

# THE FACES OF INNOVATION

Meeting the Challenge of Cancer





### Ci Yunyou

58-year old with late stage liver cancer, but benefited from medicine innovation

"I hope that our medical industry will continue to develop and save more cancer patients like me."



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# Introduction

Cancer, refers to all malignant tumors, with biological characteristics such as abnormal cell differentiation and proliferation, loss of growth control, invasiveness and metastasis. It is one of the leading causes of death worldwide, led more than 22,000 deaths every day globally<sup>1</sup>. In China, about 10,000 patients are diagnosed with cancer every day, that is, about 7 patients with cancer are diagnosed every minute<sup>2</sup>.





combined

The occurrence of cancer is increasing because of the growth and aging of the population. Meanwhile, the established risk factors for cancer, such as smoking, overweight, pathogen infection, physical inactivity, and changing reproductive patterns associated with urbanization and economic development, are increasing continuously. But more than half of cancer cases worldwide are caused by preventable causes. It means that the risk of cancer can indeed be eliminated or reduced by changing the behavior habit.





Physical inactivity

Changing reproductive patterns

Overweight





# Economic and Epidemiology Burden of Cancer

#### **Enormous Global Burden**

The global economic toll of cancer is enormous<sup>3</sup>. The 13.3 million new cases of cancer diagnosed worldwide in 2010 are estimated to have cost \$290 billion, and the 21.5 million new cancer cases anticipated to occur in 2030 are projected to cost \$458 billion<sup>4</sup>. The number of diagnosed cases of cancer, number of cancer deaths and cancer mortality worldwide every year are on the rise. The number of cancer cases worldwide is expected to increase from 15.2 million in 2015 to 24 million in 2035<sup>3</sup>.



In 2012, it is estimated that 8.2 million<sup>5</sup> died of the disease. Without significant new advances in cancer prevention, detection, and treatment. This number is projected to rise to 14.6 million<sup>3</sup> in 2035. Based on a population study, among the young people aged from 20 to 39, the annual global incidence age-standardized rate (ASR) of cancer is 43.3/10, 0000 and the cancer-related death ASR is 15.9/10, 0000<sup>6</sup>.



Cancer is the second leading cause of death in the world. About 70% of cancer deaths occur in low-income and middle-income countries, and under this circumstance, mortality increase most rapidly, resulting in more challenges on fragile healthcare systems<sup>7</sup>. A liver cancer health-economics study involved 29 counties showed that mortality-to-incidence ratios (MIRs) are high in less developed countries compared with more developed countries (economically underdeveloped areas VS economically developed areas, 0.96 to 0.92). Favorable MIRs of countries are associated with high health expenditure and good WHO ranking<sup>8</sup>.

Looking at the overall cost of the disease, the International Agency for Research on Cancer (IARC)<sup>9</sup>, Data monitor Healthcare, World Cancer Report 2014 estimated that annual sales of cancer medicines by the top pharmaceutical companies in 2010 constituted 5% of the annual economic cost of cancer in 2010, for a total of USD 1.16 trillion. The most significant portion of costs is linked with hospitalization, premature death and poor rehabilitation and re–integration programs.

IMS Institute of Healthcare Informatics' s latest research showed that spending on cancer medicines only represented about 1% of the overall projected health care spending in U.S. 2015.



#### Challenges in China

Cancer incidence and mortality have been increasing in China and it became the major public health problem in the country. With an estimated 4.29 million new cancer cases diagnosed in 2015, China accounted for over one fifth of the world's cancer diagnoses. It estimated that 2.81 million people died from cancer in 2015<sup>10</sup>. Malignant tumor is one of the leading cause of death among residents in China, with 27% and 23% respectively in urban and rural areas<sup>11</sup>.

The incidence of cancer in China accounts for about 22% of that in the world, with a standardized incidence of 174.0/100,000 and a world average of 182.3/100,000. The incidence of cancer in China ranks the  $74^{th}$  in the world, while the cancer incident number is the largest all over the world<sup>1</sup>.

The cancer profile in China is markedly different from those of developed countries. According to GLOBOCAN 2012 figures<sup>12</sup>, prostate and breast cancer are the top male and female incidence ones in the developed countries while lung and breast cancer are the top ones in China<sup>13</sup>.

Due to the differences of genetic, socio-economic, lifestyle and medical conditions and many other factors, there is an obvious difference of cancer profile between China and the United States, and the incidence of male prostate cancer and female breast cancer in the United States is significantly higher than our country, while the incidence of upper gastrointestinal cancer, e.g., gastric cancer, liver cancer and esophageal cancer, is much higher than the United States. In terms of the overall trend, the cancer incidence of male in the United States decreases by 2% per year from 2004 to 2013 and that of female remains stable. As per the statistical results published last year in our country, the overall malignant tumor incidence of male was relatively stable from 2000 to 2011, while that of female showed an increasing trend, with an average annual increase of  $2.2\%^{5,10}$ .

#### **Top 5 New Cancer Cases**

#### **Developed Countries\***





\*\* Figure of 2015





2016 Total Health Expenditure

In recent years, China's total expenditure on health spending continues to increase, and the total expenditure on health in China was 700 billion U.S. dollars in 2016, accounting for 6.2% of GDP<sup>14</sup>, but still a big gap compared with developed countries such as the United States<sup>15</sup>.

Another research done in China showed, the Chinese urban patients spent over 10,000 USD on esophageal and colorectal cancers treatment which were the highest level of expenditure. Lung and stomach cancers treatment followed at 9900 USD while liver and breast cancers treatment cost were around 8500 USD<sup>16</sup>.

Lung cancer, leading cause of death, is the top cancer profile in China. It was estimated that there were 733.3 thousand new cases in China and the mortality cases were estimated at 610.2 thousand in 2015. According to a survey done in Beijing municipality recently, for those patients diagnosed in 2010, the 5-year survival rate was about 14.04%.

#### **Expenditure of Chinese Urban Patients (USD)**



Liver cancer, a typical cancer profile in China, has the second lowest 5-year survival rate cancer in Beijing municipality<sup>17</sup> in 2015 - 12.61%. The mortality rate of liver cancer got a significant decrease in 2006 which were contributed by the effective control of the infections.

# Value of Innovative Cancer Medicine

Rapid technological advances and an emerging understanding of the underlying drivers of disease are changing the face of cancer. We now know that cancer is not a singular condition but, rather, a collection of diseases, each with unique characteristics and features. Cancer is more than 200 diseases all of which have different causes and treatments<sup>18</sup>.

#### Cancer is more than



In recent years, researchers have made significant advances in gene mutations and associated factors that can drive the seemingly random formation and proliferation of tumor non-normal cells. At the same time, genetic markers may also identify patients at a greater risk of developing cancer. These learnings not only enable better screening and diagnoses but also drive the development of a new era of cancer treatments.

The latest facts and figures of 5-year survival rates in the United States<sup>5,19</sup> showed, since 1975, the chances that a cancer patient will live 5 years or more have increased by 41% across cancers. According to a research<sup>20</sup>, 83% of survival gains in cancer are attributable to new treatments-including medicines.

41% Increase of 5-year survival rate since 1975 83% Of survival gains in cancer are attributable to new treatments, including

medicines

China' s overall 5-year relative survival rate for all cancers combined was  $36.9\%^{10}$  in 2015 compared to  $70\%^{21}$  in the United States (2012) due to the lack of efficient treatment, difference of cancer profile etc. With this rate and 4 million new cancer cases annually in China, a 5-year (or more) delay for new oncology products translates to over 2 million patients who may not survive long enough to receive the appropriate treatment with innovative therapies which may have a life-saving or life extending impact.

#### 5–Year Survival Rates among the Most Common Cancers, 1975–2012



#### 5–Year Survival Rates in China, USA and UK





#### U.S. Deaths Rates from Cancer Decline over Time



According to the Cancer Statistics, 2018<sup>22</sup>, the mortality rate of cancer in United States continued to decline from 1995 to 2015, with an average annual decrease of 1.5% and overall decrease of 26%, saving 2.4 million patients.

#### Global Availability Oncology Medicines Launched 2010–2014



IMS recent report<sup>23</sup> showed that, China was one of the last three countries have few access to the new medication 2010–2014. Only 6 of 49 new medicines were approved to be on the market in China for patient access.

# **Advances of Cancer Medicine**

The complexity of cancer is reflected in the drug development process. Cancer medicines can take an average of 1.5 years longer<sup>24</sup> to develop than medicines for other diseases.



PhRMA recent report<sup>25</sup> showed, there are more than 800 cancer medicines in development while 73% of cancer medicines have the potential to be the "Personalized Medicines". Personalized medicine, sometimes referred to as precision or individualized medicine, is an emerging field of medicine that uses diagnostic tools to identify specific biological markers, often genetic, to help assess which medical treatments and procedures will be best for each patient.





WHO clinical trial database shows that till January 2018<sup>26</sup>, there are 33407 cancer clinical trials undertaking in China, which is more than UK. United States has 114038 cancer trials, which is more than 3 times than China's.

As the end of 2017, there are more than 450 oncology clinical trials for NMEs in China<sup>27</sup>, including nearly 60 immuno-oncology trials involved PD-1/L1 (Note: not an exhaustive list, not including non-registered trials and trials at pre-clinical stage). As of Oct 23, 2017, 121 CAR-T studies are ongoing in China<sup>28-29</sup>. Currently, there are 619 qualified clinical trial sites in China, and roughly 1/3 are qualified for oncology studies.

Cancer Trials 

In the past 10 years, the development of anti-

cancer medicine has been developing rapidly. However, the doubled number of medicines in development did not bring about the increase of medicines approved to be on the market. The proportion of medicines approved to those in development decreased from 10.1% in 2006 to 1.8% in 2015, that is, 10 years ago, 1 of 10 medicine could be approved to be on the market, but now only 1 of 55 may be approved on average<sup>30</sup>.

#### New approaches<sup>31</sup> that are adding to the cancer treatment toolbox include:

Ě	Angiogenesis Inhibitors	ø	Epigenetics	+	Immunotherapies
Tumors r spread. / which ne Angiog preventir vessels t spread o	need blood vessels to grow and Angiogenesis is the process by ew blood vessels are formed. enesis inhibitors work by ng the formation of new blood o stop or slow the growth or f tumors.	Researcher cancer can l in gene exp by genetic the DNA s chemical n (epigenetic these "epi associated v to be turned	s have discovered that be influenced by changes pression caused not only mutations (changes in equence) but also by modifications of DNA changes). By targeting genetic" marks, genes vith a cancer may be able "on" and "off".	The b provid Resea such specifi the im cance	body' s immune system may e a platform for fighting cancer. Irrchers are studying therapies, as cancer vaccines and non- c immunotherapies that enhance imune system to help it prevent r or attack cancer cells.

#### Advances in Cancer Immunotherapy

Currently, the development of immuno-oncology is remarkable, and today, there are some 248 immuno-oncology medicines in the clinical pipeline in the United States. Some examples of the most recognized classes of cancer immunotherapies include adoptive cell therapy, immune checkpoint modulators, oncolytic virus therapy and vaccines<sup>32</sup>.





# **Future and Actions**

Strategic leadership is needed to address several challenges and sustain current and new initiatives.

	Scientific	Data	Capacity	Economic	Regulatory	Cultural
Challenges	Challenges associated with unanswered questions that stem from the scientific complexity of the disease	The lack of population-based cancer registries in China	Limited number of specialized professionals, inadequate cancer treatment in rural area	Diverging perceptions on that actual treatment value	<ul> <li>Regulatory requirements for clinical trial designs not always adapted to new therapies</li> <li>Patient's access to the innovative medicines impacted by the current payment and procurement policies</li> </ul>	Culture differences influence cancer approach on: • Patient's role in the continuum of care • The prioritization of certain cancer • The importance given to prevention, screening and palliative care
Facts	Cancer is more than 2 0 0 Cisease all of which have different causes and treatments	Population Base 0.3 Billion • Covered • Un-covered	* WHO Figure in 2011	Total Cost for Cancer 2010- \$1.16 TRILLION 5% 55.3 BILLION SALES OF CANCER MEDICIN ES	49 41 43 41 6 Global USA China • Available • Not Available	Myths and perception of cancer which can present challenges to cancer control Death/Helplessness - "cancer is always fatal" Fear - "cancer is a punishment" Pain and suffering Loss of control and independence Isolation - Silence surrounding the disease, especially gynecological and breast cancers
Actions <sup>33</sup>	<ul> <li>Support research to define the value for patients of treatment</li> <li>Foster consortiums and others ways to work together in order to share scientific knowledge</li> </ul>	<ul> <li>Develop capacity in China to improve the quality and completeness of cancer registries</li> <li>Enhance the importance of robust database to monitor and evaluate the impact of specific interventions in targeted populations</li> </ul>	<ul> <li>Improve and Increase the professionals skill and number</li> <li>Enhance the healthcare in rural area</li> </ul>	Increase international collaboration among stakeholders to define value of novel interventions	<ul> <li>Develop more adapted pathways that can keep pace with advances in cancer innovation</li> <li>Optimize the payment and procurement system to support the access to innovative medicines</li> </ul>	<ul> <li>Increase the public knowledge of cancer prevention and treatment</li> <li>Development of more prevention programs and national action plans from the government</li> </ul>

#### Focus and trend of tumor prevention and control study

Complicated tumor pathogenesis and uncontrollable high risk factors result in the difficulty of tumor prevention in China.
 Generally, due to lack of effective screening technology and low levels of early diagnosis, it was late when the tumor is found. The difficulty of tumor treatment is caused by the poor treatment effect, high recurrence and metastasis rate, large side effect and poor precision. Few tumor treatment guidelines developed by China, varying levels of diagnosis and treatment in primary hospitals and low homogenization of diagnosis and treatment. All the mentioned are difficulties in cancer prevention and control study in China.
 The breakthrough points of tumor prevention and control in our country include reducing incidence, increasing rate of early diagnosis and survival and improving homogenization.

◇ Our country has issued related policies and fiscal measures to support cancer prevention and control. Relevant national projects in the "13th Five–Year Plan" are in process. Malignant tumor big data network construction has achieved initial success<sup>34</sup>.



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"When your family is healthy, you have many problems; when someone in your family is sick, you have only one problem. That' s especially true for any family that has faced a cancer diagnosis."

-----Roy Blunt (U.S. Senator, 2016 Cancer Development Report)

# About RDPAC

Under the China Association of Enterprises with Foreign Investment (CAEFI), the R&D-based Pharmaceutical Association Committee (RDPAC) is a non-profit organization made up of 40 member companies with pharmaceutical R&D capability.

Till now, the member companies have 49 plants and 31 R&D centers. They invest over RMB 8 billion per year in R&D in China.

The Chinese government, local companies and RDPAC members share a similar vision to see China become a leading global innovation partner. RDPAC welcomes the opportunity to continue to partner with the government to reach our joint aspiration for the benefit of Chinese patients.



中国外商投资企业协会药品研制和开发行业委员会 China Association of Enterprises with Foreign Investment R&D-based Pharmaceutical Association Committee



# **Our Vision**

#### HEALTHIER CHINA THROUGH INNOVATION

To be a valued partner in delivering the "Healthy China 2030" goal to improve the health and quality of life of people in China:

- Provide our high-quality/ innovative healthcare products and services in a socially responsible and commercially viable manner;
- Commit to securing patients timely access to innovative & high quality drugs;
- Achieve the highest standard of integrity for ethical research and business practice;
- · Contribute to the growth of the biopharmaceutical sector in China;
- Support the development of a sustainable healthcare system in China.



中国外商投资企业协会药品研制和开发行业委员会

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# **RDPAC Member List**

(Updated: January 2018)

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