

Sanofi initiates phase 3 program for PCV21 and expands collaboration with SK bioscience for next-generation pneumococcal conjugate vaccines

- Pneumococcal disease remains a major global health challenge despite the availability of current vaccines
- This 21-valent pneumococcal conjugate vaccine (PCV21) is the first pneumococcal conjugate vaccine candidate with more than 20 serotypes to enter phase 3 in infants & toddlers

Paris, December 23, 2024. Sanofi and SK bioscience have entered into a new chapter of their collaboration in pneumococcal vaccines with an expanded agreement to develop, license and commercialize next-generation PCVs for both pediatric and adult populations, reaffirming their commitment to fighting pneumococcal disease.

Despite decades of public health vaccination programs, invasive pneumococcal disease (IPD) continues to inflict a substantial burden of disease, primarily due to *Streptococcus pneumoniae* serotypes that are not included in currently available conjugate vaccines. Next-generation PCVs have the potential to extend vaccine coverage of disease-causing serotypes.

This expansion builds on the companies' existing collaboration to develop and commercialize a PCV21 pediatric vaccine, for which the phase 3 clinical program commenced last week. This vaccine candidate is the first-ever PCV containing more than 20 serotypes to enter a phase 3 clinical study in infants and toddlers.

Thomas Triomphe

Executive Vice President, Vaccines, Sanofi

"Given the vast unmet public health needs in IPD, we're delighted to expand this collaboration and continue our pursuit of innovative work in PCV. Our collaboration leverages SK bioscience's capabilities and Sanofi's expertise in developing and bringing innovative vaccines to people worldwide with the collective aim of reducing the global impact of pneumococcal disease."

Jaeyong Ahn

CEO and President of SK bioscience

"We're thrilled about the expansion of our collaboration with Sanofi, which serves as the core of our strategy to develop new solutions to combat pneumococcal disease. The ongoing expansion of our state-of-the-art manufacturing base, cofinanced by Sanofi, will support launch of PCV21 and future next generation vaccines."

The PCV21 phase 3 program is based on positive phase 2 results communicated last year and will include more than 7,700 infants, toddlers, young children and adolescents across multiple geographies, including the US, Europe, Australia, Asia, and Latin America.

Under the terms of their expanded agreement, both companies will co-fund research and development costs. Sanofi will pay EUR 50M upfront to SK bioscience, followed by development and commercial milestone payments. Once registered, Sanofi will commercialize the vaccines worldwide except for South Korea, where SK bioscience will have commercial exclusivity. SK bioscience will receive royalty payments on product sales outside South Korea.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across the world, is dedicated to transforming

the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on Euronext: SAN and Nasdaq: SNY

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