Fully Integrated Biopharmaceutical Company

- Based in Taiwan, started in operations in January, 2003
- Employee = 151 (4 MD, 25 Ph.D., 78 M.S.)
- Extensive experience in new drug discovery/development
- Taichung manufacturing site was built in 2012
- GMP was certified by TFDA in 2013
- Inspections expected from EMA, in mid, 2017 followed FDA, in Q2, 2018
## Product Portfolio Pipeline

### Hematology
- **P1101**
  - PV-PROUD* (EU)
  - CONTI* (EU)
  - RESCUE** (Global)
  - CML** (EU)
  - PV (US)
  - ET (Global)
  - PMF** (US)

### Infectious Disease
- **P1101**
  - HCV-G2 (TW, KR)
  - HCV-G1 (TW)
  - HBV (Global)
- **PD-1**
  - HBV

### Oncology
- **Oraxol**
  - Breast Cancer (TW)
  - HCC
- **PD-1**
  - HCC

### Dermatology
- **KX01**
  - Psoriasis (TW)

---

*Conducted by AOP (Vienna)  **IIT
Core Technology

- Single-site PEGylation technology
- Purest PEG-P-IFN P1101
  - Long-acting
  - Very mild AE
  - Will apply for various indications
  - Flexible dosing adjustment
- Patent protection until 2034

The Best New Class Long-acting Interferon
Market Position & Competitive Advantages
Outstanding in PEG-IFN α Era (Purity)

**PharmaEssentia** (PEG-P-interferon alfa-2b)
- Long-acting
- Less frequent/serious AE
- Much high MTD
- Flexible dosing
- Multiple therapeutic areas

**Roche** (PEG interferon alfa-2a)

**Merck** (PEG interferon alfa-2b)
**P1101, The Best & The Future of The Long-Acting IFN**

<table>
<thead>
<tr>
<th>Merck</th>
<th>Roche</th>
<th>Novartis</th>
<th>BMS</th>
<th>PharmaEssentia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PEG-Intron</strong></td>
<td><strong>Pegasys</strong></td>
<td><strong>Albuferon</strong></td>
<td><strong>PEG-IFN λ</strong></td>
<td><strong>P1101</strong></td>
</tr>
<tr>
<td><strong>HCV</strong></td>
<td><strong>HCV HBV</strong></td>
<td><strong>HCV HBV</strong></td>
<td><strong>HBV</strong></td>
<td><strong>PV, ET, PMF, CML, HBV, HCV GT2</strong></td>
</tr>
<tr>
<td><strong>On market</strong></td>
<td><strong>On market</strong></td>
<td>Failed</td>
<td>Failed</td>
<td>Phase III in PV (finished trial)</td>
</tr>
<tr>
<td><strong>Q1W</strong></td>
<td><strong>Q1W</strong></td>
<td><strong>Q2W</strong></td>
<td><strong>Q1W</strong></td>
<td><strong>Q2W to Q4W</strong></td>
</tr>
<tr>
<td><strong>Serious lung infection</strong></td>
<td><strong>Similar AE to Pegasys</strong></td>
<td><strong>Terminated</strong></td>
<td><strong>Less Effective</strong></td>
<td><strong>Better Efficacy</strong></td>
</tr>
</tbody>
</table>
P1101 Platform Engine
Develop Rich Portfolio

MPN
(Abnormal growth of blood cells)
- Polycythemia Vera (PV)
- Essential Thrombocythemia (ET)
- Chronic myeloid leukemia (CML)
- Myeloid Fibrosis (MF)

Hepatitis
(Combo with small molecule drugs)
- Chronic Hepatitis B (HBV)
- Chronic Hepatitis C (HCV)

Cancer
(Combine with PD1/PDL-1)
- HCC
- RCC
- NSCLC
Orphan Drug Advantage

• Smaller trial size
• Fast review process
• Enjoy Market exclusivity
  ➢ 7 years in Europe
  ➢ 10 years in U.S.
• Orphan drug has pricing power advantage
  ➢ Price of Jakafi increased 5% semi-annually since 2011
• Tax advantage on new drug research & development
Myeloproliferative neoplasms (MPNs) are a closely related group of progressive blood cancers in which the bone marrow typically overproduces one of the mature blood elements.

100,000 Prevalence
Incyte documents & Jeffries 8/15 Incyte Analyst Report reflects 100,000 potential PV patients

25% PV patients estimated to be intolerant / resistant to hydroxyurea

Incyte estimates JAKAFI’s total US PV patient universe to be 25,000 patients

148,000 Prevalence
Based on MarketScan database estimates from 2010 (which were lower than the Impact database estimates), the projected prevalence for MPNs in the U.S. on December 31, 2010 was:

- MF – 12,812
- PV – 148,363
- ET – 134,534

The study results suggest that MPN prevalence is much higher than previously reported.

PV is the largest MPN group with 100,000 – 148,000 potential patients for BESREMI® including 15,000 – 22,000 PV patients at risk for MF.
Global Strategy & On-going Developments
Collaboration & Joint Activities
- License out, Foam Team or JV at Major Market

Clinical Trails
- Medical Conference
- Involve in Treatment Guideline
- Filing submission

Branding
- Distribution Channels & Insurance companies

Global Commercialization

PharmaEssentia
HQ (TW)

Europe - AOP

U.S. Team

Japan- subsidiary

China- subsidiary
PROUD-PV in Europe

AOP Orphan Pharma

Clinical Trials (257 patients in 48 sites, 13 countries)

EMA Approval

Product Launch

PROUD-PV in Europe

Status: 13.01.2015

enrolling
open, not enrolling
not open
Aligned with Key MPN Centers and Influential Treaters

MPN Centers & Clinical Sites in 20 states

States with MPN-focused centers and key treaters (identified on previous slide)
Taichung Plant
Key Milestone Achieved

<table>
<thead>
<tr>
<th>2014</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug</td>
<td>Sep</td>
<td>Oct</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Completed consecutive 4 batches of P1101 process validation.
⇒ Proven our capability of continuous production of top quality medicine.
## Man Power

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>台中廠總人員</td>
<td>16人</td>
<td>84人</td>
</tr>
<tr>
<td>品質系統人員</td>
<td></td>
<td></td>
</tr>
<tr>
<td>品保部</td>
<td>5人</td>
<td>14人</td>
</tr>
<tr>
<td>品管部</td>
<td>3人</td>
<td>20人</td>
</tr>
</tbody>
</table>

### Jan 2013

![Group Photo](image1.png)

### Dec 2015

![Group Photo](image2.png)
為與歐、美藥廠管理標準接軌，聘請資深顧問公司輔導台中廠通過FDA/EMA GMP稽核。

駐廠顧問公司團隊
稽核員表示，我們文件提供迅速、GMP概念較其他藥廠強，對整體狀況表示滿意。

查廠結果：
無重大缺失、無嚴重缺失
模擬查廠（Jan 9-13, 2017）

查廠人員

1. 英國GSK藥廠17年經驗並擔任高階主管職。
2. 英國藥物與保健產品法規管理局(MHRA)擔任官員並有十二年稽核兩百五十家藥廠經驗。
3. 協助英國MHRA撰寫新的GMP法規。

查廠結果：無重大缺失、無嚴重缺失
德國Vetter Pharma查廠
(Mar 22-23, 2017)

• Gerhard (Vetter)
  – Knowledge to answer question
  – Documents content are perfect
  – Site tour is good.

• Bettina (Vetter)
  – Good English in documentation,
  – Knowledgeable people
  – Clean/order place & label well
  – Good process design.

• Klaus (AOP)
  – Comprehensive
  – Experience & knowledgeable people
  – Facility on the right track.
Global Trade Name

BESREMI®

PEN-PV

AN OPEN-LABEL, SINGLE ARM, PHASE III STUDY TO ASSESS THE SELF ADMINISTRATION OF AOP2014 USING PRE-FILLED AUTO INJECTION PEN, DEVELOPED FOR THE TREATMENT OF POLYCYTHEMIA VERA PATIENTS

PharmaEssentia
未來三年商品化之產品進度

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>P1101 for PV</td>
<td>Phase III / 歐盟</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P1101 for PV</td>
<td>Phase III / 美國</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P1101 for PV</td>
<td>Phase III / 美國、台灣</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P1101 for ET</td>
<td>Phase III / 美國、台灣</td>
<td></td>
<td></td>
<td>PIII臨床試驗</td>
<td>審查</td>
<td>上市</td>
</tr>
<tr>
<td>P1101 for HCV. GT2</td>
<td>Phase III / 台灣、韓國</td>
<td></td>
<td>PIII臨床試驗</td>
<td>審查</td>
<td>上市</td>
<td></td>
</tr>
<tr>
<td>P1101 for HBV</td>
<td>Phase III / 台灣、韓國、馬來西亞、泰國、香港、菲律賓</td>
<td>PIII臨床試驗</td>
<td>審查</td>
<td>上市</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
JAKAFI’s 10 year Projection of PV Revenue is $1.3B

<table>
<thead>
<tr>
<th></th>
<th>2015</th>
<th>2025</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total PV Patients</td>
<td>100,000</td>
<td>126,000</td>
</tr>
<tr>
<td>HU Intolerant/Uncontrolled</td>
<td>25,651</td>
<td>32,351</td>
</tr>
<tr>
<td>JAKAFI Treated Patients</td>
<td>2,132 (8% penetration)</td>
<td>11,469 (35% penetration)</td>
</tr>
<tr>
<td>Annual Treatment Costs (WAC)</td>
<td>$97,506</td>
<td>$153,294</td>
</tr>
</tbody>
</table>

Sales Development ($ M)

- 23.8% Compound Annual Growth
- Source: Jeffries September 2016 Analyst Model
謝謝大家蒞臨參觀指導