Press Release

Montpellier
April 7, 2022
17:45 CEST

The second part of the Phase II clinical trial of DNV3837 in *Clostridioides difficile* infections to be extended to Canada

- The extension of the clinical trial in Canada will add 5 new sites to those already active in the United States and accelerate patient enrolment for the second part of the trial
- Dr. Thomas Louie, Professor of Microbiology and Infectious Diseases at the University of Calgary (Canada) and a world expert on *Clostridioides difficile*, will be the medical lead for the study in Canada

DEINOVE (Euronext Growth Paris, ALDEI), a French biotech company, pioneer in the exploration and exploitation of bacterial biodiversity to address the urgent, global challenge of antibiotic resistance, announced today the extension of its clinical trial to Canada, approved by the Canadian Health authority, with the opening of 5 new sites, complementing those already opened in the United States. This second country will accelerate patient enrollment in this Phase II clinical trial of DNV3837 in *Clostridioides difficile* infections.

This announcement follows the review of the data from the first part of the trial by the independent Data Safety Monitoring Board (DSMB), which gave a positive opinion for the continuation of the trial (see press release of January 6, 2022).

The second part of the study will be conducted in an open-label manner. Thus, all 40 patients who will be included in the trial will receive DNV3837. As a reminder, the second part of the trial has been optimized with a reduction in the dose and duration of intravenous administration to 6 hours per day during the 10-day treatment period. This modification simplifies the management of the trial for the investigating physicians and their teams.

Dr. Thomas Louie, Professor of Microbiology and Infectious Diseases at the University of Calgary (Canada) and a world expert on *Clostridioides difficile*, will lead and report on the trial in Canada. He said: *"I am delighted to join this trial to evaluate DNV3837, which could be an important advance in the management of patients with* Clostridioides difficile *infection, in particular severely affected patients with bowel dysmotility where orally administered antimicrobials may have difficulty reaching the active site of infection."*

Alexis Rideau, CEO of DEINOVE, concluded *"The extension of our trial into Canada is a major step forward for DEINOVE and provides new hope for Canadian patients. We are proud to work with leading specialists, notably Dr. Thomas Louie, a world expert in the development of innovative therapeutic solutions for* Clostridioides difficile *infections."*

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ABOUT *CLOSTRIDIOIDES DIFFICILE* INFECTIONS (ICD)

More than 40% of hospitalized patients with *Clostridioides difficile* infection (CDI) have been classified as severe disease associated with higher morbidity and mortality[1]. The Centers for Disease Control and Prevention (CDC) identifies CDI as one of the leading causes of hospital-acquired infections, ahead of even MRSA[2] infections. In the United States, it is estimated that CDI causes nearly half a million disease cases each year, and approximately 29,300 deaths[3]. This condition is not limited to the United States and recent studies[4] show that the incidence of this type of infection is greatly underestimated in other parts of the world, such as Europe and Asia.

To date, there is no proven therapeutic solution for CDI patients with severe vomiting, ileus and toxic megacolon. The oral route being compromised, the available treatments, which are mostly oral, have difficulty reaching the intestine because of the patient's pathological condition (reduced gastrointestinal motility, intubation, intestinal perforation, etc.), and the few antibiotics that could be administered intravenously do not cross the gastrointestinal barrier and therefore do not reach the infection site.

ABOUT THE DNV3837 ANTIBIOTIC CANDIDATE

DNV3837 – a prodrug[5] of the DNV3681 molecule (also known as MCB3681) – is a narrow-spectrum, hybrid oxazolidinone-quinolone synthetic antibiotic targeting only Gram-positive bacteria. It is developed as a highly active first-line treatment targeting *C. diff*.

It has demonstrated significant activity and superiority to reference treatments against isolates of *C. diff.*, regardless of their virulence (including the hyper virulent BI/NAP1/027 strain).

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[1] Zar FA et al. Clin Infect Dis. 2007 Aug 01; 45(3):302-7.

[2] MRSA: methicillin-resistant *staphylococcus aureus*

[3] Guh AY, Mu Y, Winston LG et al. N Engl J Med 2020;382:1320–30

[4] Balsells E, Shi T, Leese C, Lyell I, Burrows J, Wiuff C, Campbell H, Kyaw MH, and Nair H (2019) Global burden of *Clostridium difficile* infections: a systematic review and meta-analysis. J Glob Health 9:010407

[5] Prodrug: substance whose transformation in the body results in an active product

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DNV3837 is an intravenous antibiotic that, when converted to its active form DNV3681, crosses the gastrointestinal barrier and accumulates in the intestinal lumen, allowing it to precisely target the infection site. Several Phase I trials (on approximately a hundred healthy volunteers) have shown a high concentration of the antibiotic in stools, a strong marker of its presence in the intestine. It has also demonstrated its ability to eliminate *Clostridioides* bacteria without affecting the gut microbiota.

FDA granted the DNV3837 drug with Qualified Infectious Disease Product (QIDP) designation and Fast Track status.

For more information on the DNV3837 Phase II clinical trial in *Clostridioides difficile* infections, visit ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT03988855

ABOUT DEINOVE

DEINOVE is a French biotechnology company pioneering the exploration of a new domain of life, unexplored at 99.9%: the "microbial dark matter". By revealing the metabolic potential of rare bacteria or still classified as uncultivable, it tackles a global health and economic challenge: antimicrobial resistance.

The new therapies discovered and developed by DEINOVE target superbugs (microbes that have become resistant to one or more antimicrobials) that cause life-threatening infections which are now spreading at high speed.

This breakthrough approach gave rise to one of the world's first specialized micro-biotechnology platforms and a unique collection of nearly 10,000 rare strains and thousands of bacterial extracts. Today, DEINOVE is conducting several development programs, of which its first antibiotic candidate is currently evaluated in a Phase II clinical trial in severe Clostridioides difficile infections, one of the world's first emergencies. The Company has also developed new bacterial micro-factories that address the other issue in the race against antimicrobial resistance: the industrial production of these rare and low concentrated compounds with often too complex chemical structures to be generated by chemical synthesis.

Located at the heart of the Euromedecine park in Montpellier, DEINOVE has been listed on EURONEXT GROWTH® (ALDEI – code ISIN FR0010879056) since 2010. The Company has over 50 employees and relies on a network of world-class academic, technological, industrial and institutional partners.

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