F5: Advancing Patient Access to Innovative Health Technologies In Asia – The Role of Real-world Data in the Value Framework

- **Moderator:**
  - Boxiong Tang, PhD, Senior Director, Global Health Economics and Outcomes Research (GHEOR), Teva Pharmaceutical, USA

- **Speakers:**
  - Larry Liu, PhD, MD, Executive Director, Merck, USA
  - Jianwei Xuan, PhD, Professor and Director, Health Economic Research Institute, Sun Yat-sen University, China
  - Sang-Soo Lee, PhD MBA, Director, Corporate Affairs, Medtronic Korea, Korea
  - Makoto Kobayashi, PhD, Director and Chief Operating Officer, CRECON Medical Assessment Inc., Japan

**Agenda**

- **Introduction**
- **Project 1:** Landscape Evaluation of Real World Data in Asia
- **Project 2:** New Trends of HTA Development and Value Evidence Requirement for Access and Reimbursement in Asia
- New Development and updates from Japan and Korea
- **Summary**
Project 2
New Trends of HTA Development and Value Evidence Requirement for Access and Reimbursement in Asia

• Project Leaders: Larry Liu, Hong Li, Boxiong Tang
• Team Members:
  – Jianwei Xuan, Dong Peng, Ruoyan Gai, Makoto Kobayashi, Sang-Soo Lee, Jun Su, Bruce Wang, Eugene Salole, Hongye Wei

Project 2: Objectives and Approaches

Objectives:
• Collect information on HTA value evidence requirements for selected countries in Asia-Pacific.
• Assess current HTA status in selected countries in Asia-Pacific and the trend in five years.

Approaches:
• Conduct a literature review and baseline evaluation
• Collaborate with ISPOR regional chapters for researching country-specific HTA status and trend
• Partner with organizations such as HTAi Asia Policy Forum and HTAsiaLink.
Project 2: Methods, Deliverables and Timeline

Methods
• Define the scope of the work: HTA definition and aspects to be included
• Focus on selected countries – group by cluster: countries implemented HTA already, in process (HTA as optional tools), or within five years
• To interview and get inputs from some KOLs, government agencies if possible

Deliverables
• Summary report, with a brief summary of HTA status in Asia (see Table 1)
• One-page summary of HTA in each of the selected countries (See Table 2)
• ISPOR Asia Consortium newsletter update, an abstract for a workshop, forum, or a manuscript.

Timeline
• Initial literature review completed by May 18, ahead of ISPOR Baltimore
• Summary report on detailed findings completed by August 2018, ahead of ISPOR Asia Pacific 2018
• Abstract drafted by October 2018
• Paper completed by December 2018

Project 2: Table 1

<table>
<thead>
<tr>
<th>Country</th>
<th>Current HTA</th>
<th>HTA trend (included in reimbursement decision)</th>
<th>Value evidence requirement-RCT, RWE, ICER</th>
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<tbody>
<tr>
<td></td>
<td>Clinical effectiveness</td>
<td>Cost-effectiveness</td>
<td>Budget impact</td>
</tr>
<tr>
<td>Australia</td>
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<td>Vietnam</td>
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### Project 2: Table 2 (Australia as example)

<table>
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<tr>
<th>Government Agency</th>
<th>Pharmaceutical Benefits Advisory Committee (PBAC)</th>
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</table>
| **Assessment process** | PBPA pricing based on comparative cost-effectiveness  
Cost-plus methodology for drugs with incremental benefit  
Reference pricing for drugs considered “therapeutically similar” |
| **Value Evidence requirements** | Safety, quality, and efficacy by the Australian Drug Evaluation Committee (ADEC) of the Therapeutic Goods Administration (TGA).  
Cost and cost-effectiveness evidence |
| **Review committee** | PBAC funding recommendation based on input from Economic Sub-Committee (ESC) and Drug Utilization Sub-Committee (DUSC) |
| **Decision process** | Pharmaceutical Benefits Scheme (PBS), and the Pharmaceutical Benefits Advisory Committee (PBAC) advisory panel based on cost-effectiveness and budget effects. PBAC also evaluates new vaccines to be included in the National Immunisation Programme.  
Drugs listed on the PBS fall into three broad categories: unrestricted, restricted, and authority required benefit products |
| **Timeline** | Minimal 5 months. Average time to decision 182 days (SD 367 days) |
| **ISPOR contact** | |