Press Release

MONTPELLIER
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DEINOVE selected for a presentation at the *C Diff* Foundation annual Conference 2020

- **Yannick Pletan to present the DNV3837 mechanism of action, key features of the antibiotic candidate and the protocol of the ongoing Phase II Clinical Trial in *Clostridioides difficile* infection**

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 and the need for next-generation active ingredients in the service of healthcare, **announces a presentation at the *C.diff* foundation 8th annual Virtual Conference.**

Yannick Pletan, MD, MSc, HEC, Chief Medical Officer and member of the board of directors of DEINOVE will present in the "Research In Progress" virtual poster session "A Phase 2 Clinical Trial Evaluating a Novel Antibiotic Against a Clostridium difficile Infection". He will be presenting the results of the Phase I, the protocol of the ongoing multicenter Phase II in the United States, the clinical sites, the team and the key advantages of DNV3837 antibiotic candidate: intravenous administration, precise targeting at the infection site, ability to eliminate *Clostridioides* bacteria without affecting the gut microbiota.

Patients enrollment is ongoing in this Phase II trial despite a disrupted context due to the COVID-19 outbreak. Preliminary results of Part I of the study are expected by S1 2021.

Video presentation is online **https://youtu.be/pShknVl5kDk**

ABOUT *CLOSTRIDIOIDES DIFFICILE* INFECTIONS (CDI)

40% of patients suffering a *Clostridioides difficile* infection (CDI) have severe forms, associated with high morbidity and mortality rates. Over the past 20 years, CDIs tended to increase significantly in incidence and severity, particularly due to the development of new hypervirulent strains and the 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[1]) infections. In 2017, in the United States, there were an estimated 223,900 cases in hospitalized patients and 12,800 deaths[2]. This disease does not affect the United States only, recent studies[3] show that the incidence of this type of infection is vastly underestimated in other parts of the world such as Europe and Asia.

To date, there are no therapeutic solutions for patients with severe gastrointestinal infections. Since the oral route is compromised, the available treatments, which are mostly oral treatments, struggle to reach the intestine because of the patient's pathological condition (reduced gastrointestinal motility, intubation,

[1] MRSA: meticillin-resistant *Staphylococcus aureus*
[2] https://www.cdc.gov/drugresistance/biggest-threats.html#cdiff
[3] 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

intestinal perforation, etc.), and the few antibiotics that could be administered intravenously (IV), do not cross the gastrointestinal barrier and therefore do not reach the site of infection.

ABOUT THE DNV3837 ANTIBIOTIC CANDIDATE

DNV3837 – a prodrug[4] 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 *Clostridioides difficile*.

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

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 approx. 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. It has also shown an acceptable safety and tolerability profile.

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

ABOUT THE PHASE II CLINICAL TRIAL TESTING DNV3837 IN CDI

The antibiotic candidate DNV3837 has been in a Phase II trial since the end of January 2020. The purpose of this trial is to evaluate its efficacy in CDI (through monitoring of symptoms, stool analysis, etc.), as well as to consolidate the safety and pharmacokinetic data in patients.

This trial is taking place in the United States in two stages:

- In the first part, a cohort of 10 patients with moderate to severe CDI is treated with DNV3837. At the end of this part, the DSMB[5] has scheduled to review the interim results.
- The second part involves 30 patients with severe CDI. This is an open-label randomized trial testing DNV3837 (in 2/3 of patients) against an approved standard of care[6] (1/3 of patients) for comparison purposes.

ABOUT DEINOVE

DEINOVE is a French biotech company, a pioneer in the exploitation of the unknown or little-known part of biodiversity. By using rare or "non-cultivable" bacteria and by working on unexplored molecular pathways, the Company discovers, develops and produces antimicrobials to meet the urgent, global challenge of antibiotic resistance, and the need for next-generation active ingredients to serve Health.

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[4] Prodrug: substance whose transformation in the body results in an active product
[5] DSMB - *Data Safety Monitoring Board:* a group of independent experts tasked to review the data generated during the trial and make recommendations on patient safety as well as trial relevance and validity.
[6] Standard treatments approved in the United States for the treatment of CDIs include vancomycin, fidaxomicin and metronidazole (all three antibiotics). The choice will be at the discretion of the clinicians.

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In nearly 15 years, the Company has built a unique collection of over 10,000 bacterial strains and has developed a fully integrated technological platform that brings together the best of biological culture, synthetic biology and micro-biotechnology.

Today, DEINOVE has several development programs underway, including the antibiotic candidate DNV3837, in a Phase II clinical trial in severe gastrointestinal infections with *Clostridioides difficile*, a real therapeutic challenge. Through its other program AGIR (Antibiotics against Resistant Infectious Germs), supported by Bpifrance, it is also continuing its exploration of biodiversity to supply its portfolio with new molecules. It relies on its own biodiversity and on the one entrusted to it by other specialists in the field.

DEINOVE has also developed and brought to market four particularly innovative active ingredients: a first which is phytoene-based and a neurosporene concentrate produced by *Deinococcus geothermalis*, as well as two cell extracts developed in collaboration.

DEINOVE, located in the Euromédecine science park in Montpellier, employs 56 people, mainly researchers, engineers and technicians, and has filed over 350 patent applications internationally. It is listed on EURONEXT GROWTH® (ALDEI – code ISIN FR0010879056).

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