



## Media Release

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### **Australian Nobel Prize winner closer to delivering vaccines in food after positive first study in humans**

The Australian scientist who won a Nobel Prize for identifying a cancer-causing stomach bacterium, today said a clinical trial had shown that some strains of the bacteria (*Helicobacter pylori* or *H. pylori*) were safe and well tolerated in humans.

Dr Barry Marshall said the results, released at the 5th World Vaccine Congress Asia in Singapore, "...demonstrated that some strains of *H. pylori* are well tolerated in humans and can provide an oral delivery platform for vaccines and biologics."

The data also showed Dr Marshall and colleagues at Ondek Limited, which strains of the unique bacteria had the most benign effect on the human stomach while still inducing an immune response.

Dr Marshall said the positive results would now see Ondek move to seek approval for another round of clinical trials in which a flu virus gene would be attached to the bacteria.

Ondek wants to revolutionise the multi-billion dollar global vaccine industry by providing a simple oral delivery mechanism for vaccines that can protect against common diseases and be produced, stored and distributed faster and more cheaply.

It could make having an annual flu shot as painless as downing a spoon of yoghurt.

Researchers at Sir Charles Gairdner Hospital in Perth gave several strains of *H. pylori* to 30 healthy adults to see how their immune systems responded. The trial had three primary endpoints:

1. Colonization rates (the ideal strain must colonize humans)
  - a. High colonisation rate for all selected Ondek strains
  - b. 3 strains are persistent colonisers
  - c. 2 strains are transient colonisers
2. Safety profile (the ideal strain must have minimal side effects)
  - a. Generally mild symptoms overall
  - b. 2 strains showed very little / no symptoms
  - c. 1 strain showed mild symptoms
  - d. 2 strains associated with clinically significant gastric symptoms
3. Immunogenicity profile

- a. All strains induced systemic and mucosal immune responses, sufficient to support a vaccination strategy.

While *H. pylori* stimulate the body's immune system to produce antibodies, the bug is capable of evading immune clearance and continues to reproduce in the lining of the stomach.

Ondek plans to use this natural activity as a way of stimulating the human immune system to produce antibodies against diseases such as influenza, where specific antigens can be attached to the *H.pylori* bacteria by genetic engineering techniques in the Ondek labs.

Ondek plans to use this unique approach to develop food-like vaccines that activate an immune response in the body to fight diseases like swine flu, malaria, cholera, hepatitis B and even HIV. The platform could also be used to deliver hormones and immune modulators.

Dr Marshall was awarded the 2005 Nobel Prize in Physiology or Medicine along with his research partner Dr Robin Warren.

### **Global market background**

Dr Marshall said the global vaccine market was driven by the need to cut the time and cost of making large amounts of vaccines in the face of any potential pandemic.

Current vaccine production methods are expensive and limited by time, volume and capacity. The effectiveness of each new vaccine is also reduced over time due to the changing nature of different viruses.

Governments worldwide spend billions of dollars every year to stockpile drugs and promote pandemic readiness with the global market for vaccines estimated to be worth up to US\$40 billion in 2010, according to *Pharmaceutical Technology Europe*.

Influenza already causes 3 to 5 million cases of severe illness each year and up to 500,000 deaths worldwide. The World Health Organisation (WHO) has estimated the annual cost of influenza epidemics to the US economy at up to US\$167 billion.

About half of the world's population is infected with the *H. pylori* bacteria, according to the World Health Organisation (WHO). Most people carry the bug without developing symptoms yet it is also the main cause of gastric ulcers and stomach cancers in persons who carry it for 10 and 50 years respectively. Modern science has detected the bacterial factors which cause this risk so that they can be modified or omitted in vaccine strains as required.

For more information please contact:

Peter Hammond  
Chief Executive Officer  
Tel: (02) 9332 0600

Tim Allerton or Andrew Geddes  
CityPR  
Tel: (02) 8916 4848

### **About Ondek**

Ondek Pty Ltd is an Australian biotechnology company developing a novel vaccine and drug delivery platform, based on its patented "*Helicobacter pylori* Platform Technology" (HPPT).

The platform utilises the unique characteristics of a genetically modified *Helicobacter pylori* bacterium to deliver a diverse range of therapeutics to the patient, including vaccines or other biologicals. Ondek was founded by Professor Barry Marshall, a world authority and co-discoverer of the *Helicobacter pylori* organism and co-recipient of the 2005 Nobel Prize for Medicine and Physiology. [www.ondek.com](http://www.ondek.com)