

VACEPYLORI

A Novel Vaccine Platform for Peptic Ulcer and Gastric Cancer

AIM

VACEPYLORI is a novel vaccine platform for peptic ulcer and gastric cancer by targeting chronic *Helicobacter pylori* infection

BACKGROUND

Helicobacter pylori is a Gram-negative bacteria that chronically colonizes human stomach. *H. pylori* infection is mainly acquired in childhood and usually persists for life within the gastric mucosa. Epidemiologically, there is a huge variation in the prevalence of *H. pylori* infection among different geographic, socioeconomic, cultural, and racial groups. According to World Health Organization (WHO), *Helicobacter pylori* infects approximating 50% of the population worldwide.

H. pylori infection is associated with gastritis, peptic ulcer diseases (gastric or duodenal ulcer), atrophic gastritis, mucosa-associated lymphoid tumor lymphoma, or gastric cancer. Chronic *H. pylori* infection is the most common cause of ulcers of the stomach and duodenum, accounting for up to 80% of gastric ulcers and 90% of duodenal ulcers. Ulcers can be resulted from stress, too much acid, or some medications, but the most common cause is *H. pylori* infection. The lifetime prevalence of peptic ulcer diseases is 8-14% in the United States. Every year in the U.S., there are approximately 500,000 new cases and 4 million recurrent cases of peptic ulcer diseases. In 2004, there were about 1 million ambulatory care visits and hospital discharges with peptic ulcer as the first-line diagnosis and an equal number in which it is a secondary diagnosis. The annual prescription expenses for peptic ulcer disease are more than \$500 million in 2004, plus other direct and indirect costs.

As a definite causative factor, *H. pylori* has been classified as a class 1 carcinogen of gastric cancer by the World Health Organization (WHO) in 1994. Most infected humans remain asymptomatic; 10% will develop peptic ulcers, and about 1% will develop gastric cancer.

CURRENT TREATMENT

Antimicrobial eradication of *H. pylori* has been proved to facilitate the healing of peptic ulcer and prevent the development of gastric cancer. Because of the high prevalence of *H. pylori* infection, however, it is not feasible to conduct generalized *H. pylori* eradication in the population. Additionally, the efficacy of *H. pylori* eradication has to be evaluated carefully due to the increasing antimicrobial resistance and a high recurrence of *H. pylori* infection after successful antimicrobial eradication (10-30 % of reinfection within 3-6 years).

VACCINE DEVELOPMENT

H. pylori vaccination has the most potential as preventive and therapeutic modality. However, there is no *H. pylori* vaccine on the market.

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BTBA



Overview

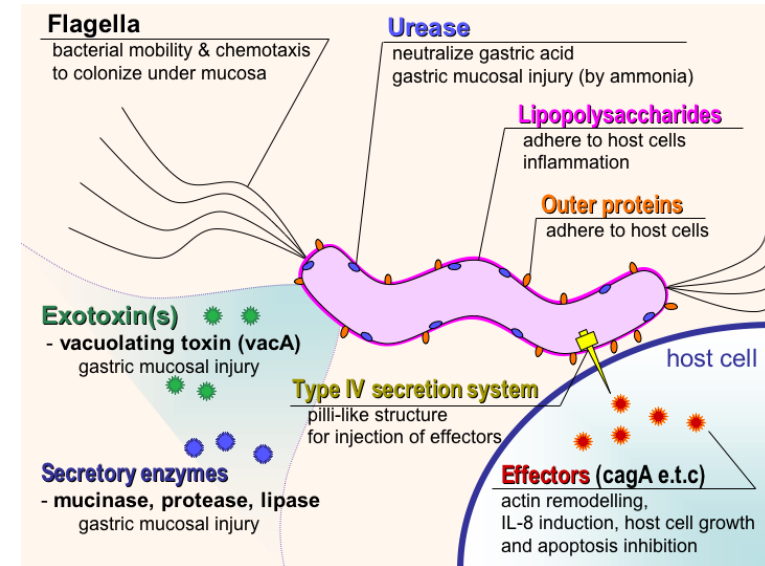


VACEPYLORI

- We are establishing a novel vaccine platform
- We will develop a vaccine for *Helicobacter pylori* (*Hp*)-associated peptic ulcer and gastric cancer and license technology for other indications.
- >\$1B market opportunity worldwide
- \$54M to get through Phase I *Hp* clinical trials

Technology

- Novel mucosal vaccine platform for *Hp* prevention and eradication
- Rational design of vaccines
- Provisional patent filed



Rational Mucosal Vaccines



- **Mucosal** vs. Injection
 - More robust mucosal immunity
 - Lower cost
- **Rational** vs. Selection
 - Less costly
 - Quicker to produce
 - Reproducible manufacturing

Helicobacter pylori (Hp)

- *Hp* is the **primary cause of gastritis, peptic ulcer and gastric cancer**

>50% population worldwide infected (*Hp*+) → gastritis

10% *Hp*+ → peptic ulcer ¹

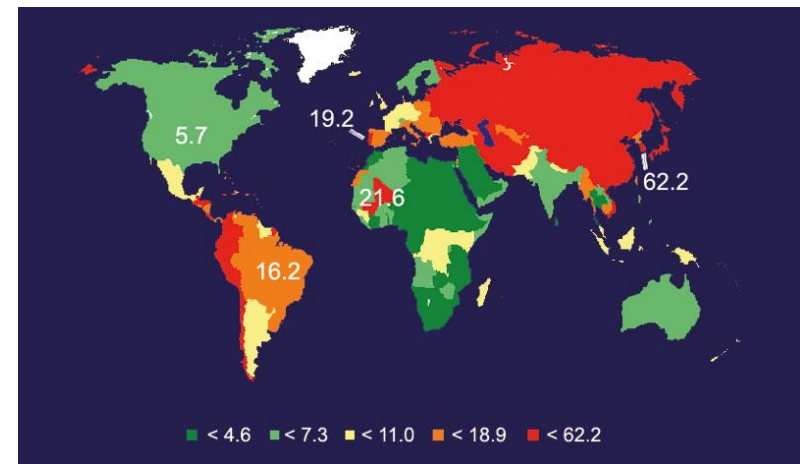
500 K cases/year in US

\$10 B direct and indirect cost

1% *Hp*+ → gastric cancer ²

0.95 M cases/year worldwide

12 K cases/year in US



1. CDC 2010 http://wwwnc.cdc.gov/eid/article/16/9/09-1126_article

2. WHO database <http://www.pubcan.org/printicdotopo.php?id=3652>

Hp Market



Market:

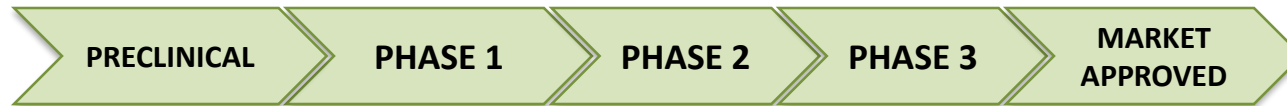
- 4 M/yr births in the US
- 500 K/yr adult peptic ulcer in the US
- 350 M/yr peptic ulcer worldwide
- $\$10 \times (4 \times 90\% + 0.5 \times 50\% + 350 \times 50\%) =$
\$1.79 B/yr market

Current Standard of Care



- No vaccine currently exists
- Antibiotic *Hp* eradication requires combination of 2 or more antibiotics
- Increasing drug resistance ¹
- Significant side effects (nausea, diarrhea, disturbance of gut microbiome)

Competition



Whole
inactivated



Recombinant

Wuhu
Kangwei



VACEPYLORI

Technology Advantage:

- Rational design
- Mucosal delivery

Team

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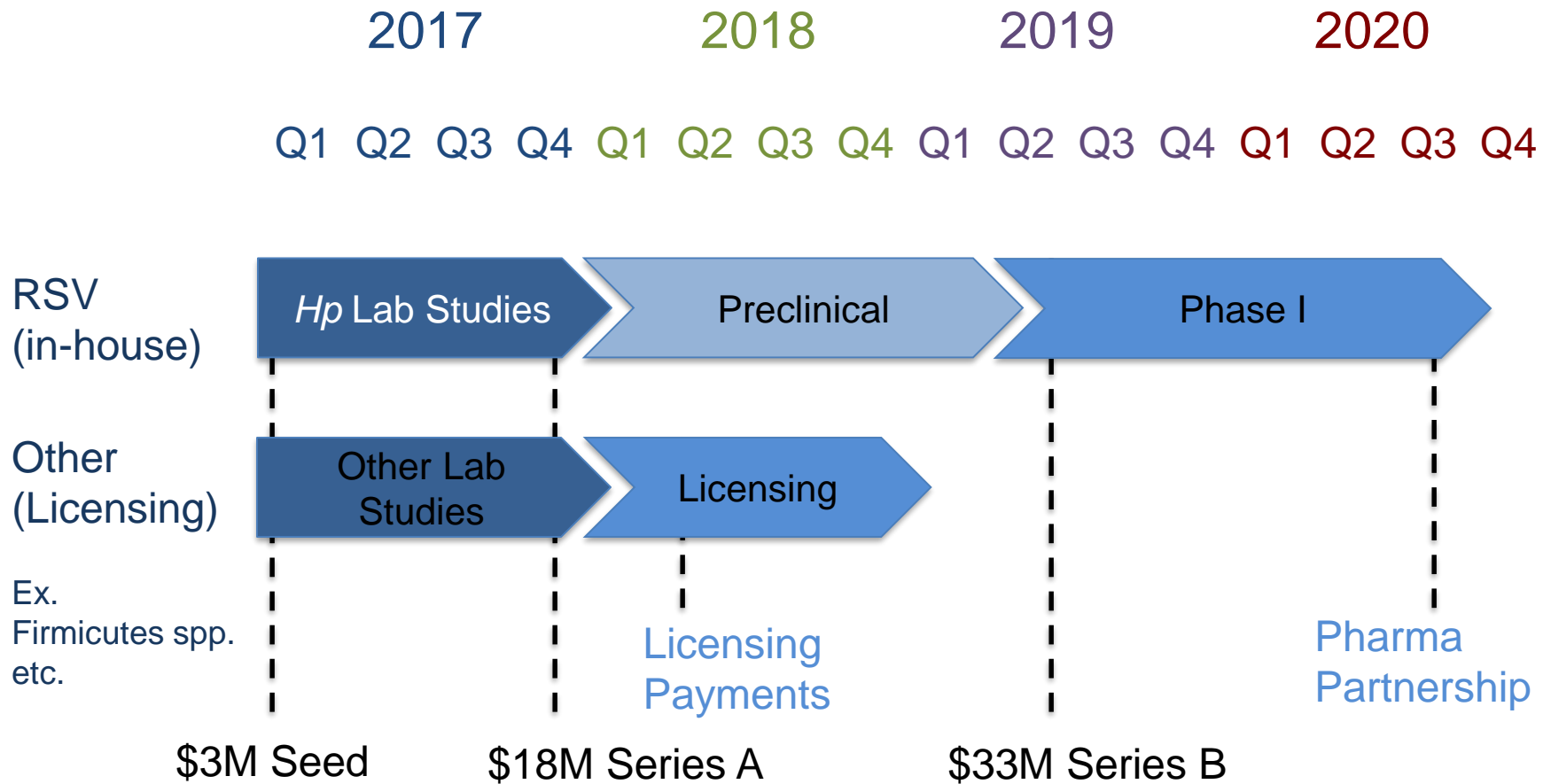
- Chung-Wei Lee, MD, PhD, Microbiology, Immunology
- Howard G. Fass, Business Development

Medical/Regulatory



- BLA (Biological License Application) after Phase 1-3 Clinical Trials in US, EU approval next
- Expect vaccine to be **fully reimbursed** after seeking ACIP (Advisory Committee on Immunization Practices) approval and addition to **standard immunization schedule**
- First: clinical trials for adults
- Second: clinical trial for infants

Timeline



Conclusion/Next Steps



- Next Steps:
 - Assemble world class SAB and BOD
 - Generate in-vivo data for *Hp*
 - Expand and strengthen IP coverage
 - Initiate licensing discussions with potential partners for applications outside of *Hp*
 - Raise seed round



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THANK YOU!