

Pharmaceuticals & Medical Products Practice

Managing China's growing oncology burden

Significant increases in incidence rates have made cancer a high priority in China. Progress has resulted from innovative treatments and greater access to care, yet much more needs to be done.

by Tina Hou, Franck Le Deu, Yi Shao, and Jody Tian



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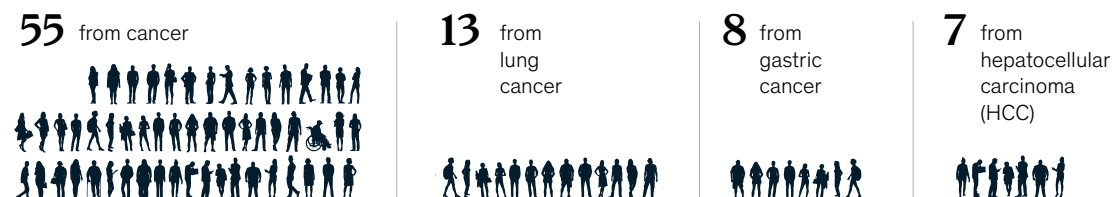
Cancer is among China's five high-priority disease areas,¹ with patients experiencing a significant health burden and unmet needs, as emphasized in the Chinese government's Healthy China Action Plan (2019–2030). Here, more than five people die from cancer every minute. Indeed, roughly 50 percent of the global gastric cancer, hepatocellular carcinoma, and esophageal cancer burden is diagnosed in patients from China.² The burden of disease is exacerbated by late diagnosis;

approximately 55 percent of patients in China are diagnosed with hepatocellular carcinoma in stages III and IV, compared with 15 percent and 5 percent in the United States and Japan, respectively.³ China also exhibits a unique epidemiological and patient profile. For example, 61 percent of patients with lung adenocarcinoma in China have a particular *EGFR* mutation that is seen in only 11 percent of such patients in the United States (Exhibit 1).⁴

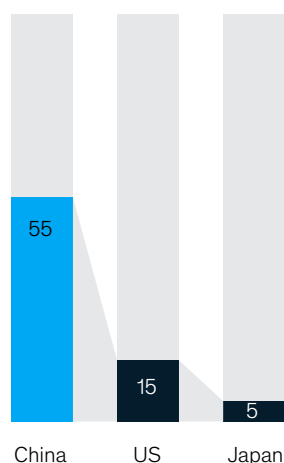
Exhibit 1

China has a huge oncology burden to manage.

Cancer mortality in China, deaths every 10 minutes



Late diagnosis, % diagnosed in stage III and IV of HCC



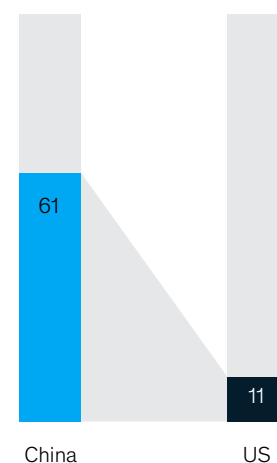
Share of global cancer,¹ %



Share of global population, %



Unique patient profile, % lung cancer patients with particular *EGFR*² subtype



¹China's share of global gastric cancer, HCC, and esophageal cancer incidence.

²Epidermal growth factor receptor.

Source: R. Wang et al., "Analysis of major known driver mutations and prognosis in resected adeno-squamous lung carcinomas" (2014); T.-Y. D. Cheng et al., "The international epidemiology of lung cancer: Latest trends, disparities, and tumor characteristics" (2016); J.-H. Zhong et al., "Tumor stage and primary treatment of hepatocellular carcinoma at a large tertiary hospital in China: A real-world study" (2017); Global Cancer Observatory, China Cancer Registry annual report; McKinsey analysis

¹ Together with cardiovascular and cerebrovascular diseases, chronic respiratory diseases, diabetes, infectious and endemic diseases.

² Global Cancer Observatory, China Cancer Registry annual report, gco.iarc.fr.

³ J.-H. Zhong et al., "Tumor stage and primary treatment of hepatocellular carcinoma at a large tertiary hospital in China: A real-world study," *Oncotarget*, Volume 8, Number 11, March 2017, pp. 18, 296–302; Kudo, Masatoshi et al., "Liver Cancer Working Group report," *Japanese Journal of Clinical Oncology*, Volume 40, Supplement 1, September 2010, pp. i19–i27; E. Fassio et al., "Etiology of hepatocellular carcinoma in Latin America: A prospective, multicenter, international study," *Annals of Hepatology*, Volume 9, Issue 1, January–March 2010, pp. 63–69.

⁴ Rui Wang et al. "Analysis of major known driver mutations and prognosis in resected adeno-squamous lung carcinomas," *Journal of Thoracic Oncology*, Volume 9, Number 6, June 2014, pp. 760–68; T.-Y. D. Cheng et al., "The international epidemiology of lung cancer: Latest trends, disparities, and tumor characteristics," *Journal of Thoracic Oncology*, Volume 11, Number 10, October 2016, pp. 1653–71.

Recent trends are now fueling China's progress in oncology innovation.

As incidence rates increase, fundamental care gaps exist. For example, while the number of oncologists per million people in China has increased from 14 in 2005 to 26 in 2018, there is a long way to go to achieve the benchmark in the United States: 60 oncologists per million people.⁵ Health outcomes in China show similar trends. For example, the five-year survival rate for lymphoma has improved from 44 percent in 2005 to 61 percent in 2015—still considerably behind the US rate of over 90 percent.

Nonetheless, we have witnessed encouraging progress in this disease space. Within R&D, the development of innovative treatments is improving patient outcomes. More equitable access to quality healthcare and medicines, seen through the improvement of China's oncology infrastructure and access environment, has had a similar effect.

The acceleration of innovation within oncology in China is critical to progress in managing China's oncology burden and ensuring that patients receive improved treatment options that are accessible and equitable, all within the context of transformational ecosystem-shaping initiatives grounded in the local environment. Recent trends are now fueling China's progress in oncology innovation, including a wave of new biotechs focused on oncology and improved quality in oncology research. To build a successful oncology business in China, we identified six key

success factors for biopharmaceutical and biotech companies to consider in planning their business strategy. We present these success factors after an overview of the key trends and the changing healthcare ecosystem in which the trends are occurring.

Oncology innovation in China

China's progress in meeting R&D goals for oncology is rapid, thanks to five trends: a wave of new biotech companies, a focused R&D portfolio, concentration on immuno-oncology, leadership in cell therapy, and a drive to improve the quality of research.

1. Many new biotechs have started up

The very significant China oncology burden, reform of the innovation ecosystem supported by the National Medical Products Administration (NMPA), and the opening of the capital market in Hong Kong to pre-revenue companies have combined to create a favorable environment for start-ups, resulting in a wave of new Chinese biotechs in recent years.

While they often get started by in-licensing programs developed in North America or Europe, those Chinese biotechs have the aspiration to innovate and are particularly active in the field of oncology. This is evidenced by IPO activity since late 2017: about two-thirds of all companies that have gone

⁵ Xiaowei Ma et al., *China Healthcare Statistics Yearbook*, Peking Union Medical College Press, 2019.

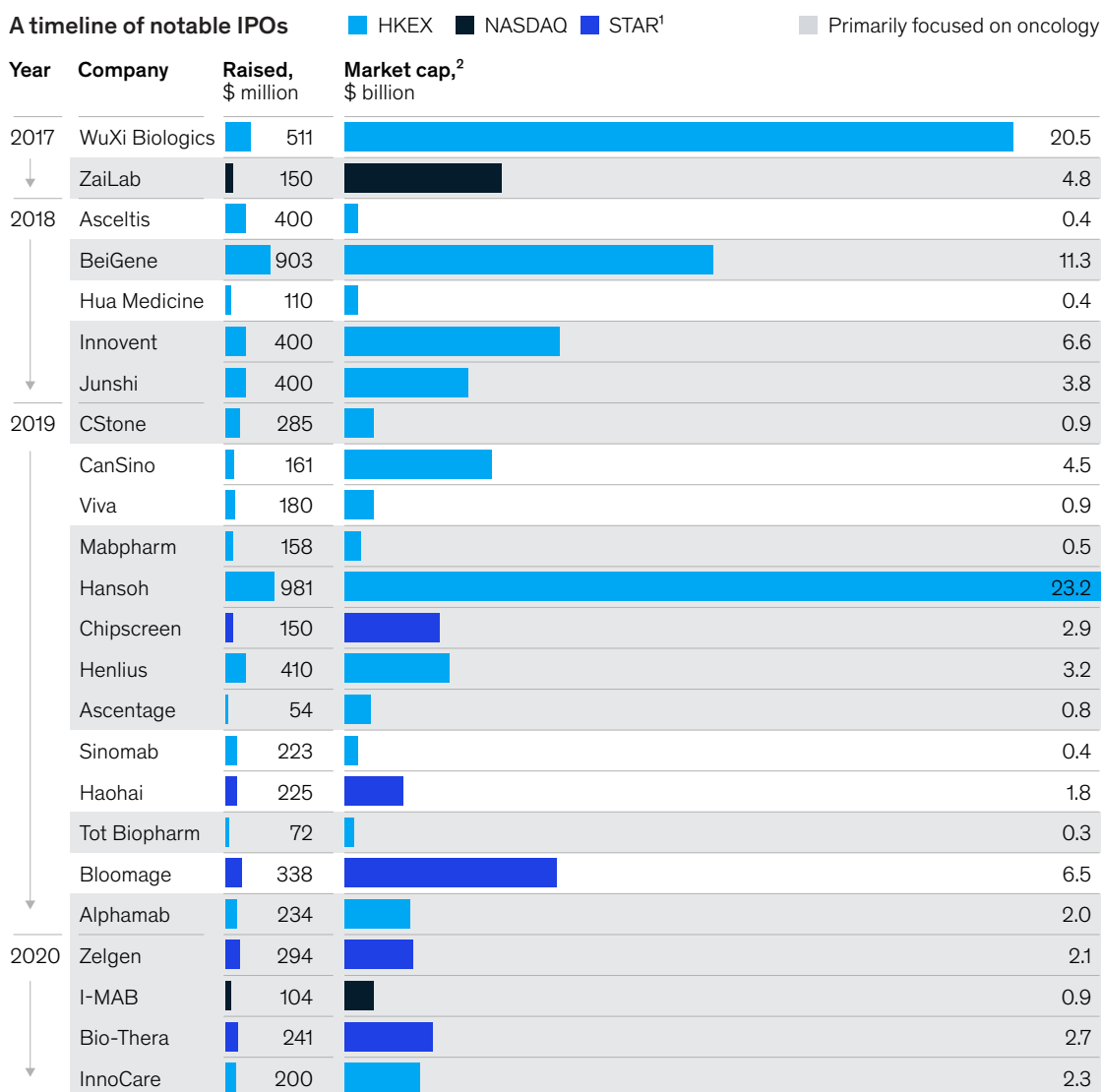
public are focused on oncology (Exhibit 2). They join a field already occupied by established biopharma multinationals, which are prioritizing China as a key market for R&D and commercial activities. Together, locally based and multinational companies (MNCs) are shaping a uniquely competitive and innovative oncology environment.

2. Portfolios are focused

In general, both multinational pharmaceutical companies and local players focus on tumor types with a high prevalence in China (Exhibit 3). Among a total of 393 assets under development by the biopharmaceutical industry in China, 60 percent focus on cancer types that represent the top five in terms of incidence rates: lung, colorectal, stomach, liver, and breast cancer.⁶

Exhibit 2

A significant number of China biotechs are oncology focused.



¹Shanghai Stock Exchange Science and Technology Innovation Board.

²Market cap calculated as of May 7, 2020. Using exchange rates USD 1 = RMB 7 and USD 1 = HKD 7.75.

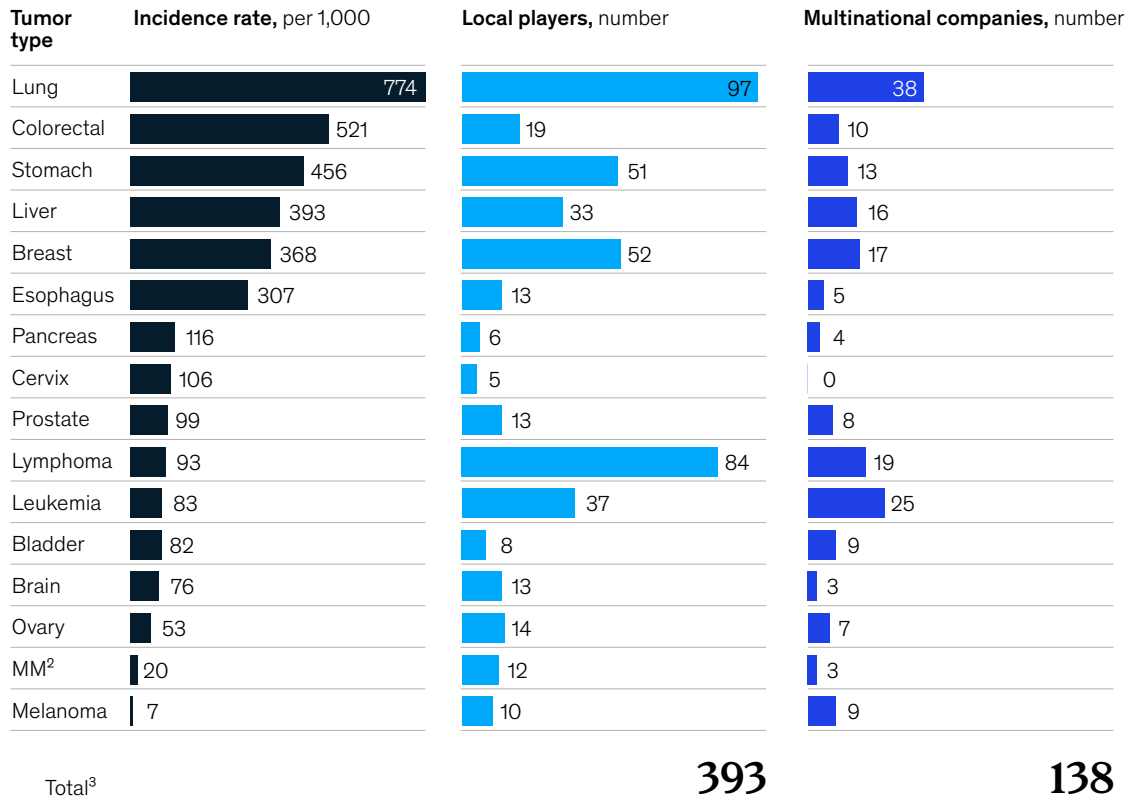
Source: Wind

⁶ As of May 15, 2020. Double-counting is possible, given that some cases could be in clinical trial for several indications.

Exhibit 3

Both multinational corporations and local players generally focus on tumor types with a high prevalence or proven record of treatment success.

Innovative tumor-treatment assets¹ under development by developer type



¹Numbers in the bar chart are indication specific, ie, assets with multiple indications counted under each indication.

²Multiple myeloma.

³Total numbers of assets are asset specific, ie, assets with multiple indications are counted as 1.

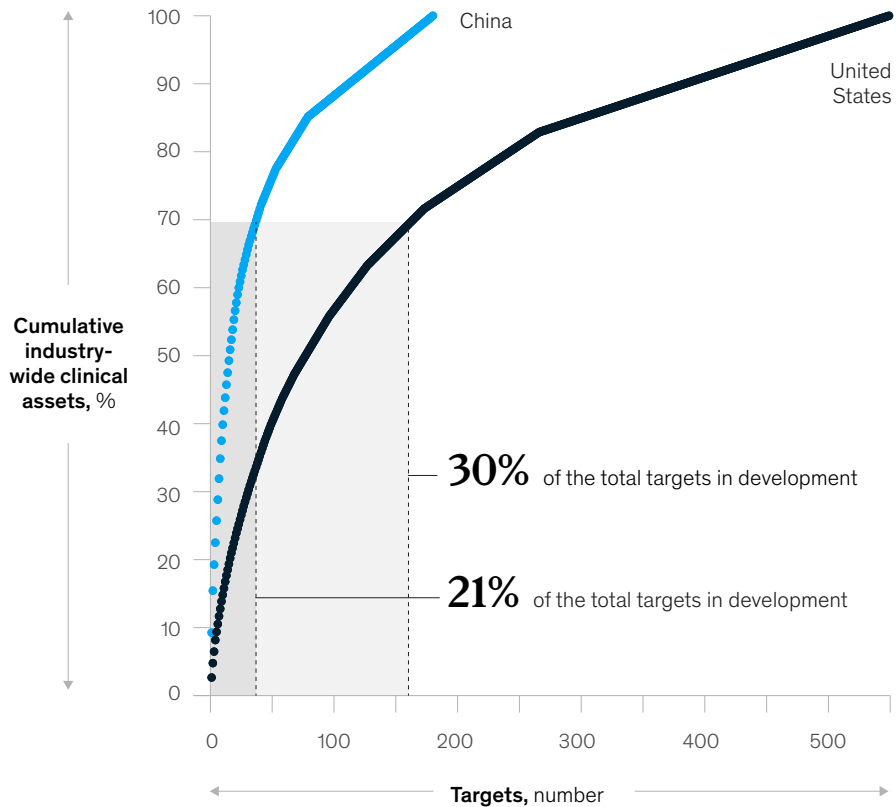
In addition, tumor types associated with a proven record of treatment success remain priorities for pharmaceutical companies. For example, 84 (21 percent) of assets under development by local biopharmaceutical companies and 19 (5 percent) of MNC assets under development are for lymphoma, which is the second most commonly targeted tumor type in China after lung cancer, despite ranking tenth in incidence rates.

China lags behind the United States in terms of the level of innovation as measured by the number of targets in the clinical stage of development. Clinical trials in the United States now cover 550 targets, compared with 160 in China. The market is also less crowded in the United States than in China. For example, while 70 percent of clinical assets focus on the top 30 percent of targets in the United States, 70 percent of clinical assets focus on the top 21 percent of targets in China (Exhibit 4).

Exhibit 4

China's clinical trials are more concentrated in top targets than US trials.

Clinical-trial targeting, clinical assets vs targets



Source: Pharmaproject; McKinsey China Cancer Center; McKinsey analysis

Considering the highly concentrated R&D space that focuses on specific cancer types and drug targets, speed to market and differentiation strategy are critical for MNCs and local companies to win in the competitive Chinese oncology market.

3. A growing share of trials apply immuno-oncology

The volume of immuno-oncology trials in China has increased rapidly in recent years. In 2015, only four immuno-oncology trials were initiated, representing 3 percent of the total number of new trials in China that year. The number of trials increased to more

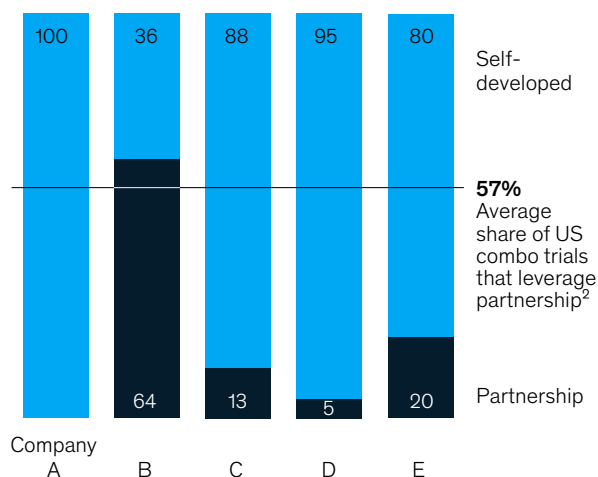
than 100 in 2018 and again in 2019, with the result that immuno-oncology accounted for one-quarter of the oncology trials initiated in China during those two years.

Local biotech companies are expanding their immuno-oncology portfolios through a combination of self-developed assets and partnerships. In the United States, 57 percent of the top five PD-(L)1 drug combination trials are under partnership (Exhibit 5). In contrast, in China, many local companies remain largely dependent on in-house assets; for example, one company has more than 40 immuno-oncology

Exhibit 5

Local biotechs are expanding their immuno-oncology combination portfolios through self-developed assets and partnerships.

China biotech PD-(L)1¹ combo trials by development types, %



Recent Chinese combo-trial announcements

PD-(L)1	+	PARP
CStone Pharmaceuticals		Impact Therapeutics
PD-(L)1	+	VEGFR
CStone Pharmaceuticals		Bayer
PD-(L)1	+	Dual VEGFR/FGFR
TopAlliance		Hutchison MediPharma
PD-(L)1	+	HDAC
Innovent		Chipscreen

¹PD-1 is cell death protein 1; PD-L1 is programmed death-ligand 1.

²For top 5 PD-(L)1 drugs in US.

Source: clinicaltrials.gov; company websites; McKinsey MIOSS

combination trials that are 100 percent self-developed, with no partners involved. Going forward, it will be critical for biopharmaceutical and biotech companies to explore external partnerships for immuno-oncology combinations beyond in-house assets, so they can accelerate development and broaden indication coverage.

4. China is a global leader in cell therapy

China has a high level of activity in cell-therapy clinical trials and is emerging as a global leader. Cell-therapy development in China is largely driven by academia and hospital-initiated projects: 89 percent of the 84 CAR-T trials⁷ initiated during the 12 months between May 2019 and April 2020 belong to this track (Exhibit 6). Like immuno-oncology, cell therapy will be a hypercompetitive

market. High-quality manufacturing capabilities and competitive pricing schemes will be important requirements for cell therapy to achieve commercial success in China.

5. Research quality is improving

The improved quality of oncology research in China is gaining recognition, although principal investigators (PIs) in China remain underrepresented globally. The number of oncology articles by Chinese PIs published in the top five journals has grown by 24 percent per year, from 20 articles in 2015 to 47 in 2019.⁸ The number of oral presentations by Chinese PIs at American Society of Clinical Oncology (ASCO) meetings also has increased, from only one in 2015 to six in 2019. However, Chinese PIs still account for only 2 percent of all speakers at ASCO meetings.⁹

⁷ Trials of chimeric antigen receptor T-cells.

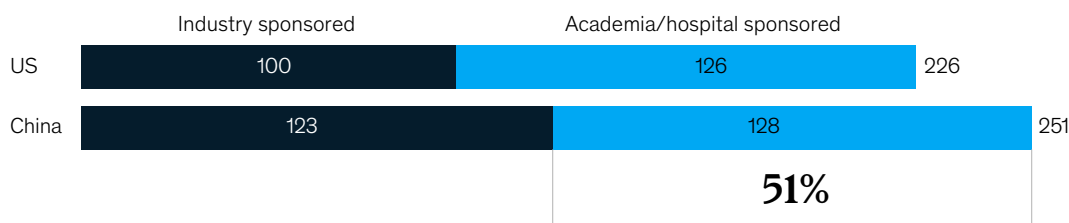
⁸ The journals are *Cell*, *Lancet*, *Nature*, *New England Journal of Medicine*, and *Science*.

⁹ ASCO; PubMed; Scimago Institutions Rankings.

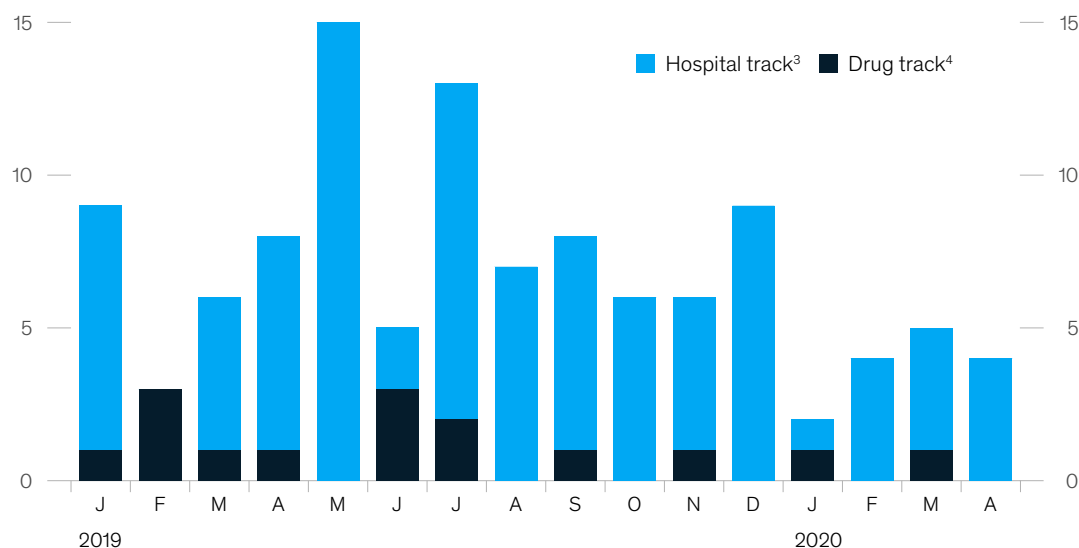
Exhibit 6

Academia/hospital-sponsored programs contribute half of CAR T-cell therapy trials in China, with only a small portion for drug registration.

CAR-T therapy¹ clinical trials by sponsorship, number of ongoing clinical trials



Initiation of new CAR-T clinical trials,² by month, number of ongoing clinical trials



¹Chimeric antigen receptor T. With oncology indication. As of May 15, 2020.

²Registered on clinicaltrials.gov.

³Hospital track: CAR-T considered a medical technology. Trials without investigational new drug (IND) application from common data element (CDE).

⁴Drug track: CAR-T considered a drug. Trials with IND approval from CDE.

Source: clinicaltrials.gov; company websites; McKinsey MIOSS

Biopharmaceutical and biotech companies should step up engagement with Chinese PIs and shape more opportunities for them to lead global programs and innovative studies.

Transformative shaping of ecosystems will improve oncology-patient access in China

Although patient access to quality care is improving, fundamental gaps remain. The three main hurdles

are late diagnosis, low biomarker testing rates, and varying treatment quality.

Most patients in China are still diagnosed at a late disease stage (stage III or IV) and have limited access to early screening. For example, the late-stage diagnosis rate in non-small-cell lung cancer is as high as 80 percent.¹⁰ Local governments and pharmaceutical companies are working on early-screening programs for some cancers. Colorectal-cancer screening programs in Shanghai

¹⁰ Shan Shan et al. "Clinical characteristics and survival of lung cancer patients associated with multiple primary malignancies," *PLoS One*, Volume 12, Number 9, September 2017.

Local governments and pharma companies are working on early-screening programs for some cancers.

have increased the early-stage diagnosis rate to 53 percent (out of the total diagnosed patients), a fourfold improvement over the previous years.

Cancer biomarkers have improved the success of oncology treatment, yet the adoption rate of cancer-biomarker testing varies across different hospital tiers in China. Experts tell us that in the top 500 hospitals, the testing rate for key biomarkers such as *EGFR* and *HER2* can reach 80 to 95 percent. However, due to high costs and constrained availability, the rate of next-generation sequencing testing is only 15 percent. Treatment capacities, capabilities, and standards also vary across different classes of hospitals, complicated by the surge in available therapy options.

Cancer-care ecosystems are evolving in order to support improved patient access

Multiple stakeholders, including pharmaceutical companies, hospitals, diagnostics and imaging companies, and direct-to-patient (DTP) pharmacies, have been building a cancer-care “Ecosystem 1.0” at scale. Centers of Excellence (CoE) are an example of output from this broad set of stakeholders. These centers aim to improve patient outcomes by providing patients with one-stop services, such as consultation, laboratory testing and imaging, pathology examination, and treatment.

Moving forward, a broader set of stakeholders—including artificial-intelligence (AI) and digital companies, real-world-evidence data integrators,

and private insurance companies—are joining forces to shape a more advanced “Ecosystem 2.0.”

At the center of this new Ecosystem 2.0 is the use of data and analytics. The use of AI in medical imaging, for example, is expected to assist clinical decision making in the diagnosis and risk stratification of different cancers, which can help improve the (early) diagnosis of disease, particularly in lower tier hospitals.¹¹ AI solutions related to lung nodules and melanoma diagnoses are likely to be the first or second wave of innovations that will receive a Class III medical-device certificate in China.

Policy tailwinds have pushed attention to real-world evidence in China. For example, in 2019, the indication of Avastin was expanded to non-small-cell lung cancer, based on real-world evidence generated in China. The Chinese government has been working on a regulatory framework to guide local development of real-world evidence, with the first indicative guideline published in January 2020. While challenges remain—including suboptimal data quality resulting from fragmented electronic-health-record systems and lack of a data standard—more use cases of real-world evidence along the pharmaceutical value chain are expected to emerge.

Also, private healthcare insurance companies are actively shaping the cancer-care ecosystem by providing affordable insurance products to the mass population. For example, WeSure offers an oncology insurance policy for six renminbi per month via the

¹¹ In China, hospitals are categorized into Class III, Class II, and Class I based on a set of defined metrics, with Class III being the largest and most advanced ones.

WeChat platform; it covers all in-market oncology drugs with a cap of three million renminbi for three years after first diagnosis. Commercial health insurance (CHI), despite being in its nascent stages, is expected to play an even bigger role in improving patients' access to oncology drugs.

With the scale-up of the cancer-care ecosystem, cancer patients are expected to enjoy improved convenience and access, as well as better treatment outcomes.

Building a successful oncology business in China

For biopharmaceutical and biotech companies that aim to build a successful oncology business in China, here are six key success factors:

1. **Build cutting-edge portfolios with differentiation.** Explore differentiation opportunities around patient subgroups, asset mechanism of action, and modality innovation to achieve superior clinical benefits. New waves of innovation beyond conventional small molecules and biologics are showing great potential in oncology—for example, multivalent antibodies, cell therapies including CAR-T, TCR-T, TiL,¹² and beyond, nucleotide-based therapy, and microorganism-based therapy (for example, oncolytic-virus). Critical actions include systematically assessing existing portfolios and identifying new opportunities for differentiation to avoid simply following market trends and the tactics and strategies of leading players. Assessment of these new technology platforms should take into consideration market attractiveness, scientific and technological maturity and innovativeness, and the company's internal capabilities and future aspirations.
2. **Find the right partners and maximize opportunity for combination therapies.** Leverage external partnerships for combinations beyond in-house assets to maximize the value

of the core assets at hand and optimize internal resource allocation. This is especially true for immuno-oncology assets. Beyond synergies at the asset level, an equally important concern is the strategic fit of the partner, including development and commercial capability and the alignment of cultural norms to ensure successful alliance management.

3. **Step up the game in local engagement with key opinion leaders (KOLs).** In this hypercompetitive environment, deeper engagement with Chinese PIs is increasingly important. Engagement approaches should be tailored to the needs of each KOL. Typical programs include a leading or co-leading role in global clinical trials, to enhance the KOL's global presence, and opportunities to work on even earlier stages of innovation via programs such as translational research like biomarker research.
4. **Execution, execution, and execution—make time to market the number-one priority.** Identify opportunities and pursue initiatives that can accelerate development timelines without compromising quality, through trial-design optimization and innovation, patient-recruitment acceleration, and trial-site capability planning. Though still at a nascent stage, innovative solutions to patient recruitment and trial design have emerged with the introduction of new technologies. For example, cancer-patient recruitment is the main challenge for many pharmaceutical companies, due to the lack of a well-established database in this increasingly competitive market. Leading local data integrators are improving the patient-recruitment process by leveraging their own databases and proprietary AI algorithms to identify the most appropriate patients for recruitment. Using real-world data to reduce recruitment cost while ensuring trial quality could be further explored in China.

¹² Chimeric antigen receptor (CAR) T-cells, T-cell receptor (TCR)-engineered T cells, tumor-infiltrating lymphocytes (TiL).

5. *Pursue all health access pathways to reach China's 1.4 billion people.* Beyond NRDL (the National Reimbursement Drug List), commercial health insurance (CHI) and Patient Assistant Program (PAP) should be explored for a more holistic access plan. No matter which access program is pursued, health economics will become more important. Pharmaceutical companies should also consider crafting an integrated evidence-generation plan and explore earlier engagement with PIs and data management companies.

6. *Stay at the forefront of the market, and lead in ecosystem building.* The oncology market in China is large but underdeveloped. Opportunities exist for pharmaceutical companies to deepen partnerships with a broader set of Ecosystem 2.0 stakeholders (for example, AI and digital companies and healthcare data integrators), shaping the oncology ecosystem and leading business-model innovation in China. Many pharmaceutical companies have started to work with local data companies on tasks from market-insight generation and patient recruitment to

prospective-study development. New frontiers and opportunities exist; pharmaceutical companies that are leaders in building long-term strategic partnerships with a broader set of stakeholders will be better able to serve the oncology needs of China and ensure long-term resilience and success.

The burden of cancer in China cannot be understated. As rates of incidence continue to grow, China will continue to face numerous challenges in access and treatment. Innovation is critical in managing this disease, and recent trends show promise in helping accelerate China's advances in R&D. China has also focused on its cancer-care ecosystem and infrastructure, and encouraging progress is being made in improving patient outcomes and more equitable access to quality healthcare and medicines. For companies building an oncology business in China, the market is still underdeveloped, and success may depend on the right partnerships, local engagement, and acceleration of time to market.

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