Press Release

Montpellier
January 6th, 2022
17:45 CET

DEINOVE announces a favorable opinion from the DSMB for the continuation of the Phase II clinical trial of DNV3837 in *Clostridioides difficile* infections

- The DSMB[1] considered that the benefit/risk balance of antibiotic therapy with DNV3837 was in favor of continuing the clinical trial
- The design of the second part of the trial has been modified to integrate the investigators' feedback

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 that the independent Data Safety Monitoring Board (DSMB) has completed its review of the safety data from the first part of the Phase II clinical trial of DNV3837 in the treatment of *Clostridioides difficile* infection (CDI). The DSMB considered that the benefit/risk balance of antibiotic therapy with DNV3837 was in favor of continuing the recruitment in this trial.

The experience acquired during this first part of the study has made it possible to improve the trial protocol, with a reduction in dose by a factor of 4 and a reduction in the duration of administration by a factor of 2, reducing the intravenous treatment from 12 to 6 hours per day. This improvement simplifies the management of the trial for the investigating physicians and their teams.

The second part of the study will be conducted in an "open-label" manner, as DNV3837 is administered intravenously, while the standards of care are administered orally. Thus, all patients included in the trial (40 in total) will receive DNV3837.

To improve patients inclusion in the trial, it was decided to rapidly open new centers in addition to those active in the United States.

Dr. Yannick Plétan, DEINOVE's Medical Director, commented: *"This favorable opinion from the DSMB is an important step for the development of DNV3837. We are very proud to bring a potential solution to this high medical need disease."*

[1] The Data and Safety Monitoring Board ("DSMB") is an independent group of experts responsible for monitoring the patient safety data of a clinical trial, and when appropriate, balancing it against the efficacy data. It may make recommendations regarding the continuation, modification or discontinuation of the trial.

Press Release

Montpellier
January 6th, 2022
17:45 CET

"We have been delayed by the COVID 19 pandemic during the first part of the trial. The upcoming opening of new centers and an easier protocol for investigators should simplify recruitment" **concluded Alexis RIDEAU, Chief Executive Officer of DEINOVE.**

ABOUT *CLOSTRIDIOIDES DIFFICILE* INFECTIONS (CDI)

More than 40% of hospitalized patients with *Clostridioides difficile* infection (CDI) have been classified as severe disease associated with higher morbidity and mortality[2]. The Centers for Disease Control and Prevention (CDC) identifies CDI as one of the leading causes of hospital-acquired infections, ahead of even MRSA[3] infections. In the United States, it is estimated that CDI causes nearly half a million disease cases each year, and approximately 29,300 deaths[4]. This condition is not limited to the United States and recent studies[5] 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[6] 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).

---

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

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

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

[5] 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

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

Montpellier
January 6th, 2022
17:45 CET

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.

Press Release

Montpellier
January 6th, 2022
17:45 CET

CONTACTS

Investors

Mario Alcaraz

Chief Financial Officer

+33 (0)4 48 19 01 00

ir@deinove.com

Media

ATCG Partners – Marie PUVIEUX

+33 (0)9 81 87 46 72 / +33 (0)6 10 54 36 72

communication@deinove.com

Visit www.deinove.com