Press release

MONTPELLIER
JANUARY 31, 2019
08:00 AM CET

DEINOVE

Deinove is preparing initiation of Phase II for DNV3837 in *Clostridium difficile* infections, with a key partner

- ***The test design has been improved for a better assessment of DNV3837 effectiveness in treating Clostridium difficile infections,***
- ***This will be a multicenter trial, taking place mostly in the United States, where the prevalence of the disease is high,***
- ***DEINOVE has chosen Medpace as its Clinical Research Organization (CRO)[1] to prepare and oversee the trial, notably because of their experience with the target disease,***
- ***The trial is scheduled to begin mid-2019,***
- ***This clinical program will be the focal point of DEINOVE's antibiotic strategy in the coming months, as the Company has decided not to exercise its option on the NBTI program.***

DEINOVE (Euronext Growth Paris: ALDEI), a French biotech company that uses a disruptive approach to develop innovative antibiotics and bio-based active ingredients for cosmetics and nutrition, **is preparing the Phase II study that will test DNV3837, its most advanced antibiotic candidate, for use against *Clostridium difficile* infections (CDI). DEINOVE has chosen Medpace (NASDAQ: MEPD) to act as its CRO and to oversee the clinical trial scheduled to begin in 2019.**

DNV3837 is a *first-in-class* antibiotic candidate targeting the treatment of *Clostridium difficile* infections (CDIs), a disease classified as a priority by the WHO and one of the leading causes of healthcare-associated infections[2]. DNV3837 has demonstrated a promising efficacy profile and acceptable tolerance in Phase I trials. The FDA[3] has already approved the start of a Phase II study and has granted the DNV3837 program the *Qualified Infectious Disease Product* (QIDP) designation and *Fast Track* status[4] for accelerated product development.

DEINOVE acquired the DNV3837 program in the 1st half of 2018. Since then, their clinical development team has worked with a group of healthcare experts in CDI to prepare for the start of a Phase II clinical trial whose purpose is to demonstrate the efficacy of DNV3837 in patients

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[1] A CRO is a service provider dedicated to biomedical research for the pharmaceutical and biotechnology industries, as well as for research organizations.
[2] Source: CDC (American Centers for Disease Control)
[3] United States Food and Drug Administration
[4] "*Fast Track*" status facilitates the development of the molecule through a faster and more flexible regulatory review of the application. The QIDP designation gives the drug exclusive access to the market for an additional five-year period. These status are granted by the FDA to drugs under development that meet critical and unmet therapeutic needs.

suffering from CDI. Several aspects of the trial design, which had been presented to the FDA prior to the acquisition, have been improved:

- the target patient population was expanded and now covers moderate to severe CDIs for greater progressiveness in treatment assessment;
- it will be a multicenter trial with a major part taking place in the United States, where there is greater prevalence and the regulatory authorities are looking for new treatment options.

The design of the trial has now been finalized for submission of the updated version to the FDA. The selection process of clinical investigation centers is underway. The trial is scheduled to begin mid-year.

DEINOVE has chosen Medpace to oversee the trial. Medpace is an internationally-recognized full-service CRO that notably has a great deal of experience in infectious diseases, especially gastrointestinal infections like CDIs.

Its mission includes support for the clinical trial's design and set-up (protocol review, contacting the clinical investigation centers, etc.), gathering and analyzing data, and interacting with the FDA.

Georges Gaudriault, Scientific Director at DEINOVE, said: *"Preparations for the Phase II clinical trial for DNV3837 are moving forward as planned and we are delighted to have executed such an agreement with Medpace for this trial's oversight. Their experience in both the pathology and American regulatory procedures will help us to secure and maximize this trial's progress."*

The DNV3837 program is followed by the AGIR program (backed by Bpifrance), whose aim is to add to the portfolio of new molecules from DEINOVE's biodiversity. The option on the NBTI[5] program will indeed not be exercised, as the data gathered during the assessment phase were not considered to be in line with DEINOVE's expectations for pursuing the program.

Emmanuel Petiot, CEO of DEINOVE, added: "*The antibiotics field is a priority for DEINOVE and the DNV3837 program is our spearhead. Furthermore, we have decided not to exercise our option on the NBTI program with REDX Pharma, insofar as our teams' assessment showed obstacles to its development without further optimization. We want to respond quickly and effectively to the health emergency and the lack of innovative antibiotics, and we are focusing our efforts on those programs with the highest possible probability of success."*

[5] See press release of 22 March 2018

ABOUT *CLOSTRIDIUM DIFFICILE* INFECTIONS

40% of patients suffering a *Clostridium difficile* infection (CDI) suffer from severe forms, with mortality rates as high as 50%. Over the past 20 years, CDIs have had a strong tendency to increase in incidence and severity, particularly due to the development of new, hyper virulent strains, and a high risk of recurrence. The US Center for Disease Control and Prevention (CDC) recently identified CDIs as one of the leading causes of healthcare-associated infections before *Staphylococcus aureus* (MRSA[6]) infections. In 2011, about half a million Americans were infected and more than 29,000 patients died within 30 days of diagnosis.

The treatment of CDI represents a real therapeutic challenge.

To date, no effective antibiotic treatment is available for severe gastrointestinal infections. The oral route is made largely ineffective due to the pathological state of the patient (gastrointestinal tract motility, intubation, intestinal perforation, etc.). Existing treatments, mostly oral, struggle to reach the intestine while the few intravenous (IV) antibiotics do not penetrate the gastrointestinal barrier sufficiently well to attain a therapeutic level in the intestine.

ABOUT THE DNV3837 ANTIBIOTIC CANDIDATE

DNV3837 – a prodrug 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 1st line treatment targeting *Clostridium difficile*.

It has demonstrated significant efficacy and superiority to reference treatments (fidaxomicin in particular) against isolates of *C. diff.*, regardless of their virulence (including the hyper virulent strain NAP1).

DNV3837 is administered intravenously and is able to cross the gastrointestinal barrier, allowing it to precisely target the infection site. Several Phase I trials (on approx. one 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 *C. diff.* bacteria without altering the gut microbiota in the long term, a definite advantage for patient prognosis. It has also shown an acceptable tolerance profile.

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

[6] MRSA : methicillin-resistant *Staphylococcus aureus*

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ABOUT DEINOVE

DEINOVE is a French biotechnology company, a leader in disruptive innovation, which aims to help meet the challenges of antibiotic resistance and the transition to a sustainable production model for the cosmetics and nutrition industries.

DEINOVE has developed a unique and comprehensive expertise in the field of rare bacteria that it can decipher, culture, and optimize to disclose unsuspected possibilities and induce them to produce biobased molecules with activities of interest on an industrial scale. To do so, DEINOVE has been building and documenting since its creation an unparalleled biodiversity bank that it exploits thanks to a unique technological platform in Europe.

DEINOVE is organized around two areas of expertise:

- **ANTIBIOTICS, New-generation anti-infectives**: DEINOVE is preparing to enter a first antibiotic candidate into Phase II. The Company is also pursuing the systematic exploration of biodiversity to supply its portfolio with new leads, drawing notably on partnerships with Naicons and bioMérieux (AGIR program supported by Bpifrance).
- **BIOACTIVES, Active ingredients of natural origin** with cosmetics as the first market and potential in nutrition and health: DEINOVE already markets a first innovative active ingredient, a second in partnership with Greentech, while two others are in development with Oléos (Hallstar Group). It also runs a program in animal nutrition with Groupe Avril. Several other partnerships are also being planned.

Within the Euromedecine science park located in Montpellier, DEINOVE employs 62 employees, mainly researchers, engineers, and technicians, and has filed more than 260 patent applications internationally. The Company has been listed on EURONEXT GROWTH® since April 2010.

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