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# PnuVax awarded \$29.4 million USD grant to advance innovative vaccine into clinical trials

- Pneumonia, one of the diseases caused by pneumococcal bacteria, is currently the leading single killer of young children worldwide, despite advances in prevention and treatment
- \$29.4 million USD grant from the Bill & Melinda Gates Foundation will advance vaccine's clinical development and biomanufacturing scale-up
- Novel low-cost approach that may lead to increased access to vaccine, with potential to save millions
  of lives

Kingston, Canada – 2 October 2017 – PnuVax Incorporated, an organization dedicated to the production of high quality vaccines and biopharmaceuticals for the promotion of public health worldwide, today announced that it is the recipient of a \$29.4 million USD (\$36 million CDN) grant. The grant will be used to further develop and clinically evaluate PnuVax's innovative pneumococcal conjugate vaccine. Milestone payments will be received over the next three years as the vaccine progresses from process development through to biomanufacturing scale-up and proof-of-concept clinical trials.

Despite the current commercial availability of pneumococcal conjugate vaccines, pneumonia remains the single leading cause of death for children under 5 years of age worldwide. "Children are still dying of preventable diseases such as pneumonia worldwide, largely due to high dosage costs and supply shortages that can thwart delivery to developing countries," said PnuVax Co-Founder Jonas Elliott Gerson.

PnuVax's vaccine provides coverage against multiple serotypes, or distinct variations, of the pneumonia-causing *pneumococcus* bacterium. Use of PnuVax's unique patented conjugation platform technology to produce the vaccine is expected to speed up biomanufacturing and increase yield for a greatly reduced perdose cost. PnuVax plans to manufacture its vaccine in Montreal, Canada using innovative methods to create a low-cost product to be distributed to the developing world via <a href="Gavi, the Vaccine Alliance">Gavi, the Vaccine Alliance</a> and <a href="Unicef">Unicef</a>, to the world's poorest communities, significantly increasing access.

"Creating a healthy marketplace for vaccines is crucial to our efforts to protect every child through immunization," said Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance, "That's why this grant to a potential new and innovative supplier is so important. Gavi has now helped 58 countries to introduce pneumococcal vaccine since our support started in 2009 and coverage is steadily increasing. This vaccine is at the forefront of our fight against pneumonia."

Donald F. Gerson, PnuVax CEO, said: "PnuVax is delighted to partner with the Bill & Melinda Gates Foundation to develop and evaluate this needed vaccine during our upcoming early stage clinical trials. Once licensed, this vaccine is expected to increase supply of low-cost pneumococcal conjugate vaccine on a global scale."

In addition to aiding the international community, PnuVax also intends to provide this vaccine to Canadians at a reduced cost, especially those in communities most in need. PnuVax Co-Founder Allison Turner said: "Pneumonia remains a significant problem in many of Canada's Northern communities<sup>1</sup> and one of PnuVax's specific objectives, in addition to serving the developing world, is to help reduce the incidence of childhood pneumonia in Canada.<sup>2</sup>"

PnuVax's platform technology can be used in the manufacture of vaccines for a broad range of infectious diseases. Prior to the current funding, PnuVax received two grants from the Bill & Melinda Gates Foundation for the pre-clinical development of their vaccine.<sup>3</sup>

- Respiratory disease in Canadian First Nations and Inuit children, <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3448538/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3448538/</a>.
- 2. PnuVax's large-scale biomanufacturing facility in Canada is fully equipped to produce large quantities of GMP material for both vaccines and therapeutic proteins. This is in line with <u>Government of Canada's partnership with the Gates Foundation</u> to move global health forward and the Gates Foundation and UN's \$2.3 billion USD <u>Muskoka Initiative</u>.
- 3. PnuVax received funding in 2014 from the Gates Foundation to develop a pneumococcal conjugate vaccine, to be manufactured at a significantly reduced cost. This funding was increased in 2015 to allow for continued product testing of PnuVax's vaccine.

#### **About PnuVax Incorporated**

PnuVax Incorporated is dedicated to the production of high quality vaccines and biopharmaceuticals for the promotion of public health worldwide. PnuVax's transformational approach is based on innovative and restructured conjugate vaccine development and manufacturing that is focused on high quality scalability, efficiency, high-volume production, and GMP compliance to produce affordable vaccines for children in lower income countries. For more information about PnuVax, visit our website at www.pnuvax.com.

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