藥華醫藥(股)有限公司
法說會簡報

2019年6月27日（星期四）
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Agenda

• 營運進度說明
  – PV各國申請進度
  – 臨床進度

• Q&A
Our Mission

我們致力於打造以台灣為基地從事新藥創新發明、試驗發展、生產製造，進而行銷全球的全方位生物藥廠。
藥華藥簡介

2003年由一群從事新藥研發、旅美歸國學人創立

2008年發現P1101同時完成專利申請

2012年台中廠動工

2016年完成真性紅血球增生疾病(PV)第一階段三期臨床試驗

2016年7月16日於台北櫃買中心正式上櫃

• 2017年申請PV歐盟EMA藥證
• 真性紅血球增生(PV)第二階段三期臨床試驗

2017年申請PV歐盟EMA藥證

2018年藥華藥廠台中廠獲得歐盟GMP認證

2019年2月BESREM®獲得歐盟授予行銷藥證，治療紅血球增生疾病(PV)
藥華藥台灣佈局

中部科學園區
• 生物新藥GMP廠
• 鈔劑充填廠

台北總公司
南港軟體園區

F棟 13F 辦公室
F棟 19F GMP實驗室

辦公室擴展計畫 - G棟 2F
PV各國計劃進度

2019

Q1 | Q2 | Q3 | Q4 | 2020

Q1 | Q2 | Q3 | Q4

EU

藥證獲准

持續出貨並認列營收/ 台中廠接受歐盟定期查廠

US

申請Pre-BLA 會議/ 召開會議/ 送件/ 審核

TW

準備TFDA查台中針劑填充廠/ 查廠/ 送件/ 審核*

JP

Phase 1 種族性測試

小型橋接性試驗

小型橋接性試驗

備註：台中針劑填充廠將做為未來供給台灣藥證申請時用。
臨床試驗進度
ET Study Design

Eligible ET patients per WHO 2016 criteria

Resistant or intolerant to HU

Naïve to IFN-a

1:1 randomization & stratification by
1. palpable splenomegaly,
2. driver mutation,
3. thrombotic/he morrhagic history,
4. PLT counts (≥800x10^9/L)

Investigational arm: P1101, Q2W, S.C. (N=80)

250 (W0)->350 (W2)->500 (W4)

Fixed dose

Reference arm: Anagrelide, P.O. (N=80)

Labelled dose

Maintain optimal blood counts control at acceptable toxicity

China (45) Japan (25), Korea (20), Taiwan (35), USA (35)

52W treatment

4W follow up

Dose escalation

Baseline

4W

Primary Analysis 9 to 12M
HBV 临床试验计划

Primary Endpoint:
HBeAg seroconversion status at week 72

Baseline 48 weeks 72 weeks

Group 1
P1101 (450 μg) Q2W (N=106)

Group 2
Entecavir (0.5 mg) QD (N=106)

Secondary Endpoint:
- Undetectable HBV DNA
- HBsAg reduction
- ALT normalization
- Time to HBeAg seroconversion
- Safety

试验进行地点：
台湾、中国、韩国、越南

Interferon Treatment Naive;
ALT >ULN, <5x ULN;
Anti-HBc ≥ 4.4 log_{10} IU/mL;
HBV DNA ≥ 2 x 10^4 IU/mL,
< 2 x 10^8 IU/mL;

Interferon Treatment Naive HBeAg+ chronic HBV infection
# Our Pipeline

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**IIT Trial**
Thank you

2019年3月藥華醫藥全體員工以及KOLs於Besremi上市慶祝典禮暨MPN醫學研討會