

New HIV Hope

Promising results across US & Mexico trials

Australian Company Offers Four Guardians Life Sciences Offers

New Hope for the People Facing Death,

In Mexico and the US.

With a growing Mexico HIV population of 200,000 and in the US, the CDC estimates one in every 52 Hispanics/Latinos out of 48.4 million will be diagnosed with HIV in their lifetime.

John Majewski, retired Founder & CEO of Narhex Life Sciences Limited ("NLS"), has negotiated an exclusive technology license from NLS for the territories of Mexico and the USA with the intention of registering Australia's first New generation small molecule boosted protease inhibitor treatment for people living with HIV in those regions, through a new corporate entity, Four Guardians Life Sciences ("Four Guardians")

John's clear objective is one of creating a profitable company that can grow to save human life. The company's strategy to introduce a new generation boosted small molecule protease inhibitor combination treatment, for a market that until now receives older generation antiviral treatments that are no longer the physician's choice in the more lucrative western markets. John views this approach as possible game changer for second world countries like Mexico who need first world antiviral treatments but cannot afford western pricing.

Under John's direction until his retirement in 2005 the Narhex Life Sciences undertook ongoing research programs for the development of this new generation protease inhibitor and successfully completed Phase I and Phase IIa clinical trials programs. The reason he has now negotiated an exclusive technology license is because of two significant milestone advances subsequently made by NLS with this new generation protease inhibitor, and the significant support he has received from his Mexican CRO partner and the Mexican Ministry of Health;

The costly & complex scale up solutions required to move from laboratory bench chemistry syntheses to producing Clinical trial drug in large commercial batch GMP manufacturing has been completed.

Proving up in second Phase I clinical trials a combination of this protease inhibitor into a booster drug with significant reduced pill burden as a result of a possible 70% reduction in daily dosage amount.

Mexican Ministry of Health Registration (MoH), means a far less clinical trial cost to MoH registration translating to a much shorter time to market.

By following the same path as used by the big Pharmaceutical companies (*1), Four Guardians plan is to complete the remaining Phase IIb/III clinical trials with its appointed Mexican CRO drug registration partner, in order to register with the Mexican Health Department (MoH), a new generation "boosted" protease inhibitors requiring dosage only once or twice a day. This reduces pill burden and lessens side effects including lipid and metabolic disturbances.

The Mexican Ministry of Health reviewed the clinical data second Phase I clinical trial results in testing an improved enteric coating dosage formulation and earlier Phase I/IIa clinical trial results. Four Guardians Clinical Research Organization (CRO) has, with involvement from the Mexican health department, submitted a Phase IIb & III clinical trial program and budget plan that will combine both clinical trials into one thus shortening time to market to an estimated two and a half years.

On achieving registration in Mexico the company's objective to grow to service around 60,000 patient's annual treatment across the Mexican and cross boarder US markets achieving an estimated annual income in excess of US\$150 million within the first few years commencing operations.

Four Guardians is seeking to raise US\$8.0 million through issuing seed capital to suitable investor groups to fund completion of fast track Mexican clinical trials, drug registration and initial commercialisation.

This is compared to a cost of circa US\$80 million and a time in excess of five years if the company's strategy was to attempt securing the same drug registration with the US FDA.

Mexican and US Hispanics/Latinos HIV population – Datamonitor (US) estimates that the current generation of Protease Inhibitors ("PI") account for 25% or US\$1.5 billion of all HIV antiviral sales. Currently the available large Pill burden, however of the older 1st generation PI, has been an outstanding issue affecting the PI class. The frequency of dosage prescribed in second world countries not only affects patient quality of life and ability to adhere to their recommended regimen, but it also continually reminds them of their condition.

In the US the average annual wholesale cost of treatment for the commercially available for 1st world class protease inhibitors is in the range of US\$5,000 to US\$45,000 per patient. This opens up an opportunity for small Biotech companies like Four Guardians Life Sciences Limited to replace old PI's markets with the latest boosted combo Protease Inhibitor treatment offerings that are still very profitable but more affordable.

Mexico and the USA Latin market represent an excellent opportunity to service a large and mostly forgotten anti-HIV/AIDS market. The 2008 USAID/Mexico estimated an HIV population of about 200,000 (150,000- 310,000). Then there is a larger more affluent Latin market of cross boarder patients looking for less expensive protease inhibitor booster drugs from North America and Latin America with a total HIV population of about 2.9

million.

Cross-border population mobility is also a factor in HIV/AIDS transmission in Mexico, including immigration from Central America and the influx of those returning from migrant work in the United States, has contributed to the spread of the epidemic, particularly in rural parts of the country. (USAID) USA Hispanics/Latinos population is 48.4 million (US Census Bureau July 2009) Hispanics/Latinos are also disproportionately affected by the AIDS epidemic in America. It is estimated that 1 in every 52 = 930,000 Hispanics/Latinos will be diagnosed with HIV in their lifetime.

In New York City, where 40% of all households are made up of Latinos born outside the US, the majority of health and civil society organizations cite a lack of bilingual and culturally sensitive HIV and AIDS services as a key obstacle to dealing with the city's epidemic. HIV was the fifth leading cause of death for Hispanics/Latinos aged 35–44 and the sixth leading cause of death for Hispanics/Latinos aged 25–34 in the US in 2007. (Source HIV & AIDS in America AVERT)

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References;

(*1) For large pharma registration strategies examples in Mexico MoH & FDA Drug Registration – see attachment.

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