

Bharat Biotech to Advance Development of GSK's Shigella Vaccine Candidate for Severe Bacterial Diarrhoea

- Bharat Biotech in-licenses altSonflex1-2-3, a promising Shigella vaccine candidate, from GSK for continued clinical development and scale-up
- Shigella is the leading bacterial cause of diarrhoeal disease in children under five, with a significant impact in low- and middle-income countries
- Innovative Generalized Modules for Membrane Antigens (GMMA) technology and strong early trial results signal significant potential to reduce disease burden and address rising antimicrobial resistance (AMR)

**Hyderabad, India – 12 June 2025** – Bharat Biotech International Limited (BBIL), a global leader in vaccine innovation and manufacturing, today announced that it has partnered with GSK plc (LSE/NYSE: GSK) for the ongoing development and potential use of the Shigella vaccine candidate, altSonflex1-2-3. The agreement marks a critical step in the advancement of this promising vaccine, targeting Shigellosis—a severe form of bacterial diarrhoea that disproportionately affects children under five in low- and middle-income countries.

This collaboration reflects Bharat Biotech's continued commitment to global public health and equitable vaccine access. The in-licensed candidate, altSonflex1-2-3, has already shown encouraging results in early-stage clinical trials. A Phase 1 study conducted in Europe demonstrated a favourable safety profile and strong immune response. Subsequent Phase 2 trials in Africa, including vaccination of 9-month-old infants—the primary target population—reported no safety concerns. Interim results from 2024 confirmed that the candidate met its pre-set immunogenicity goals.

The altSonflex1-2-3 vaccine candidate, developed by GSK and now advancing through a strategic collaboration with Bharat Biotech, represents one of the most advanced Shigella vaccine candidates globally. With no licensed Shigella vaccine currently available and rising antimicrobial resistance, this candidate stands out for its broad serotype coverage, innovative Generalized Modules for Membrane Antigens (GMMA)-based platform, and robust early clinical results. It has already demonstrated a strong safety and immunogenicity profile in both European and African trials, including in the primary target population of 9-month-old infants. Now entering Phase 3 trials under Bharat Biotech's leadership, altSonflex1-2-3 is poised to become the first scalable, affordable, and globally accessible vaccine to combat this urgent public health threat.

GMMA technology is an innovative platform that uses bacterial outer membranes to deliver the O Antigen to the immune system. This novel approach allows for high-yield production with a simple and cost-effective manufacturing process, offering a pathway to create affordable vaccines for underserved populations.

**Dr. Krishna Ella, Executive Chairman, Bharat Biotech**, said, "As the market leader in vaccines for diarrhoeal infections, including rotavirus, typhoid, polio, non-typhoidal salmonella, cholera, and paratyphi, Bharat Biotech is proud to partner with GSK to develop a next-generation Shigella vaccine candidate, for a severe form of bacterial diarrhoea affecting millions of children under five. With no approved vaccine currently available and antimicrobial resistance on the rise,



there is an urgent need for scalable, science-backed solutions focused on low and middle-income countries. This collaboration combines our strengths in innovation, manufacturing, and global health commitment. The use of GMMA technology reflects our mission to deliver accessible vaccines that protect and improve lives worldwide."

As part of this agreement, Bharat Biotech will lead the further development of altSonflex1-2-3, including Phase 3 clinical trials, regulatory advancement, and large-scale manufacturing. GSK will continue to support the programme by assisting with clinical trial design, securing external funding, and contributing to the Access and Delivery Plans and commercialization strategy. GSK has an established relationship with BBIL, after signing a product transfer agreement for the world's first malaria vaccine, RTS,S, to the Indian Biotech company in 2021.

**Thomas Breuer, Chief Global Health Officer, GSK, said,** "With young children in lowerincome countries disproportionately impacted by *Shigella*, the development of a low-cost vaccine is an important goal for global public health. With no licensed vaccines widely available, the development of our *Shigella* vaccine candidate which has demonstrated promising clinical trial results, fills us with immense pride. We are proud to collaborate with Bharat Biotech, whose expertise in developing and supplying vaccines for infectious diseases, especially as a trusted supplier to Gavi, the Vaccine Alliance, and UNICEF, positions them to further advance this important work. This agreement allows us to combine our strengths in science, research, and technology with Bharat Biotech's capacity to develop and deliver vaccines at scale, potentially preventing illness and saving lives around the world."

Shigella is a major contributor to child morbidity and mortality, and the emergence of drugresistant strains underscores the urgent need for a preventive vaccine. By helping reduce illness and antibiotic use, this vaccine has the potential to play a critical role in combating antimicrobial resistance (AMR).

This collaboration reinforces Bharat Biotech's dedication to tackling neglected diseases through cutting-edge science and partnerships. The ultimate goal is to deliver life-saving vaccines to the people who need them most.

## About the vaccine candidate

GSK's vaccine candidate, called altSonflex1-2-3, combines *S. sonnei* with *S. flexneri* 1b, 2a and 3a O Antigens, has been designed by scientists in the Global Health team with the ambition to develop an affordable vaccine with broad protection against the most prevalent *Shigella* serotypes. The vaccine uses the GMMA technology (Generalized Modules for Membrane Antigens), a novel platform based on bacterial outer membranes for delivery of the O Antigen to the immune system. GSK's goal is to advance vaccine innovation against *Shigella*, contributing to the fight against antimicrobial resistance, which still causes millions of deaths worldwide.

## About Shigella

Shigellosis is an acute human inflammatory disease of the large intestine caused by Gram-negative Shigella. It is characterized by watery diarrhea, fever, abdominal cramps and pain, and bloody and mucus-filled stools. Humans are the only natural hosts for *Shigella*.



*Shigella* is a facultatively anaerobic, non-motile Gram-negative rod, from the family *Enterobacteriacae*. There are four different *Shigella* species: *S. dysenteriae*, *S. flexneri*, *S. boydii*, *S. sonnei*, divided into more than 50 different serotypes by the outer polysaccharide (O Antigen) of the lipopolysaccharide expressed on the bacteria surface. The prevalence of these serotypes varies by country economic status, between geographical regions and changes over time, even within one region, which has long presented a major challenge for vaccine development.

## **About Bharat Biotech International Limited**

Bharat Biotech has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 19 vaccines and four biotherapeutics, registrations in more than 125 countries, and the World Health Organization (WHO) Pre-qualifications. Located in Genome Valley in Hyderabad, India, a hub for the global biotech industry, Bharat Biotech has built a world-class vaccine & bio-therapeutics research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution. Having delivered more than 9 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis (JENVAC<sup>®</sup>), Rabies, Chikungunya, Zika, Cholera, and the world's first tetanus-toxoid conjugated vaccine for Typhoid.

Bharat's commitment to global social innovation programs and public-private partnerships resulted in introducing path-breaking WHO pre-qualified vaccines BIOPOLIO<sup>®</sup>, ROTAVAC<sup>®</sup>, ROTAVAC 5D<sup>®</sup>, and Typbar TCV<sup>®</sup>, combating polio, rotavirus, typhoid infections, respectively. HILLCHOL<sup>®</sup>, an oral vaccine against cholera, was launched in 2024. The RTS,S malaria vaccine is an ongoing partnership between GSK and Bharat Biotech. The acquisition of Chiron Behring Vaccines has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer with Chirorab<sup>®</sup> and Indirab<sup>®</sup>. To learn more about Bharat Biotech, visit www.bharatbiotech.com.

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## About GSK

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.