The Opportunities and Prospects of Nemo Oral Drug China NDA

TaiGen Biopharmaceuticals Holdings Limited (4157.TWO)

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Safe Harbor Statement

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Taigexyn® - Approved by CFDA and TFDA

- **Novel Non-Fluorinated Quinolone** *(Brand Name Taigexyn®)*
- Broad-spectrum antibiotic, active against MRSA, VRSA, MDRSP, and PRSP
- Low propensity for resistance development - require mutations in three different bacterial genes
- Safety: No cardio-side effect
- Convenience: empirical treatment
- Oral and IV available
- Global IP protection until 2030

NDA From Cross Strait FDAs
Obtained CFDA 1.1 class NDA within 10 years

1.1 class new drug: the NCE drug not launched world wide
Leading Edge for CFDA approval

First 1.1 Class NDA Among Domestic & Foreign Companies Since New CFDA Regulation Came into Effect in July 2015

Established Novel Clinical Trial Model for New Drug

TFDA/CFDA Cooperation in Clinical Trials

Mutual recognition of clinical data by TFDA and CFDA

China Clinical Trial Data and QIDP

Clinical Trial Results and Quality approved by CFDA

Fast review and one time approval

Clinical trial site inspection and data audit
Antibiotics Market In Mainland China

- Potential for other indications
- Completed two clinical Phase II for the treatment of community-acquired pneumonia (CAP) and diabetic foot infection (DFI)

China Antibiotics Sales in 2015
79.7B (RMB)

Quinolone
6.4B (RMB)

Source: 2015 IMS
Sales Trend of Two Competing Quinolones in China

Unit: Million RMB

Avelox (Bayer)  Lai Li Xin (ZXC)  Source: IMS
Successful Model for other Pipeline Products

The experience gained will be used in the development and registration of TaiGen’s pipeline

- Nemonoxacin – IV formulation
  - Quality protocol Clinical trials
  - Execution speed of Clinical Trials
  - Efficacy of Clinical Trials
  - NDA submission
  - NDA license of IV formulation

- Burixafort
  - Mobilization for Stem Cell Transplantation
  - Chemo sensitization
  - Regenerative medicine

- TG-2349 (Furaprevir)
  - Market potential for China HCV Market
  - High Demand in China
  - All-oral dosage for HCV developed by Chinese
  - Acquired CFDA Priority review
HCV Market in China

Market share of domestic Chinese companies will surpass MNC in 2026

MNCs  Local Companies

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<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
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Source: IMS consulting
HCV Market in China

Domestic companies will account ~2/3 of CNY 28.3B HCV market by 2030

Unit: billion CNY

Source: Patients pool predicted by IMS consulting,
Significance of Nemonoxacin China Drug License

1. Built a reputation and brand value of TaiGen and its products in the market
2. Attested the high quality and standard of TaiGen’s clinical development team
3. Established an NCE development platform to facilitate the development of other products
4. Create a solid foundation for our existing and future partners
   • Zhejiang Medicine/Mainland China
   • R-Pharm/Russia, Turkey, and Commonwealth of Independent States (CIS)
   • Holding Disp./Taiwan (the first market launched)
5. Sustainable partnership with local and international companies
Thank you

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