Building an Innovation Ecosystem for a Healthier and More Secure Future

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Fighting COVID-19: Where We Are Today

Since the start of the pandemic, the biopharmaceutical industry has made tremendous progress toward developing safe and effective vaccines and therapeutics to help fight COVID-19

- **2,131** Global Active Clinical Trials for Vaccines and Therapeutics
- **606** Unique Therapies in Clinical Trials
- **140** Unique Vaccines in Clinical Trials
- **335** Vaccine Manufacturing and Production Deals Around the Globe
- **116** Treatment Manufacturing and Production Deals Around the Globe
- **9.6 Billion** Vaccines Administered Globally
- **Nearly 5 Billion** People with at Least 1 Dose

(As of 14 January 2022)
(As of December 2021)
(As of 12 January 2022)
An Innovation Ecosystem Enabled Scientific Advances in the Fight Against COVID-19

<table>
<thead>
<tr>
<th>Vaccines</th>
<th>Therapeutics</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMIRNATY®</td>
<td>VEKLURY®</td>
</tr>
<tr>
<td>VAXZEVRIA®</td>
<td>RONAPREVE™</td>
</tr>
<tr>
<td>Janssen COVID-19 Vaccine</td>
<td>OLMUANT®</td>
</tr>
<tr>
<td>SPIKEVAX™</td>
<td>Bamlanivimab and Etesevimab</td>
</tr>
<tr>
<td>BBIBP-CORV</td>
<td>XEVUDY®</td>
</tr>
<tr>
<td>CORONAVAC™</td>
<td>ACTEMRA®</td>
</tr>
<tr>
<td>COVAXIN®</td>
<td>LAGEVRI®</td>
</tr>
<tr>
<td>NUVAXOVID™</td>
<td>REGKIRONA™</td>
</tr>
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<td></td>
<td>PAXLOVID™</td>
</tr>
</tbody>
</table>

Source: PhRMA analysis of World Health Organization, U.S. Food and Drug Administration, European Medicines Agency and Japan Pharmaceuticals and Medical Devices Agency data, January 2022.
Rapid Advancement of COVID-19 Treatments
Baricitinib: A third therapeutic drug for COVID-19

- To date, **747,000 people** have been treated with baricitinib for COVID-19 worldwide including approximately **20,000 patients in Japan**

- **Approved in Japan** in April 2021
  - **Baricitinib**, a Janus-associated kinase (JAK) inhibitor is indicated for pneumonia caused by COVID-19 (Limited to patients who require supplemental oxygen)

February 2020
Artificial intelligence identified **baricitinib** as a potential treatment

May 2020
NIH-NIAID: Investigator-initiated clinical trial started; Japan NCGM joined

November 2020
U.S. FDA issued Emergency Use Authorization

December 2020
Application for approval of additional indication in Japan

April 2021
First regulatory approval for COVID-19, conditioned on PMS to track patient safety

Note: NIH = National Institutes of Health; NIAID = National Institute of Allergy and Infectious Diseases; NCGM = National Center for Global Health and Medicine; FDA = Food and Drug Administration; PMS = Post-Marketing Surveillance
The Economic Impact of the Biopharmaceutical Industry

Driving Economic Impact, Sustaining Productive Workforces and Addressing the Challenges of a Super-Aging Society

140,000+
Direct Biopharmaceutical Sector Jobs in Japan

$1.7 Trillion
Global R&D Investment in the Last Decade (¥14 Trillion in Japan)

8,000+
Medicines in Development Worldwide

Hundreds of thousands+
Indirect Jobs

$1.2 Trillion
Global R&D Investment Estimated in the Next 5 Years

74%
Are Potential First-In-Class Treatments
Tackling Unmet Medical Need

Progress in Dementia and Alzheimer’s Disease

• The number of patients is expected to double every 20 years, reaching 139 million by 2050.
• The costs associated with caring for patients with dementia and Alzheimer’s disease makes this a top public health priority.

• Industry has been investing in research and development in dementia and Alzheimer’s disease for more than 30 years.
• Many therapies were not successful, but our understanding of the disease and the science supporting it continues to advance.
• Today there are nearly 100 molecules in late-stage development.
• This progress would not be possible without the world’s leading economies investing in health and rewarding innovation.

Estimated growth in number of people with dementia, 2019-2050

- 2019: 55m
- 2030: 78m
- 2050: 139m

Total estimated annual worldwide cost of dementia is $1.3 trillion and is forecast to be $2.8 trillion by 2030

- USD 1.3 trillion in 2019
- USD 2.8 trillion in 2030

Japan Needs to Enhance its Biopharmaceutical Innovation Ecosystem

Unmet Medical Needs

Drug Discovery System

Research & Development

Regulatory Review & Approval

Delivering New Medicines

Reinvestment

Industry-academia collaboration in Japan and other countries

Simultaneous global drug development under harmonized regulations

Appropriate reward for medicines allows reinvestment

Health improvement and economic growth

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Simultaneous global drug development under harmonized regulations
Recent Policy Changes Have Negatively Impacted Biopharmaceutical Industry R&D Investment in Japan

Japan implements pro-innovation policies
- Japan: 22% GROWTH
- Global: 16% GROWTH

Japan implements anti-innovation policies
- Japan: 9% DECLINE
- Global: 33% DECLINE

Biopharmaceutical Clinical Trial Activity Has Slowed in Japan While Growing in the United States and China

Number of Medicines in Development Across All Clinical Trial Phases in Japan, China and the United States

<table>
<thead>
<tr>
<th>Country</th>
<th>2009</th>
<th>2016</th>
<th>2020</th>
<th>CAGR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>659</td>
<td>1,127</td>
<td>1,319</td>
<td>8%</td>
</tr>
<tr>
<td>China</td>
<td>109</td>
<td>881</td>
<td>3,003</td>
<td>35%</td>
</tr>
<tr>
<td>United States</td>
<td>6,999</td>
<td>9,649</td>
<td>13,422</td>
<td>5%</td>
</tr>
</tbody>
</table>

Source: Health Advances analysis of Pharmaprojects data, February 2021.
China Recently Surpassed Japan in Developing the Next Generation of New Medicines

Country Share of Early-Stage Pipeline Based on Company Headquarter Location, 2005-2020

Note: Due to co-development by companies headquartered in different countries, the sum of percentages within a given year can exceed 100 percent.
A Return of the Drug Lag?

The Speed With Which Global New Medicines Are Launched in Japan Has Steadily Declined Following Harmful Policy Changes

Percentage of Prior Five Years of Global New Medicines Available in Japan vs. the United States from 2016 to 2020

Source: PhRMA analysis of IQVIA Analytics Link, U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japan Pharmaceuticals and Medical Devices Agency (PMDA) data, June 2021.
Note: New active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2011 and December 31, 2020.
### Now Is the Time for Japanese Policymakers To Return To Prioritizing Innovation

**Our requests to help ensure that Japan remains at the forefront of global biopharmaceutical innovation**

- Ensure a transparent and predictable drug pricing system that rewards innovation
- Improve expedited regulatory review systems and adopt new accelerated regulatory pathways
- Incorporate digital technology and real-world data to enhance the speed, predictability and safety of drug development
- Foster public-private collaboration through increased opportunities for dialogue on shared goals
An Innovation Ecosystem Should Serve as the Foundation for a Sustainable & Resilient Health Care System

Innovation
Continuous innovation in health technologies and delivery systems enabled by evidence generation

Sustainable Health Care System
Goal: Best patient outcomes in most efficient manner

Budget Optimization
Flexible, evidence-based management of health care budget

Data and Digitalization
Effective data collection and use for decision-making

Best Care for Patients
Optimal patient and provider experience and access leading to best possible care

The Biopharmaceutical Industry Is Ready To Do Our Part

Coming Together To Tackle Common Goals

- Supporting a thriving biopharmaceutical innovation ecosystem
- Ensuring the sustainability and resiliency of the health care system
- Enhancing pandemic preparedness
- Promoting early access to needed medicines for Japanese patients