Plasma-Derived Therapies Basics

July 12, 2019
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Takeda Pharmaceutical Company Limited

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Takeda’s financial statements are prepared in accordance with International Financial Reporting Standards ("IFRS"). The financial statements of Shire plc ("Shire") are presented in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). Therefore, the respective financial information of Takeda and Shire are not directly comparable.

The Shire acquisition closed on January 8, 2019, and our consolidated results for the fiscal year ended March 31, 2019 include Shire’s results from January 8, 2019 to March 31, 2019. References to “Legacy Takeda” businesses are to our businesses held prior to our acquisition of Shire. References to “Legacy Shire” businesses are to these businesses acquired through the Shire acquisition.
AGENDA:

1. What are plasma-derived therapies (PDT)?
2. What is the PDT market?
3. What is Takeda’s PDT business?
What is Plasma?

**Definition of Plasma:**
Plasma is the clear, straw-colored liquid portion of blood that remains after red blood cells, white blood cells, and platelets are removed. Plasma has multiple components with different clinical uses and it cannot be manufactured in a laboratory.

Blood contains...

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>55%</td>
<td>Plasma</td>
</tr>
<tr>
<td>44%</td>
<td>Red blood cells</td>
</tr>
<tr>
<td>1%</td>
<td>White blood cells &amp; platelets</td>
</tr>
</tbody>
</table>

What are blood products? What are plasma-derived products?

**Blood Products Market in Japan**

- **Blood Products for Transfusion**
  - Whole Blood Products
  - Blood Component Products
    - Red Blood Cell Products
    - Platelet Products
    - Fresh Frozen Plasma Products

- **Plasma-Derived Products**
  - Immunoglobulin
  - Albumin
  - Coagulation Factors
  - Other Replacement Therapies

Clinical uses of plasma products span four primary categories

<table>
<thead>
<tr>
<th>Description</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Assists in the destruction of foreign molecules</td>
<td>▪ IVIG/SCIG – congenital antibody deficiencies, neurologic, hematology – 200+ diseases</td>
</tr>
<tr>
<td>▪ Main function of the humoral immune system</td>
<td>▪ Hyperimmune – target antigens of specific conditions</td>
</tr>
<tr>
<td>▪ Maintains intravascular colloid osmotic pressure</td>
<td>▪ Albumin – Fluid loss, sepsis/septic shock, plasma exchange, burn therapy, renal dialysis</td>
</tr>
<tr>
<td>▪ Can compete with non-protein based volume replacement solutions such as starches, Ringer’s Lactate, or saline</td>
<td></td>
</tr>
<tr>
<td>▪ Replaces missing factors in the clotting cascade due to deficiencies or dysfunctions</td>
<td>▪ Factor VIII/IX – Hemophilia A/B</td>
</tr>
<tr>
<td>▪ ▪ vWF – Von Willebrand Disease</td>
<td></td>
</tr>
<tr>
<td>▪ ▪ Factor II, V, VII, X, XI, XIII &amp; fibrogen – deficiencies for blood loss or congenital</td>
<td></td>
</tr>
<tr>
<td>▪ ▪ AT-III – excessive clotting</td>
<td></td>
</tr>
<tr>
<td>▪ ▪ AAT/A1PI – COPD, cirrhosis, jaundice</td>
<td></td>
</tr>
<tr>
<td>▪ ▪ C1-INH – Hereditary Angioedema</td>
<td></td>
</tr>
<tr>
<td>▪ Plasma proteins used to treat extremely rare diseases</td>
<td></td>
</tr>
<tr>
<td>▪ ▪ Immune globulin (IG)</td>
<td></td>
</tr>
<tr>
<td>▪ ▪ Albumin</td>
<td></td>
</tr>
<tr>
<td>▪ ▪ Coagulation Factors</td>
<td></td>
</tr>
<tr>
<td>▪ ▪ Other Replacement Therapies</td>
<td></td>
</tr>
</tbody>
</table>

It can take 1000+ donations to derive a 1-year-therapy for 1 patient and, for some patients, plasma products are the only treatment they can rely on

<table>
<thead>
<tr>
<th>Estimated donations needed for one patient for one year</th>
<th>Availability of non-Plasma Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>130: Primary immunodeficiency disease</td>
<td>Immunoglobulin: None globally</td>
</tr>
<tr>
<td>900: Alpha 1 antitrypsin deficiency</td>
<td>Albumin: Recombinant albumin*</td>
</tr>
<tr>
<td>1200: Hemophilia</td>
<td>FVIII/FIX/FXIII: Recombinant FVIII, Recombinant FIX, Bi-specific Antibody</td>
</tr>
<tr>
<td></td>
<td>Inhibitor Products: Recombinant FVII, Bi-specific Antibody</td>
</tr>
<tr>
<td></td>
<td>Anti Thrombin III: Recombinant Anti Thrombin III</td>
</tr>
<tr>
<td></td>
<td>Prothrombin: None globally</td>
</tr>
<tr>
<td></td>
<td>C1 inactivator: Icatibant acetate</td>
</tr>
<tr>
<td></td>
<td>Protein C: None globally</td>
</tr>
<tr>
<td></td>
<td>Fibrin Sealant: None globally</td>
</tr>
</tbody>
</table>

* Reombinant albumin product was approved but not available

Source: PPTA (Plasma Protein Therapeutics Association), MHLW
Plasma can be collected either as recovered plasma or as source plasma via a process called apheresis.

**Recovered plasma is obtained from whole blood donations**
- Plasma is separated after the blood has been removed from the body.
- Whole blood donations are governed by different regulations than plasma donation:
  - Generally non-remunerated
  - Less frequent because the body takes more time to replenish blood cells than plasma.
- ~16% of total global plasma supply; ~75% of total Japanese plasma supply.

**Source plasma is obtained by apheresis while blood cells are returned to the donor**
- Plasmapheresis collects plasma but returns blood cells to the donor simultaneously, using sterile single-use equipment.
- Few countries allow donor remuneration, e.g., US, Germany, Austria, Hungary, Czech Republic.
- Commercial plasma centers are either owned and operated by fractionators or by third party collectors who resell the plasma to fractionators.
- ~84% of total global plasma supply; ~25% of total Japanese plasma supply.

### Plasma Collection Requirements vary by country

<table>
<thead>
<tr>
<th></th>
<th>U.S.</th>
<th>Austria</th>
<th>Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Regulator/Regulations</strong></td>
<td>FDA Blood Safety Law</td>
<td>EMA Blood Donor Decree</td>
<td>MHLW Blood Law</td>
</tr>
<tr>
<td><strong>Plasma Collection</strong></td>
<td>Private and Public</td>
<td>Private and Public</td>
<td>Red Cross only (no private centers allowed)</td>
</tr>
<tr>
<td><strong>Plasma Donation Volume</strong></td>
<td>690 - 880 ml per donation depending on body weight</td>
<td>600-850 ml per donation depending on body weight</td>
<td>~600 mL (no more than 12% of circulating blood)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>18 and older</td>
<td>18 and older</td>
<td>18 – 69 years old</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>110 lbs (≒ 50 kg) or greater</td>
<td>50kg or greater</td>
<td>Male: 45kg or greater Female: 40kg or greater</td>
</tr>
<tr>
<td><strong>Plasma Donation Intervals</strong></td>
<td>48 hours between donations No more than 2 donations in 7 days</td>
<td>72 hours between donations No more than 2 donations in 7 days No more than 3 donations in 14 days No more than 50 times per year</td>
<td>Every 2 weeks or less No more than 24 donations per year</td>
</tr>
</tbody>
</table>

Compensation for source plasma is only allowed in US, Germany, Austria, Hungary and Czech Republic.

Variations in donation frequency, number and volume exist amongst all 5 countries.
From donor to patient, typical PDT production journeys can take ~12 months to complete

Plasma-Derived Therapies

<table>
<thead>
<tr>
<th>Collection, Testing</th>
<th>Fractionation</th>
<th>Purification</th>
<th>Filling</th>
<th>Packaging &amp; Distribution</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 days holding period*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

"Traditional" Pharma

- Compound Mixing
- Capsule Filling/Tableting
- Packaging & Distribution

<table>
<thead>
<tr>
<th>Start</th>
<th>3 months</th>
<th>6 months</th>
<th>9 months</th>
<th>12 months</th>
</tr>
</thead>
</table>

* This is Takeda’s inventory hold period based on PPTA GMQ standard. In Japan, JRC’s inventory hold is 6 months. Source: Japan Red Cross Website [http://www.jrc.or.jp/brt/blood_product/takeda/inventory_hold/], MHLW: Blood Business Report (2018)(2019)

Throughout the value chain, Takeda products are based on pathogen safety principles

Donor related measures
- Plasma origin (licensed and regularly inspected centers)
- Donor qualification program (including questionnaire to identify high risk donors)

Donation related measures
- Serological test program (Antibodies to HIV-1, HIV-2, HCV, HBs Antigen)
- Inventory hold and look back procedure
- NAT (Nucleic Acid Testing) program (HIV, HBV, HCV, HAV, Parvo B19)

Production related measures
- Virus removal / inactivation steps

Product surveillance system
- Pharmacovigilance
Plasma fractionation is the core of our production process leading to more than 20 different plasma products that meet the patients needs.

* Not manufactured by Takeda

COGS are the major cost driver in the plasma industry, typically attributed to high raw-material and fractionation process cost.

Source: Industry Reports & Estimation 2011, S&P Capital IQ
Plasma has a unique financial profile with relatively lower R&D costs as a proportion of revenue and is generally not subject to patent cliffs.

The Plasma business is different from traditional pharma:

- Plasma is collected from human donations – precious supply
- It can take **1,000+ donors** to derive a 1-year-therapy for **1 patient**
- Plasma collection is **heavily regulated**
- Plasma donation is a **sensitive topic**
- It’s a capital intensive business
- **Production** timeline is longer, **COGS** are higher
- **Plasma economics** add further complexity
- Plasma products are **not subject to patent cliffs**
What is the PDT market?

There is a growing need for PDT products led by Immunoglobin (IG) and Takeda is one of the top 3 global companies.

Global Plasma Market ($B), 2015-23

Global PDT Revenue Market Share (2018)

Source: MRB, Evaluate Pharma, PDT Analysis

* These are examples and not an exhaustive list

Source: MRB, Evaluate Pharma, PDT Analysis
Immunoglobulin (IG) demand is growing globally

- **Global IG Market (Tons)**
  - CAGR (2003–2016)
    - S. America +12%
    - EAMEA +8%
    - JAPAC +9%
    - Europe +8%
    - N. America +9%

- **Supplying plasma to meet the increasing demands is challenging**
- **Reasons for Growth**
  - Improved standard of care
  - Improved diagnosis rate and disease awareness
  - Expanded indications

In Japan, although overall PDT market is decreasing, IG growth is still strong

- **Japan Plasma Market ($M), 2015-18**
- **Japan PDT Revenue Market Share**
  - Coagulation Factors
  - Albumin
  - Other
  - Today’s Focus

**NOTE:** The category of product type is based on Takeda’s internal standards. Converted at April 2018–March 2019 average exchange rate of 111 JPY/USD

In Japan, while Immunoglobulin (IG) demand is growing, IG product price is decreasing, resulting in ~30% lower compared to 2007.

**Note:** 2018 data is annualized with April-September actual data.

**Source:** MHLW "Building a Plan for Stable Supply of Blood Products in 2019" [https://www.mhlw.go.jp/content/11121000/000452750.pdf](https://www.mhlw.go.jp/content/11121000/000452750.pdf).

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Immunoglobulin (IG) has multiple usages and available indications are increasing both in Japan and globally.

<table>
<thead>
<tr>
<th>Indication</th>
<th>Primary immunodeficiency (PID)</th>
<th>Chronic inflammatory demyelinating polyneuropathy (CIDP)</th>
<th>Multifocal motor neuropathy (MMN)</th>
<th>Others (Secondary immunodeficiency (SID), Kawasaki Disease, Infections, MG, GBS etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic area</td>
<td>Immunology</td>
<td>Neurology</td>
<td>Neurology</td>
<td>Multiple</td>
</tr>
<tr>
<td>Primary physician</td>
<td>Immunologist, Pediatrician</td>
<td>Neurologist</td>
<td>Neurologist</td>
<td>Multiple</td>
</tr>
<tr>
<td>Age groups</td>
<td>Various</td>
<td>Middle age to older adults</td>
<td>Middle age to older adults</td>
<td>Various</td>
</tr>
<tr>
<td>2017 Global Volume Growth</td>
<td>9%</td>
<td>9%</td>
<td>17%</td>
<td>6%</td>
</tr>
</tbody>
</table>

*MG: Myasthenia Gravis, GBS: Guillain-Barre Syndrome*

*Note: Indications of Immunoglobulins vary by country; For indications of each product of specific country, please refer to local product labeling.*
PID, SID, and CIDP composed of 60% of total usages of Immunoglobulin (IG)

**US & EU IG Market by TA, 2018e Forecast**

PID: Primary Immunodeficiency; SID: secondary immunodeficiency; MMN: Multifocal motor neuropathy; CIDP: Chronic Inflammatory Demyelinating Polyradiculoneuropathy


In Japan, immunoglobulin (IG) usage per population is still lower than other countries and its growth is also slower

**IVIG/SCIG Consumption by Country (Kg per Million people)**

<table>
<thead>
<tr>
<th>Country</th>
<th>2014</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>200</td>
<td>100</td>
</tr>
<tr>
<td>Canada</td>
<td>180</td>
<td>99</td>
</tr>
<tr>
<td>Australia</td>
<td>174</td>
<td>92</td>
</tr>
<tr>
<td>France</td>
<td>128</td>
<td>63</td>
</tr>
<tr>
<td>Germany</td>
<td>93</td>
<td>28</td>
</tr>
<tr>
<td>UK</td>
<td>85</td>
<td>52</td>
</tr>
<tr>
<td>Spain</td>
<td>70</td>
<td>53</td>
</tr>
<tr>
<td>Italy</td>
<td>66</td>
<td>50</td>
</tr>
<tr>
<td>Japan</td>
<td>34</td>
<td>27</td>
</tr>
<tr>
<td>China</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>Brazil</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Russia</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>


**Reasons for differences among countries**

- Product availability and history of commercial product introduction
- Diagnosis rate and disease awareness
- Price differences
- Influence of patient advocacy groups
- Market structure and purchasing process
- Medical education
- Available usage of IG (difference in indications/off-label usage)
While in the U.S. and Europe, 10% IVIG is the majority, Japan still uses 5% IVIG.

Europe IG Market, 2017

The U.S. IG Market, 2017

Japan IVIG Market*, 2018

5% IVIG is mainly used in Japan partially because of late introduction and limited product options of 10% IVIG and SCIG.

5% IVIG
10%IVIG

10% SCIG
20% SCIG

IVIG: Intravenous Immunoglobulin, SCIG: Subcutaneous Immunoglobulin

NOTE: The category of product type is based on Takeda internal standards.
Source: Copyright © 2019 IQVIA. (Calculated based on JPM Jan-Dec 2018) Reprinted with permission. The U.S. and EU data is based on Takeda internal analysis based on LoC’s self-report.

What is Takeda’s PDT business?
Takeda has a long history in the PDT business

1954

**Gammabulin**
(Italy, Health Ministry Approval)

**Partobulin**
(Austria, Health Ministry Approval)

**Subcuvia**
(Sweden, Health Ministry Approval)

**Cuvitru**
(EMA Approval)

**Endobulin**
(Austria, Health Ministry Approval)

**Endobulin S/D**
(Finland, Health Ministry Approval)

**Partobulin S/D**
(Czech Republic, Health Ministry Approval)


**Tatabulin**
(Canada, Health Ministry Approval)

**HyQvia**
(EMA Approval)

Takeda has access to global plasma as well as Japan plasma for Japanese market

**Japan PDT Market**

**Collection**

- **Japan Red Cross**
  - Whole Blood Collection Centers
  - 146 Donation Centers
  - 288 Donation Busses

- **Takeda Plasma Centers**
  - (BioLife)

- **Independent Plasma Collectors**

- **Competitors Plasma Centers**

**Fractionation/Purification**

- **JBPO**
- **KM Biologics**
- **Nihon Pharmaceutical**
- **Takeda**

**Delivering**

- **WS**
- **Hospital/Pharmacy**
- **Patients**

- **Other Fractionators**

Takeda is accelerating investments to grow plasma collections globally

**MANUFACTURING:**
**RAMPING UP OPERATIONS AT COVINGTON**
- Received US FDA approval to manufacture FLEXBUMIN in March 2019
- Ramp up to full production over next several years, with a focus on manufacturing the IG portfolio and Albumin, covering 1 million+ square feet with the opportunity to further expand with the aim of reducing the gap between demand and supply
- Additional internal capacity expansion under evaluation

**SUPPLY:**
**INVESTING IN PLASMA COLLECTION**
Acquired 10 additional plasma collection centers since Shire acquisition close
- 1 center in Maryland, U.S.
- 2 centers in Austria
- 7 centers in Hungary
Current footprint of 105 centers in the US, and 30 ex-US
Intend to continue to invest in increasing plasma collection footprint aiming for double-digit increase in number of centers each year

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Takeda Plasma Collection Operations

105 U.S. Centers across 27 states
30 Centers in Europe
3 Screening Labs

3rd Party Plasma Supplies

5 US suppliers
~50 EU suppliers
~50 locations across 7 countries

Plasma manufacturing network is state-of-the-art with ongoing capacity investments

**Cryo Precipitation, Absorption and Fractionation**

Los Angeles, USA  Rieti, Italy  Vienna, Austria  Sanquin, NL*  Covington, USA

**Downstream Processing**

Lessines, Belgium  Covington, USA

**Worldwide Distribution**

*: Owned by Takeda’s partner company
We have a broad PDT portfolio globally

**Key uses / clinical indications**

**Immunoglobulin**
- Primary Immunodeficiency (PID), Idiopathic Thrombocytic Purpura (ITP), Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) etc.

**Albumin**
- Fluid loss, sepsis/septic shock, plasma exchange, burn therapy, renal dialysis

**Plasma derived coagulation factors**
- Factor VIII/IX – Hemophilia A/B
- vWF – Von Willebrand Disease

**Inhibitors**
- Hemophilia with inhibitors

**Alpha-1 anti-trypsin**
- AAT – Chronic Obstructive Pulmonary Disease (COPD)

**C-1 esterase inhibitor**
- HAE – edema (swelling) in various parts of the body

**Prothrombin**
- Reversal of acquired coagulation factor deficiency induced by warfarin

**Others**
- Protein C deficiency
- Wound healing

**Global TAKEDA Products**

**Japan TAKEDA Products**

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Takeda has extensive portfolio of IG

<table>
<thead>
<tr>
<th>Intravenous (IV) IG</th>
<th>Subcutaneous (SC) IG</th>
</tr>
</thead>
<tbody>
<tr>
<td>~5%</td>
<td>10% Weekly</td>
</tr>
<tr>
<td>10%</td>
<td>20% Weekly</td>
</tr>
<tr>
<td></td>
<td>10% Monthly</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CSL</th>
<th>✓</th>
<th>✓</th>
<th>✓</th>
</tr>
</thead>
<tbody>
<tr>
<td>GRIFOLS</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>JB</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>kmb</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

*: Not available in Japan, **: Just approved in March 2019, ***: Only available in Japan
IG and Albumin continue to be growth drivers

**KEY GROWTH PRODUCTS**

- **Gammmagard LIQUID**
  - Approved in 50+ countries (Kiovig in EU)
  - Continue to build on GAMMAGARD LIQUID’s position as a highly recognized IVIG brand that is standard of care treatment for PID and MMN

- **HyQvia**
  - HYQVIA approved in the U.S., EU, LATAM, and Middle East; CUVITRU approved in the U.S. and EU
  - Provides patients flexibility in their schedule of subcutaneous IG administration, whether monthly (HYQVIA) or more frequently (CUVITRU)
  - Phase 3 study ongoing for CIDP indication (HYQVIA)

- **Cuvitru**
  - PID, SID (US)

- **FLEXBUMIN**
  - Approved in 40+ countries
  - Maximize opportunity to priority markets
  - FLEXBUMIN uses a closed system (collapsible bag) which is lightweight, aimed at reducing the risk of hospital infections, and allows minimal wastage

- **Human Albumin, Hypoalbuminemia**

*PID: Primary Immunodeficiency; SID: secondary immunodeficiency; MMN: Multifocal motor neuropathy; IVIG: Intravenous Immunoglobulin; CIDP: Chronic Inflammatory Demyelinating Polyradiculoneuropathy

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We put the patients first to conduct our PDT business

1. **Patient**
   - Putting the patient at the center

2. **Trust**
   - Build trust with society

3. **Reputation**
   - Reinforcing our reputation

4. **Business**
   - Development our business

*1. Pro-forma April 2018–March 2019 combined revenue of Legacy Takeda and Legacy Shire products converted at April 2018–March 2019 average exchange rate of 111 JPY/USD*
Take Home Messages

• PDT products are **very different and unique business** from traditional pharmaceuticals

• Plasma market is **growing** led by IG

• **Takeda** is one of the **top three** global plasma fractionators

• To continue delivering our PDT products, Takeda is **enhancing plasma collection and manufacturing** capabilities

• **Immunoglobulin (IG) and Albumin** are growth drivers for Takeda PDT business