JAPAC ADVISORY BOARD BIOSIMILARS MEETING REPORT

Intercontinental Seoul Coex

Seoul, South Korea

24 November 2013

PhAMA

1ST NATIONAL BIO-THERAPEUTICS

JAPAC Biotherapeutics Advisory Board Objectives

- The JAPAC Advisory Board on Biosimilars brought together physicians from Asia Pacific countries across different specialties to provide expert opinions on the use of biosimilars.

- Topics discussed and feedback obtained included:
  - Regulatory approval
  - Nomenclature
  - Pharmacovigilance
  - Indication extrapolation
  - Education programs

- Assessment of impact of biosimilars on treatment approaches

JAPAC Advisory Board Participant Advisors:

Tang Ching Lau	Singapore
Khoon Lin Ling	Singapore
Masayoshi Harigai	Japan
Kazuhiko Yamamoto	Japan
Yashiki Takura	Japan
David Wilking Nicholls	Australia
Howard Lee	South Korea
Daniel Wai Tho Ching	New Zealand
Rong Mu	China
Lau Ing Soo	Malaysia
Ping Nigh Hsu	Taiwan

Executive summary

- The advisory board members suggested that both clinical efficacy and safety of biosimilars demonstrated in head-to-head comparative studies with the innovative product would be important considerations for clinical use.
- Local clinical data on biosimilars would also be necessary due to the differences in environmental and genetic factors among different countries.
- Most members did not totally agree with indication extrapolation based on mechanism of action and clinical data in the most sensitive population. The mechanism of action of TNF blockade is not fully understood across all indications.
- Safety profiles and the development of anti-drug antibodies in different disease conditions are the major concerns when extrapolating to a different indication.
- In most countries, both generic and brand names are used for prescription. Most members suggested that a unique naming system is required for biosimilars for easier tracking and adverse event reporting.