



Media Release

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Ad hoc announcement pursuant to Art. 53 LR

A factory in a lab: Idorsia's breakthrough synthetic glycan vaccine platform validated for the first time in humans

- Potential first-ever vaccine directed against *C. difficile* bacteria and spores induces positive antigen titers in humans that recognize the bacteria
- Initial data from healthy participants confirm the vaccine is safe, well-tolerated and immunogenic
- The study serves as a clinical validation for Idorsia's revolutionary synthetic glycan vaccine technology
- Idorsia will now activate partnering discussions to advance as fast as possible the development of the *C. difficile* vaccine and the advancement of a portfolio based on the technology platform

Allschwil, Switzerland – June 30, 2025

Idorsia Ltd. (SIX: IDIA) today announced a milestone in the development of its first bacterial vaccine based on the company's synthetic glycan chemistry platform. The *Clostridioides difficile* (*C. difficile*) vaccine is based on a synthetic glycan mimicking a surface glycan antigen and covers more than 90% of all existing strains of *C. difficile* bacteria and also targets the spores. Initial data showed that the vaccine is well-tolerated and showed immunogenicity in a Phase 1 study.

C. difficile infection

C. difficile is a spore-forming and toxin-producing bacterium. It is the leading cause of antibiotic-associated diarrhea in developed countries. It infects the gastrointestinal tract when there is an imbalance in the gut flora, resulting, for example, from the use of antibiotics. *C. difficile* infection (CDI) symptoms can range from mild diarrhea to pseudomembranous colitis, which in some cases – particularly in the elderly – can lead to death. CDI is a major public health threat, particularly because recurrences are frequent, and is increasing with aging of the population.

In the US, *C. difficile* is estimated to cause almost 400,000 infections each year. One in eleven people over 65 diagnosed with healthcare associated CDI die within one month. *C. difficile* infections cause more than 25,000 deaths each year in the US alone. CDI places a significant economic burden on the healthcare system. The acute care direct costs of CDI are estimated to be \$5–6 billion per year in the US and €3 billion per year in Europe.

Standard treatments of CDI are efficacious in clearing primary CDI. However, CDI recurs in up to 25% of treated patients. The *C. difficile* vaccine identified by Idorsia targets both spores and vegetative *C. difficile* bacteria and, therefore, could prevent not only colonization but also transmission. Frail patients, elderly persons, persons in nursing homes, on antibiotic treatment, hospitalized, or expected to be hospitalized, could be target population for this prophylactic vaccine.

Martine Clozel, MD, Chief Scientific Officer of Idorsia, commented:

“There is a huge medical need in older age populations for the prevention of CDI and I am so excited by the breakthrough that Idorsia could bring to the community. The first clinical results of this *C. difficile* glycoconjugate vaccine are a clinical validation of our revolutionary technology, which transforms biology into chemistry for creating novel vaccines. Our first vaccine could potentially prevent infection, symptoms, recurrences and transmission. We must now find the right partner, who



could rapidly advance the development of this promising vaccine but also of our other advanced bacterial vaccines. The technology also has additional potential, for multiple bacterial targets, and then potentially fungal, parasitic and oncological threats.”

Idorsia’s vaccine IDOR-1134-2831 is intended to be developed for the prevention of CDI in patients at risk in hospital and community settings, with the potential to eradicate bacteria and spores.

A unique approach to vaccination – what is a synthetic glycan vaccine?

Pathogenic bacteria like *C. difficile* express carbohydrates (glycans) on their surface which are recognized by the hosts immune system, leading to the production of glycan specific antibodies. This makes glycans on the surface of pathogens attractive candidates for vaccine development.

The synthetic glycan in Idorsia’s *C. difficile* vaccine is synthesized in a carefully designed chemical process. This transforms a complex biochemical extraction, which is associated with heavy investment, into a purely chemical process driven by medicinal chemistry.

Idorsia’s *C. difficile* synthetic glycan vaccine has the advantage of being stable, immunogenic, fully characterizable and millions of doses can be manufactured in a chemistry lab – limiting manufacturing costs.

About the Phase 1 study

The Phase 1 clinical pharmacology study is a double-blind, randomized, placebo-controlled, two-part trial to assess the safety, tolerability, and immunogenicity of up to 3 ascending dose levels of the IDOR-1134-2831 vaccine in healthy participants aged < 50.

About Idorsia’s vaccine portfolio

In addition to the *C. difficile* vaccine that is in Phase 1 clinical development, Idorsia is also developing synthetic glycan vaccines for infections caused by *Klebsiella pneumoniae* and *Neisseria gonorrhoeae*.

Notes to the editor

About Idorsia

Idorsia Ltd is reaching out for more – we have more passion for science, we see more opportunities, and we want to help more patients.

The purpose of Idorsia is to challenge accepted medical paradigms, answering the questions that matter most. To achieve this, we will discover, develop, and commercialize transformative medicines – either with in-house capabilities or together with partners – and evolve Idorsia into a leading biopharmaceutical company, with a strong scientific core.

Headquartered near Basel, Switzerland – a European biotech hub – Idorsia has a highly experienced team of dedicated professionals, covering all disciplines from bench to bedside; QUVIVIQ™ (daridorexant), a different kind of insomnia treatment with the potential to revolutionize this mounting public health concern; strong partners to maximize the value of our portfolio; a promising in-house development pipeline; and a specialized drug discovery engine focused on small-molecule drugs that can change the treatment paradigm for many patients. Idorsia is listed on the SIX Swiss Exchange (ticker symbol: IDIA).

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the company and anticipated customer demand for such products and products in the company's existing portfolio. Such statements reflect the current views of the company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.