Regional Workshop on IP management around WIPO Re: Search and WIPO GREEN

Practices of IP applied to economic and social development: Experience from Japan Industry

March 3, 2016, Manila

Takeda Pharmaceutical Company Limited
Head of Operations (IP), Intellectual Property
Seiji Mori
Menu

1. Introduction of Takeda
2. Pharma Industry and Patent
   - Unmet Medical Needs
   - High Risk and Huge R&D cost on Drug Discovery
   - Unique Nature of Pharma Patent

3. Japan's capability to generate New Drug Generation
4. Patent Drives Innovation
   - Secure Investment to Develop New Drug
   - Facilitate Flow of New Technology
   - Takeda's case

5. New Paradigm in Drug Generation
   - Unmet Medical Needs
   - Open Innovation in Japan for Drug Discovery
   - Open Innovation to Improve Global Health
     - Background
     - GHIT
     - WIPO Re:Search
1. Introduction of Takeda

For more than 230 years, Takeda has developed its business with integrity while undergoing a process of continuous transformation.

History of Innovation

1781
Foundation
Takeda began operations in 1781 when Chisaburo Takeda started a business selling traditional Japanese and Chinese medicines in Osaka. Following Japan's Meiji Restoration in the late 1860s, Takeda was one of the first companies in Japan to begin importing western medicines.

1895
Pharmaceutical Manufacturing Business Launched
In 1895, the Company established its own factory in Osaka, thereby achieving its transformation into a pharmaceutical manufacturer.

1914
Research Activities Begin with Establishment of the Takeda Research Division
A researcher performing an experiment in the laboratory (1939)

1950
First multikentan in Japan
Panvitan Launched

1954
Vitamin B6 derivative
Almamin Launched

1962
Entered Overseas Markets
Takeda greatly expanded its overseas activities by entering Asia, Europe, and the U.S.

1989
For Prostate Cancer, Breast Cancer, and Endometrial Leuprolide Acetate Launched (U.S. and Europe)

1991
For Peptic Ulcer
Lansoprazole Launched (Europe)

1997
For Hypertension
Canvansar CA001 Launched (Europe)

1999
For Type 2 Diabetes
Pioglitazone Hydrochloride Launched (U.S. and Japan)

2005
For Insomnia
Ramelteon Launched (U.S.)

2008
Millennium Pharmaceuticals, Inc. Integrated

2009
For Acid Reflux Disease
DEXILANT Launched (U.S.)

2011
For Hypertension
EDARI Launched (U.S.)

2012
Vaccine Business Division Established
Takeda strengthened its global vaccine operations.

2013
For Hyperlipidemia
LOTTRIGA Launched (Japan)

Imvira, Inc. Integrated
Takeda obtained promising vaccine candidates against dengue and hand, foot and mouth disease.

For Type 2 Diabetes
NESINA, KAZANO and OSENI Launched (U.S.)

Multislab Industria e Comércio de Produtos Farmaceuticos Ltda. Integrated
Through this integration, Takeda has increased its presence in the Brazilian market.

Ligasys Pharmaceuticals, Inc. Integrated
Takeda gained first-in-class non-virus vaccine candidate and virus like particle platform.

Envoy Therapeutics, Inc. Integrated
Takeda gained innovative Research Platforms in ERT technology and added novel CNS programs.
Business Overview

- Sales (2014): ¥1,777.8 bn
- R&D (2014): ¥382.1 bn (21.5% of Sales)
- Presence in over 70 countries
- Employee: 31,328 (as of 2015 March)
2. Pharma Industry and Patent

■ Unmet Medical Needs

Strive to develop and provide new therapies to Patients

Unmet medical needs

Source: questionnaire survey by mail
Survey period: October 15 to December 22, 1999
Target: medical doctors (128 respondents)

Source: The Japan Health Sciences Foundation: “Report on Key Domestic Technologies 2000 – Outlook of medical needs in 2010 –”
# Takeda Key Products and Pipeline (as of Aug, 2015)

**Recently Launched and Filed**

<table>
<thead>
<tr>
<th><strong>Gastroenterology</strong></th>
<th><strong>Key Late-stage Pipeline</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>ENTYVIO® Ulcerative Colitis and Crohn’s Disease</td>
<td>TAK-114 Ulcerative Colitis</td>
</tr>
<tr>
<td>TAKECAB® Acid-related Diseases</td>
<td></td>
</tr>
</tbody>
</table>

**Oncology**

<table>
<thead>
<tr>
<th>ADCETRIS® Hodgkin Lymphoma</th>
<th>Ixazomib Multiple Myeloma</th>
<th>TAK-264/MLN0264 Gastric and Pancreatic Cancer</th>
<th>TAK-228/MLN0128 Breast Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TAK-385 Prostate Cancer</td>
<td>Alisertib Lung Cancer</td>
</tr>
</tbody>
</table>

**Central Nervous System**

| BRINTELLIX® Major Depressive Disorder | Glatiramer (COPAXONE®) Multiple Sclerosis | AD-4833 TOMM40 Alzheimer’s Disease | Rasagiline (AZILECT®) Parkinson’s Disease |

**Cardiovascular & Metabolic**

<table>
<thead>
<tr>
<th>NESINA® Type 2 Diabetes</th>
<th>CONTRAVE® Obesity</th>
<th>TAK-272 Diabetic Nephropathy</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>AZILVA® Hypertension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ZAFATEK® Type 2 Diabetes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Vaccines**

| TAK-850 Influenza | TAK-003 Dengue | TAK-214 Norovirus |

**Other therapeutic areas**

| Namilumab Psoriasis and Rheumatoid Arthritis | | |

---

August 2015
High Risk and Huge R&D cost on Drug Discovery

9 to 17 years

2–3 years  3–5 years  3–7 years  1–2 years

Number of compounds 652,336  203  75  26  21

Cumulative success rate 1:3,213  1:8,698  1:25,090  1:31,064

- Extremely low success rate
- R & D costs: several 10 billions~ over100 billions yen (JPMA)
  1,300 millions $ (PhRMA)

2005 to 2009 Survey by JPMA
Lowering of PTS for Drug Development

2005-2009 : 1/31,064
2004-2008 : 1/25,482
2003-2007 : 1/21,677
1999-2003 : 1/12,324
1989-1993 : 1/ 3,700
Unique nature of pharma patent

Patent for Automobiles, IT

- Hundreds, thousands patents for one product
- Value of individual patent is not so high
- Unlikely that a third party patent constitutes an absolute bar for product development and launch
- International Standardization

Patent for Pharma Products

- One basic patent for one product
- Value of individual patent is high
- Not rare to give up product development due to a third party patent
- International Standardization
### 3. Japan's Capability to Generate New Drug

<table>
<thead>
<tr>
<th>Rank</th>
<th>Medicine Name</th>
<th>Company</th>
<th>Year</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>16th</td>
<td>Crestor</td>
<td>Shionogi</td>
<td>1960s;</td>
<td>2 products</td>
</tr>
<tr>
<td>17th</td>
<td>Actos</td>
<td>Takeda, Type II diabetes</td>
<td>1970s;</td>
<td>4 products</td>
</tr>
<tr>
<td>21st</td>
<td>Blopress</td>
<td>Takeda, hypotensive agent</td>
<td>1980s;</td>
<td>18 products</td>
</tr>
<tr>
<td>26th</td>
<td>Aricept</td>
<td>Eisai, anti-Alzheimer agent</td>
<td>1990s;</td>
<td>14 products</td>
</tr>
<tr>
<td>30th</td>
<td>Abilify</td>
<td>Otsuka, antipsychotic agent</td>
<td>1980s;</td>
<td>18 products</td>
</tr>
<tr>
<td>31st</td>
<td>Takepron</td>
<td>Takeda, antiulcer agent</td>
<td>1990s;</td>
<td>14 products</td>
</tr>
<tr>
<td>35th</td>
<td>Cravit</td>
<td>Daiichi-Sankyo, antibiotic agent</td>
<td>1980s;</td>
<td>18 products</td>
</tr>
<tr>
<td>39th</td>
<td>Pariet</td>
<td>Eisai, antiulcer agent</td>
<td>1990s;</td>
<td>14 products</td>
</tr>
<tr>
<td>41st</td>
<td>Harnal</td>
<td>Astellas, prostatic hypertrophy</td>
<td>1990s;</td>
<td>14 products</td>
</tr>
<tr>
<td>49th</td>
<td>Olmetec</td>
<td>Daiichi-Sankyo, hypotensive agent</td>
<td>1990s;</td>
<td>14 products</td>
</tr>
</tbody>
</table>

Source: Uto Brain
Japan is rated as the third capable country to generate new drugs in the world.

- USA: 44
- Switzerland: 16
- Japan: 13
- UK: 9
- France: 5
- Denmark: 5
- Germany: 4
- Others: 3

4. Patent Drives Innovation

- Secure investment to develop new drug

Sales Revenue (B) - R&D Investment (A) ⇒ Investment for new drug

- R&D Period: 10~20 years
- Exclusive period: 10~15 years
- Patent expiration
- Patent Term Extension

- Investment for new drug
- Generic Drug
Patent facilitates flow of new technology

☆ Innovation by Disclosure of Technology

Perception

Publication

Advanced R & D

Patent

A

Patent

B

Techs./Know-How

Collaboration

Advanced R & D

License

Techs./Know-How

☆ Innovation by Technology Transfers
1. Leuprolelin Product Case

2. Lansoprazole Product Case

3. Collaboration Research Cases
## Overview of Leuprolelin Product Case

<table>
<thead>
<tr>
<th>Item</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Name</td>
<td>Leuprolelin Acetate</td>
</tr>
<tr>
<td>Indication</td>
<td>Prostate Cancer</td>
</tr>
<tr>
<td><strong>Product Options</strong></td>
<td><strong>Daily injection</strong>&lt;br&gt;1-month Depot(Administration: daily to 1 month)&lt;br&gt;1-month Depot(improved)(Elimination of BSE risk)&lt;br&gt;3-month Depot(Administration: 1 month to 3 months)&lt;br&gt;6-month Depot(Administration: 3 months to 6 months)&lt;br&gt;6-month Depot(improved)(Decrease of administration volume by higher drug content)</td>
</tr>
<tr>
<td>Sales Country</td>
<td>70-80 countries including Asian countries such as Philippines, Malaysia, Singapore, Indonesia, Taiwan, Thai, China, Korea, etc.</td>
</tr>
<tr>
<td>Characteristic</td>
<td>1M, 3M, 6M Depot is sustained-release microsphere production consisting of Leuprolelin Acetate and Biodegradable Polymer such as PLGA, PLA. Those Depots can suppress the initial excess release and achieve a stable release speed over a long period of time.</td>
</tr>
</tbody>
</table>
Characteristic of Leuprolrelin Products

The products need to be injected.

All Leuprolrelin substance patent expired before 1996.

Japanese Patent 01761586

1-month Depot
(improved)

1-month Depot

6-month Depot
(improved)

6-month Depot

3-month Depot

Daily injection


Japanese Patent 02653255
Philippines Patent 28683

Japanese Patent 4819172
Philippines Patent 1-2003-501343

The products need to be injected.
Contributions to Health Care Professionals using Leuprolelin

DPS (dual-chamber prefilled syringe) was applied for workload reduction of health care professionals.

DPS (all-in-one)

1st
Vial & Ampule

2nd
Japanese Patent
02911086
Philippines Patent
1-1993-47573-A

3rd
DPS with safe device (needle stick protection)
PCT application filed in 2015

Simple, convenient, efficient and safe!!!

Complex procedures and some potential risk

User Friendliness

Time
## Overview of Lansoprazole Product Case

<table>
<thead>
<tr>
<th>Item</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Name</strong></td>
<td>Lansoprazole</td>
</tr>
<tr>
<td><strong>Indication</strong></td>
<td>Stomach and intestinal ulcers Erosive esophagitis (damage to the esophagus from stomach acid) Other conditions involving excessive stomach acid such as Zollinger-Ellison syndrome</td>
</tr>
<tr>
<td><strong>Sales Country</strong></td>
<td>about 890 countries including Asian countries such as Philippines, Malaysia, Singapore, Taiwan, Thailand, China, Korea, etc.</td>
</tr>
<tr>
<td><strong>Characteristic</strong></td>
<td>Stabilized gastro-resistant capsules can protect against degradation in the stomach, improve bioavailability and acquire better absorption properties. OD tablets can improve adherence.</td>
</tr>
</tbody>
</table>
Lansoprazole capsules and granules

15mg (#3)  30mg (#1)

Cross-Section

Sugar Crystal
Nonpareil
Active Compound Layer
Lansoprazole Stabilizer
Enteric Coating Layer

downsized 30mg capsules

Easy for patients to take because of adherence improvement!

Japanese Patent 04331930
Philippines Patent 1-2004-500385
Lansoprazole oral disintegrating (OD) tablets and microgranules

Enteric-coated microgranules comprised of seven layers

Comparison of granules of between capsules and OD tablets

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Capsules</th>
<th>OD tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>particle</td>
<td>granules</td>
<td>microgranules</td>
</tr>
<tr>
<td>particle size</td>
<td>ca. 1,000μm</td>
<td>ca. 300μm</td>
</tr>
<tr>
<td>number of particles</td>
<td>ca. 200</td>
<td>ca. 10,000</td>
</tr>
<tr>
<td>(30mg products)</td>
<td>![granules image]</td>
<td>![microgranules image]</td>
</tr>
</tbody>
</table>

Japanese Patent 03746167
Philippines Patent 1-1999-01163

Easy for patients to take without water because of adherence improvement!
The following technologies produced with the third party are being used for Leuprolelin Product.

<table>
<thead>
<tr>
<th>Formulation Technology</th>
<th>Collaboration Research Partner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradable polymers</td>
<td>Japanese Company A</td>
</tr>
<tr>
<td>Dual chamber pre-filled syringe</td>
<td>Japanese Company B</td>
</tr>
</tbody>
</table>
5. New Paradigm in Drug Development

Unmet Medical Needs

Strive to develop and provide new therapies to Patients

Source: questionnaire survey by mail
Survey period: October 15 to December 22, 1999
Target: medical doctors (128 respondents)

Source: The Japan Health Sciences Foundation: “Report on Key Domestic Technologies 2000 – Outlook of medical needs in 2010 –”
Authentic Drug Discovery Model
Many areas are connected by advanced networks.
New drug seeds from academia or bio-venture (1998–2007)

<table>
<thead>
<tr>
<th>Country</th>
<th>Large Pharmaceutical Company</th>
<th>University-discovered, transferred to pharmaceutical company</th>
<th>Biotechnology company; or university-discovered, transferred to biotechnology company in the same region</th>
<th>University-discovered, transferred to biotechnology company in a different region</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>117.6</td>
<td>61.4</td>
<td>3.3</td>
<td>7.7</td>
</tr>
<tr>
<td>Japan</td>
<td>45.3</td>
<td>23.0</td>
<td>2.0</td>
<td>2.3</td>
</tr>
<tr>
<td>UK</td>
<td>18.8</td>
<td>22.8</td>
<td>1.9</td>
<td>0.5</td>
</tr>
<tr>
<td>Germany</td>
<td>18.0</td>
<td>21.4</td>
<td>1.4</td>
<td>2.4</td>
</tr>
<tr>
<td>Switzerland</td>
<td>13.1</td>
<td>13.1</td>
<td>1.4</td>
<td>2.0</td>
</tr>
<tr>
<td>France</td>
<td>6.8</td>
<td>12.1</td>
<td>0.6</td>
<td>8.2</td>
</tr>
<tr>
<td>Other European</td>
<td>3.2</td>
<td>3.1</td>
<td>0.3</td>
<td>5.5</td>
</tr>
<tr>
<td>Canada and Australia</td>
<td>6.8</td>
<td>6.8</td>
<td>1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>Others</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
</tr>
</tbody>
</table>

US: 60% from Academia or biotechs

Open innovation looks the mainstream.

Japan: Less than 20% from academia or biotechs

Large Pharma

Robert Kneller, Nature Reviews Drug Discovery 9, 867-882, 2010
More drugs from academia / biotech company

- Facilitate networking
  - Pursue originality by conjugating various and creative research activities
  - Needs to create new mechanism where academia and pharma companies get together more easily and spontaneously

More Openness and Accessibility (data, information, strategy, etc.)
Shift into More "Open Innovation"

- **Traditional Model**
  - Small Molecule
  - Lifestyle Disease
  - Blockbuster

- **Closed - all things done in house –**

- **Patent Strategy to protect in-house R&D fruits**

- **Diversified, Complicated**
  - Large molecule, Molecularly targeted drug, biologics, regenerative medicine

- **Open Innovation for innovative therapy / medicine**

- **Open Innovation for Global Health by Innovative R&D model**
  Unmet medical needs in Neglected tropical diseases and communicable diseases

More exposure to cutting-edge technologies.
Open Innovation in Japan

Academia - Pharma
- Kyoto Univ. - Takeda: T-CIRA

Pharma – Pharma
- Daiichi-Sankyo – Astellas: Co-use of Compound Library

Public offer by Pharma
- Shionogi: FINDS
- Daiichi-Sankyo: TaNeDS
- Astellas: a-cube
- Takeda: Cockpi-T, RINGO-T

Academia – Academia
- Tokyo Univ.: Drug Discovery Open Innovation Center
- Kyoto Univ.: Center for Innovation in Immunoregulative Technologies and Therapeutics

Government Driven
- Drug Discovery Supporting Network
1. Center for iPS Cell Research and Application (CiRA) at Kyoto University and Takeda Pharmaceutical Company Ltd. (Takeda) start a ten-year-long research collaboration (T-CiRA Joint Program).

2. iPS cell and its related technologies to pharmaceutical R&D activities, such as drug discovery, cell therapy and drug safety.

3. Professor Shinya Yamanaka, the head of CiRA, directs the Program.

4. Takeda will provide:
   i. Total research budget: Approximately 20 billion-yen per over ten years
   ii. Research facility: Dedicated space in Shonan Research Center (Fujisawa, Japan) of Takeda
   iii. In-kind research support: 50 Takeda researchers, drug discovery technologies and other R&D know-hows.
Unique T-CiRA academic/industry collaboration

1. Long term (10 years) commitment by both CiRA and Takeda to a nationally important project.

2. The program is solely directed by Professor Yamanaka, the discoverer of iPS cell.

3. "Open Innovation": Housed in the center of a drug company's research headquarter.

4. A large scale collaboration: Over 100 researchers at one site.

5. Public Contribution: After filing patents, CiRA and Takeda encourage publication of outcomes that will accelerate public research.

6. Internationality: The Program will recruit scientists from all over the world.
• Invite academia to present new assay systems.

• Takeda will put its compound libraries into screenings, using the assay system.

• Takeda reports back to the presenter the findings gained by the screenings.

• The presenter can freely disclose and utilize the outcome.

• The outcome may lead to breakthrough to new drug discovery by academia, industries or Takeda.
• Encourage and invite junior researchers at universities, research institutes and private industries to apply for sponsorship by Takeda.

• Innovative idea on drug target or research technology relating to specific therapeutic areas and themes designated by Takeda
  – Central Nervous System, Gastro Intestinal, Oncology, Immunology, inflammatory, Microbiome

• Support
  – 100,000 USD (at max.) funding
  – Relevant Takeda's technology and assets

• Resulting invention and patents
  – Vested in Partner
  – Not enforced against Takeda’s research activities
  – Takeda has first right to negotiate for exclusive license
Open Innovation to Improve Global Health

Indicator: Poverty headcount ratio at $1.25 a day (PPP) (% of population)
Year: 2014

© 2014 The World Bank, All Rights Reserved.
Global Health and Open Innovation

- HIV/ AIDS, Tuberculosis, Malaria, NTDs (Neglected Tropical Diseases) in developing countries ---> "Unmet Medical Needs"

- Public health care system, health insurance system, distribution system, pricing system, healthcare professional, public education and new drug development......

- It is essential to realize Flexible Partnerships between public sector and private sector as well as other forms of cooperation within the various stakeholders. >>> Product Partnership.

- Patent drives technology flow and open innovation, and brings the life to the Technology

- Cases involving Japan
  - GHIT
  - WIPO Re:Search
GHIT - The Global health Innovation Technology Fund

Why products not being provided?
GHIT

PDPs

Pharmaceutical Companies
- Contributions to global health
- Expanded portfolios for developing countries
- Global branding

Bioventure business
- Business opportunities
- System for fixed volume purchases by public agencies targeting developing nations

Universities
- Expanded research opportunities
- Participation in product commercialization

Research institutions
- Expanded research opportunities
- Reduced public hygiene risks

Promote R&D and supply of products targeting infectious diseases in developing nations
GHIT
Takeda's case: Lead Optimization for Aminopyrazole

• DNDi and Takeda Collaborate
• for the Lead Optimization for Aminopyrazole Series for Visceral Leishmaniasis drugs

Takeda and DNDi collaboration

for Developing a Drug for Treating
Visceral Leishmaniasis

Efforts Funded by GHIT Fund
GHIT
Collaboration by Multiple Pharmas

NTD Drug Discovery Booster

- Launched May 2015
- Participants: DNDi, Eisai, Shionogi, Takeda, AstraZeneca
- Target disease: Chagas Disease and Leishmaniasis, 450 million people are at risk of contracting worldwide
- Time frame: From 2015-2017 with the possibility of extension & expansion
- Speed up the process and cut the cost of finding new treatments for the target diseases
- DNDi will access millions of unique compounds, generated over many decades of research, to screen for potential treatments or cures for the target diseases.
- Companies will continually examine their libraries for better matches as the search is refined.
- The GHIT Fund supports EUR 640,000 (79.5 million JPY), and the involvement of the three Japanese companies.
WIPO Re:Search - background

• Founded in 2011 by the World Intellectual Property Organization (WIPO), BIO Ventures for Global Health (BVGH), and several leading pharmaceutical companies

• Global initiative established to encourage and facilitate the sharing of intellectual property assets to advance drug, vaccine, and diagnostic development for malaria, tuberculosis, and neglected tropical diseases (NTDs)

• Consortium membership includes academic and non-profit research institutions, governmental and non-governmental organizations, and biopharmaceutical companies

• Any resulting product would be made available royalty free in the least developed countries and at a reasonable cost in other developing countries.

⇒ Takeda joined WIPO Re:Search in Sept. 2015
WIPO Re:Search - Structure

- Manage asset database
- Access to academic journals
- Member workshops
- Member engagement
- Recruit new User and Provider Members
- Identify, establish, and manage collaborations
- Research sabbaticals
- Communications and publications
Dr. Jim McKerrow (University of California, San Diego [UCSD], USA) & Eisai Co., Ltd. (Japan)
- Jim is assessing inhibitors of ergosterol synthesis as potential leishmaniasis and Chagas disease drugs
- Eisai shared a novel squalene synthase inhibitor with Jim

Dr. Alister Craig (Liverpool School of Tropical Medicine) & Eisai Co., Ltd. (Japan)
- Alister is searching for adjunct treatments for cerebral malaria by targeting PAR1
- Eisai shared its PAR1 inhibitors with Alister to assess in his in vitro cerebral malaria model
APPENDIX
Marketed Drugs in Japan

( ) : still under development or examination

In 2003 - Marketed drug among 99 (out of TOP103)

<table>
<thead>
<tr>
<th>USA</th>
<th>UK</th>
<th>FR</th>
<th>DE</th>
<th>KR</th>
<th>CN</th>
<th>Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td>98</td>
<td>97(2)</td>
<td>97(2)</td>
<td>97(2)</td>
<td>94</td>
<td>70</td>
<td>63(23)</td>
</tr>
</tbody>
</table>

Improved Data Protection period in Japan
8 year period instead of 6 year one

In 2013 - Marketed drug among Top100

<table>
<thead>
<tr>
<th>USA</th>
<th>UK</th>
<th>FR</th>
<th>DE</th>
<th>KR</th>
<th>CN</th>
<th>Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>100</td>
<td>99(1)</td>
<td>100</td>
<td>95(2)</td>
<td>73(12)</td>
<td>93(3)</td>
</tr>
</tbody>
</table>

• **Existing Data**
  Any and all existing data and findings owned by a product development partner at the initiation of a project, including but not limited to information, know-how or intellectual property, will remain that of the original holder. The original holder may share, assign, or license their rights to a third party.

**New Data**
Ownership of any and all data and findings that is obtained or created through activities invested by the GHIT will be discussed and negotiated between participants and/or product development.

**Patent Applications**
Any existing data owned by a product development partner and/or any new data obtained through activities invested by the GHIT Fund may be disclosed by the GHIT Fund to a third party if such data is used in a patent application for a product which was derived from the activities invested by the GHIT Fund; provided, however: (1) that the disclosure of such data shall be limited to the proposed title of the invention, a draft of the abstract, the international non-proprietary name (INN) where applicable, and an outline of the specifications of such patent application; and (2) such third party shall take reasonable measures to keep confidential any such data received from the GHIT Fund.

• **Principle of Product Access Policy**
• **Licenses**
When product development partners and/or participants are successfully granted a patent deriving from projects invested by the GHIT Fund, product development partners and/or participants will grant royalty-free licenses to users operating in Least Developed Countries (LDCs) as categorized by the United Nations classification and Low-Income Countries (LICs) categorized by the World Bank classification. License-related matters concerning middle income countries will be reviewed on an individual basis with the goal of ensuring reasonable royalty licenses.

**Pricing**
In LDCs, LICs and middle income countries, product development partners and/or participants will set prices for products on the basis of a no gains/no loss policy that can improve access to the product for patients and citizens of LDCs, LICs and middle income countries.
• Compounds & compound libraries
  • HMG-CoA reductase inhibitors
• Technologies
  • High-throughput screening platform
• Reagents
  • Anti-dengue virus antibody
• Know-how and therapeutic area expertise
  • Drug structure-activity relationship (SAR) advice
• Clinical/field samples
  • Severe and asymptomatic malaria patient samples
• Data
  • Investigator’s brochure, clinical trials data summary
• Other support
  • Vaccine thermostability formulation