

## ASX Announcement and Media Release

Thursday 6 February 2003

SciGen Limited - ASX Code: SIE

### SCI GEN RECEIVES REGISTRATION FOR NEW HEPATITIS B VACCINE IN HONG KONG

SciGen Limited ("SciGen") today announced the registration of **Sci-B-Vac**<sup>TM</sup> its new 3<sup>rd</sup> generation mammalian cell-derived Hepatitis B vaccine in Hong Kong. This new Hepatitis B vaccine aims to control the spread of the Hepatitis B disease in Hong Kong, and thereby reduce its associated morbidity and mortality. Chronic Hepatitis B infection can cause liver cirrhosis and liver cancer.

Mr Mark Compton, Managing Director and CEO of SciGen said that "**Sci-B-Vac**<sup>TM</sup> is the principal product in SciGen's portfolio and that its registration in Hong Kong is a very important milestone in the vaccine's commercialization journey".

The incidence of Hepatitis B in Hong Kong is around 10% and the government is increasing its focus on immunisation programs including the prevention of Hepatitis B. Hong Kong already has an immunisation schedule advising Hepatitis B immunisation from birth.

"Prevention against Hepatitis B infection is not only important for newborns, but also adolescents, adults, healthcare workers, sex workers and anyone involved in "at risk" activities" Mr Compton said

**Sci-B-Vac**<sup>TM</sup> has already been launched by SciGen in Vietnam (December 2002) and in the Philippines (January 2003).

SciGen will launch sales of **Sci-B-Vac**<sup>TM</sup> in Hong Kong as soon as practicable now that the product has been registered. Registration is for the 2.5mcg and 10mcg presentations, with registration for the 5mcg presentation expected to follow. The estimated market for Hepatitis B vaccines in South East Asia is estimated to be in the order of \$US350 million.

Registrations for other of SciGen's products such as recombinant human insulin are in train in a number of other countries in the region including India. SciGen already generates sales from its recombinant human growth hormone (**SciTropin**<sup>TM</sup>) in five countries in the Asia Pacific region using its own sales and marketing infrastructure. SciGen has offices and sales teams in Singapore, Australia, Philippines, Hong Kong, Korea and Vietnam and works with strategic partners in India.

### About SciGen

---

SciGen Ltd is a progressive biotechnology/biopharmaceutical company involved in co-developing and marketing genetically engineered biopharmaceutical products for human healthcare. SciGen focuses in the areas of gastroenterology, endocrinology and immunology. Its product portfolio includes vaccines and therapeutics.

SciGen has acquired the rights to manufacture, distribute and market biopharmaceutical products under exclusive licensing arrangements. SciGen's portfolio currently includes proprietary biotechnology-derived products, and biogeneric products, which allows for faster entry into the

market, as the biogeneric products have undergone much of the clinical development and trials required to bring new drugs to market. This minimises the risks associated with early stage product development. SciGen currently undertakes R&D activities in collaboration with strategic partners and institutions.

SciGen's major strength lies in its ability to recognise the potential of new products in their early stages of development. Through joint collaboration with its strategic partners, SciGen uses its extensive expertise in regulatory and clinical environments, in conjunction with marketing and promotional infrastructure, to bring to market products which will have significant long-term benefit.

SciGen's business was established in 1988. SciGen is a Singaporean biotechnology company, publicly listed on the Australian Stock Exchange (ASX code SIE). SciGen's headquarters is in Singapore and it also has offices in Australia, USA, Korea, Vietnam, Hong Kong and Philippines.

=====**ENDS**=====

## **Media enquiries**

Mark Compton

Managing Director & CEO

Telephone: +61 2 9234 1700

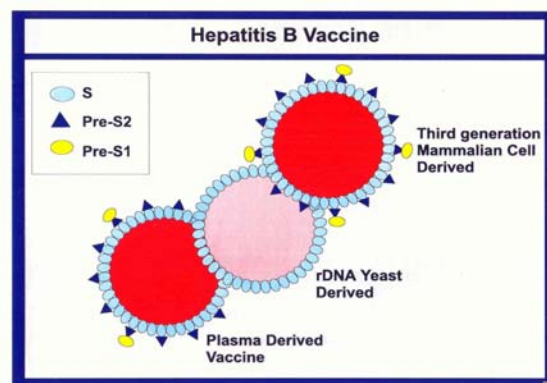
Web: [www.scigen.com.au](http://www.scigen.com.au)

## How Sci-B-Vac™ works

**Sci-B-Vac™** is a third generation vaccine, derived by genetically modifying the Chinese hamster ovary cells with DNA sequences coding for the three surface proteins of the Hepatitis B virus (HBV). These contain the S, pre-S<sub>1</sub> and pre-S<sub>2</sub> epitopes, which act as markers on the surface of the HBV. Therefore **Sci-B-Vac™** resembles the authentic virus, without containing the infective DNA. When the vaccine is injected into a patient, the patient's immune system recognises the S, pre-S<sub>1</sub> and pre-S<sub>2</sub> epitopes and produces antibodies specific for the HBV. These antibodies remain in the body, and immunise the patient against future infections by the virus.

**Sci-B-Vac™** is superior to other Hepatitis B vaccines. The commonly used yeast-derived vaccine has only the S epitope. In comparison **Sci-B-Vac™** has the S, pre-S<sub>1</sub> and pre-S<sub>2</sub> epitopes. Research shows that the presence of these three epitopes in a vaccine will stimulate a high cellular response and increase the antibody levels. These antibodies promote viral clearance and prevent hepatocyte (liver cell) binding. The overall result is a vaccine that is more immunogenic and efficient.

In addition, as **Sci-B-Vac™** contains all three epitopes, it will overcome cases where patients' immune systems may not respond to the S antigen alone. Another commonly used vaccine is the plasma-derived vaccine. While this



type of vaccine contains the three epitopes, it also contains disease-causing DNA viral material, which may compromise the vaccine's safety. As **Sci-B-Vac™** is not derived from plasma, it does not have this problem.

### Clinical Benefits of Sci-B-Vac™

**Sci-B-Vac™** has a number of clinical advantages over current Hepatitis B vaccines, including:

- Faster onset of action - **Sci-B-Vac™** shows earlier seroconversion (presence of antibodies in the patient) and seroprotection (having sufficient antibodies present to protect the patient from the disease)
- Higher level of Hepatitis B antibodies
- Highly immunogenic and effective at low doses
- Offers protection to neonates (newborns) whose mothers are HBV carriers

With these superior characteristics, **Sci-B-Vac™** is set to make a positive impact upon the prevention of the Hepatitis B in the Asia Pacific region.