「日本発のシーズを迅速に実用化する為にアカデミアが果たすべき役割」

早期臨床試験

Collaboration with Academia
-For early clinical development-

ファイザー株式会社
クリニカルリサーチ統括部
オンコロジー疾患領域部

廣橋 朋子
Objective

• To propose a new collaboration model between academia and industry in drug development of academia discovered seeds.

NOTE: The content of my presentation comes from my personal experiences
Open innovation

Closed innovation

Open innovation

Revenue

Long product life
Differentiation with the competitor

Internal research cost

External Collaborative cost

Revenue

Internal research cost

Issues of open innovation in Japan

For industry (esp. J-subsidiary of global com.)
- Less effort for collaboration with academia
  - Because HQ already has the function or system/process
  - But open innovation is not a process, but comes from “WILL”
- Lack of knowledge about basic science
- Less experiences to evaluate academia discovered seeds

For academia (not only Japan, but also US)
- Little know-how about marketing strategy, clinical development strategy, regulatory strategy

For academia and industry (not only Japan, but also US)
- Overly protective of their/our science
- Lack of relationship, reliance

* Academia includes venture company
Solutions

New Role

New competency

New way of thinking
New Role
The timing of hand-over from academia to industry

Preclinical

Phase I

Phase II

Phase III

After POC is established

<Industry>
Demerit: Lots of competitors
Merit: High success rate of launching

<Academia>
Demerit: Need more resource and funds
Merit: Develop based on the founder’s concept
New role of academia and industry in drug development of academia discovered seed

- **Role of Academia** –
  - Basic science
  - Innovation
  - Translational research
  - Early development as investigator initiated trial

- **Role of Industry** -
  - World wide expansion
  - Use internal network, experiences and knowledge
  - Regulatory strategy
  - Marketing strategy

POC
Expectations of academia driven clinical development

- Develop therapies for rare diseases
- Leader of clinical development for next generation therapies
  - New innovative technology
  - New therapeutic concept
New competency
Assessment points for buy-up of academia discovered seeds by industry

- **Overall research/clinical development plan**
  - POC data is reliable
  - No additional study/research is required
  - Any advantage over the competitors

- **Intellectual property**

- **Market**
  - Enrich the pipeline
  - Potential indication expansion
  - No critical obstacle to expand to other countries

- **Regulatory Strategy**
  - No critical regulatory issues

**Reliability of POC data**
What is reliable POC data?

- No critical issues of CMC
  - If there is, POC study should be repeated
- Scientific rationale of POC establishment
  - Adequacy of comparator
  - Adequacy of efficacy assessment method
    - RECIST or other appropriate criteria
- Quality of data
  - Data management concept/system is applied
- No critical GCP issues

NOTE: These are not mandatory criteria.
Based on these points, the company will evaluate the seeds.
Proposal of new competency for academia

Adapt to an *industry-like approach* of drug development plan

- Research/clinical development plan
  - Market potential
  - Regulatory Strategy

- The seeds from industry and academia will be reviewed based on the same review points.
- This competency will lead to *meaningful dialogue* with industry and to *successful partnership*.
Proposal of new competency for the company (Japan subsidiary)

1. Improve knowledge of basic science
2. Understand the company policy

- Capability of understanding the quality of the underlying hypothesis/discovery/science
  - Discussion between Japan subsidiary and academia sometimes works effectively and leads to successful collaboration (for global company)
- Avoid unnecessary approach
Where company policy is written?

Each company may have particular areas of interest for collaboration with an external partner.

Approach to the appropriate partner is the fastest way.

http://www.pfizer.com/partnering/areas_of_interest/research_and_development.jsp

Anti-Cancer Symposium Poster Nov 18, 2011
New way of thinking
(new approach)
Proposal of new way of thinking (1)

Knowledge transfer

• Mini-trial inspection or site visit
  – Regulatory strategy (CMC, GLP, GCP)
• Mini-consultation
  – IP assessment
• Mini-consortium
  – Lecture exchange
    • Development plan, market strategy
• Routine interaction

Establish reliance
Proposal of new way of thinking (2)

Resource sharing

• Human resource sharing
  – Academia-Industry
    • Company employee can be a member of academia project
  – Academia-Academia
    • Make up for deficient resources each other

• Partnering/Team research (Function sharing)
  – One company – multi sites of academia
  – Multi-company – multi sites of academia
  – Not much focus on who should do what,

But “What skills should be brought to the table?”
Summary
For a development of academia discovered drug

• **New role** of academia
  – Leader of basic science, translational research and early development
  – Develop therapy for rare disease
  – Leader of development for next generation therapies

• **New competency**
  – Academia: Adapt to an industry-like approach of drug development
  – Industry: Capability of basic science and review of seeds

• **New way of thinking**
  – Knowledge transfer
  – Resource sharing

Develop new model from seeds to the market
Thank you for your attention!
ご静聴ありがとうございました。