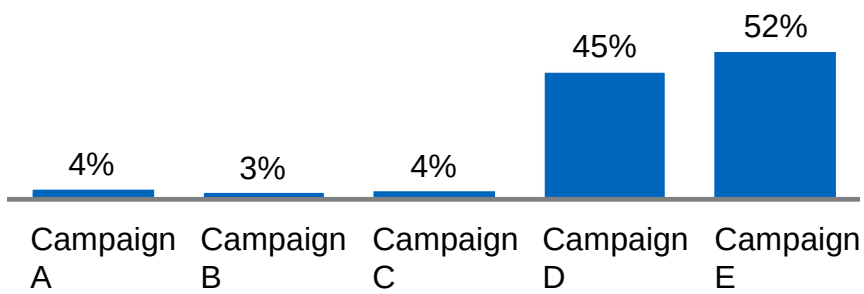
- **Extracted campaign-specific page-view metadata** from Veeva iRep content:
  - Slides opened (by rep and by call)
  - Time spent per slide
  - Overall exposure per campaign

Impact

- Demonstrated **potential for 40% reduction in volume in customer-facing content pipeline**
- **Objective "mirror"** to support conversations between marketing and sales
- **Permanent dashboard** to monitor marketing utilization

Field force open rates

Percentage of reps



This CRM data analytics approach could be applicable in China, with significant amount of meta-data stored on CRM cloud that can be used much better to facilitate decision making

SOURCE: McKinsey Target Test CRM service line (blinded case example)

5 Holistic pricing strategy: develop forward-looking pricing strategy in preparation for evolving access scenarios and competitive landscape

Regulatory environment
Recent pricing policy trends and scenarios on reimbursement negotiations

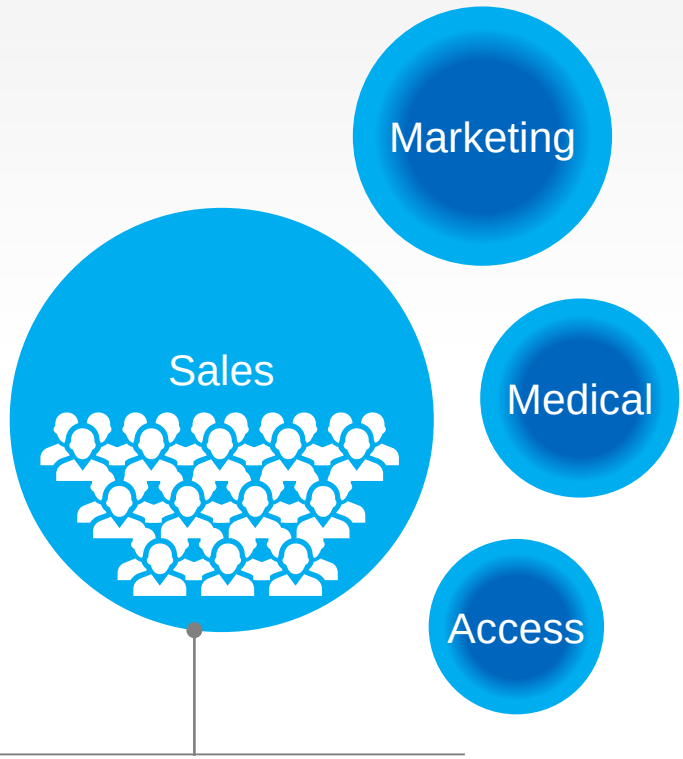
Physician value-price perception
HCP perception on current treatment paradigm, future treatment landscape evolution and impact of pricing on prescription

Patient unmet needs and willingness to pay
Patient perception on unmet clinical needs, access to care challenges, and willingness to pay

Competition
Product competitive landscape including MNC originators and local Gx products

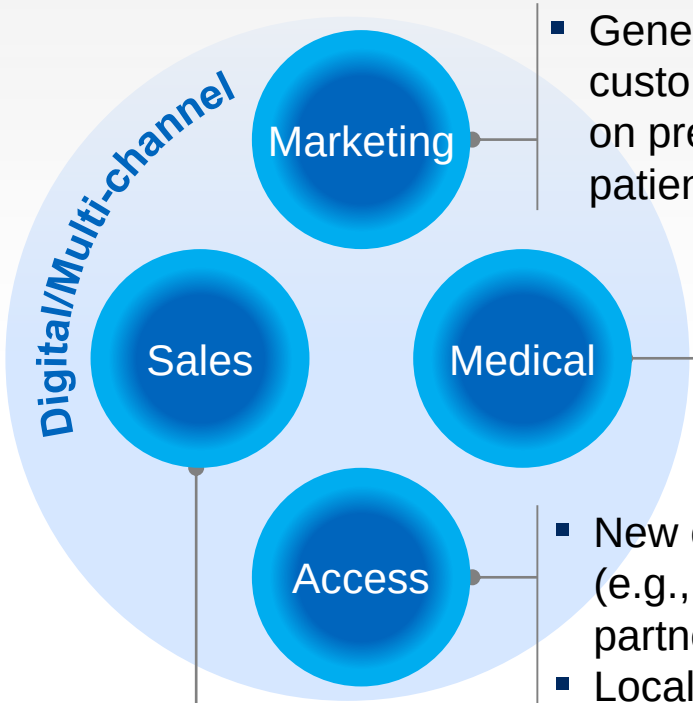
6 Evolve GTM model to deliver launch aspiration

Traditional GTM paradigm



- Dominant function acting often independently
- Low productivity creating drag on overall P&L with increasingly dispersed market potential

Future GTM paradigm



- Generating deeper customer insights on prescribers and patients
- RWE
- Larger MSLs team
- New capabilities (e.g., HTA, strategic partnership)
- Localized and Central capabilities

- Smaller team with more focused coverage
- Leverage of distributors/CSOs to expand footprint

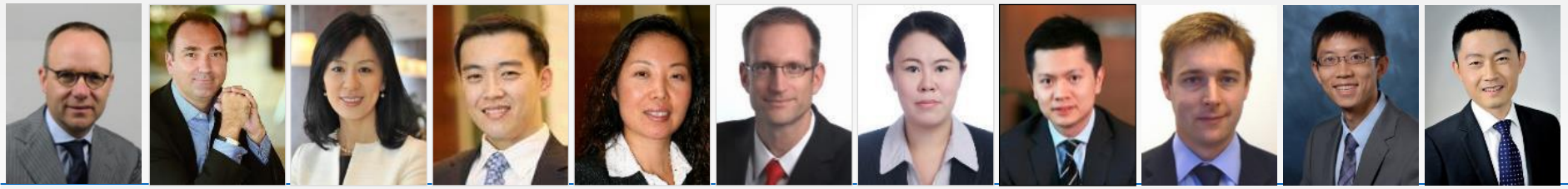
Closing thoughts

1. **We are on a narrow, but broadening bridge**
   Cause for optimism across the board, albeit with some acute challenges to address
2. **Innovation is coming at fast and furious pace**
   Local biotechs emergence, tsunami of NMEs, real opportunity to shape the dialogue with Chinese regulators
3. **We expect an acceleration of disruption trends impacting GTM models**
   Window for mature brands starting to close, rising expectations on profitability, new regulatory hurdles for traditional model
4. **Stakes are sky high for new launches –**
   Not everyone will succeed as launch muscles are atrophied and competition for access will be acute, from KOLs, to hospital listing, to public funding listing, to budget
5. **Partnership and collaboration increasingly valuable**
   MNCs and local, pharma and device, healthcare and beyond healthcare, China and international

For more on China healthcare …

www.mckinseychina.com

Our China healthcare leadership team (Partners and Associate Partners)



Industry insights

2017

2016

2015

2014

2013

Collaboration with CPA

Collaboration with CEIBS & Korn Ferry on Healthcare CEO Salons

CEIBS 中欧国际工商学院

KORN FERRY

2017 New product launch roundtable

2017 Biopharma roundtable

2017 PE roundtable