

Press release

DEINOVE TAKES ON A WHOLE NEW DIMENSION WITH THE ACQUISITION OF MORPHOCHEM'S CLINICAL-STAGE ANTIBIOTIC COMPOUND

- MORPHOCHEM's MCB3837 antibiotic compound aims to treat severe gastrointestinal infections caused by *Clostridium difficile*, a priority pathogen according to the WHO and the CDC¹.
- The Food and Drug Administration (FDA) granted the MCB3837 program the Qualified Infectious Disease Product (QIDP) status and Fast Track² designation. MORPHOCHEM had already received "the study may proceed" FDA letter for the upcoming Phase II.
- Through a contribution in kind, DEINOVE acquires the Austrian company BIOVERTIS and its German subsidiary MORPHOCHEM (100% owned), and therefore this antibiotic program, in particular from specialized investment funds managed by TVM Capital (majority shareholder of BIOVERTIS).
- Following the completion of this operation (subject to the approval of the shareholders' meeting of 23 May 2018), TVM Capital, one of the most prominent European life science venture capital funds, will become one of DEINOVE's shareholder.
- This operation significantly reinforces DEINOVE's Antibiotics activity with the integration into its pipeline of a compound already in clinical development.

Montpellier, 13 April 2018 (6:30am CEST) - DEINOVE (Euronext Growth Paris: ALDEI), a biotech company that discovers, develops, and produces high-value compounds from rare bacteria, **announces the acquisition, through a contribution-in-kind transaction, of the entire capital³ of the Austrian company Biovertis AG ("BIOVERTIS"), which owns the entire capital of the German company Morphochem AG für kombinatorische Chemie ("MORPHOCHEM"), with the latter developing the clinical-stage antibiotic compound "MCB3837". Subject to approval by DEINOVE's shareholders' meeting, all shareholders, option and right holders of BIOVERTIS will become shareholders of DEINOVE.**

In addition to its AGIR⁴ program for the discovery of new antibiotics, and its recently announced agreement with RedX Pharma, DEINOVE acquires a clinical-stage molecule, ready to enter Phase II, targeting the treatment of severe *Clostridium difficile* gastrointestinal infections (CDI) generally related to a disruption of the gut microbiota in weakened patients.

The incidence of CDI has doubled or quadrupled over the last 20 years in Europe and North America⁵. The US Center for Disease Control and Prevention recently identified CDI as one of the leading causes

¹ World Health Organization and Centers for Disease Control and Prevention: https://www.cdc.gov/drugresistance/biggest_threats.html

² The Fast Track status facilitates the development of the molecule through a faster and more flexible regulatory review of the dossier. This status is granted by the FDA to drugs under development that meet critical and unmet therapeutic needs.

³ With the exception of 316 treasury shares.

⁴ AGIR (Antibiotics against Resistant Infectious Germs) consists in the exploration by DEINOVE of new bacterial strains with antibiotic activity. This project benefits from the support of the 'Investments for the Future' Program amounting to € 14.6 million.

⁵ *Aspects épidémiologiques et médico-économiques des infections à Clostridium difficile*, A. LE MONNIER, 14es Journées Nationales d'Infectiologie 2013

of healthcare-associated infections, even ahead of MRSA.⁶ In 2011, about half a million Americans were infected and more than 29 000 patients died within 30 days⁷ following the diagnosis – two times more than the number of AIDS victims. In 2021, experts predict 1.5 million cases of CDI in the United States and Europe combined.

To date, no effective antibiotic treatment is available for severe gastrointestinal infections because of the very nature of the disease: oral treatments struggle to reach the intestine because of the pathological state of the patient (reduced gastrointestinal motility, intubation, intestinal perforation, etc.), while current intravenous (IV) antibiotics do not penetrate the gastrointestinal barrier and thus do not reach the infection site.

The MCB3837 compound, under development by the German biotechnology company MORPHOCHEM, is a first-in-class antibiotic effective on Gram-positive bacteria and more particularly on *Clostridium difficile*. In addition to its spectrum of activity, its interest lies mainly in the way the product is administered and distributed in the body, which makes it particularly interesting in the treatment of severe gastrointestinal infections.

MCB3837 is an antibiotic administered by intra-venous infusion and able to cross the gastrointestinal barrier. It precisely targets the infection site. Several Phase I trials (on healthy volunteers) have shown a high concentration of the antibiotic in stools, which is a strong marker of its presence in the intestine. It has demonstrated an ability to eliminate *Clostridium difficile* bacteria without destroying other microorganisms of the gastrointestinal flora. It has also shown an acceptable tolerance profile.

The next stage of development will be a Phase II clinical trial on a small number of patients. Green light has already been given by the FDA for the initiation of this study.

Furthermore, in 2016, MCB3837 was granted the QIPD designation as well as Fast Track status from the US Food and Drug Administration (“FDA”).

Terms of the transaction

The acquisition of the entire capital of BIOVERTIS will be achieved through a contribution in kind of shares, within Article L. 225-147 of the French Commercial Code, by BIOVERTIS' shareholders, option and right holders for the benefit of DEINOVE. In consideration of this contribution in kind, the contributors, including two specialized investment funds managed by TVM Capital which hold 82.98% of the contributed rights, will receive 500,001 DEINOVE shares to which will be attached 8 million warrants (*Bons d'attribution d'actions*, BAA). The total value of the rights granted is equal to 500,001 multiplied by 1.80 euro, i.e. the closing share price on January 17, 2018, which is the last trading day preceding the signature of a letter of intent between the parties. The total value of the rights amounts to €900,001.80. No cash payment will be made by DEINOVE.

In accordance with Article L. 225-147 of the French Commercial Code and recommendation no. 2011-11 of the French Financial Markets Authority (*Autorité des marchés financiers*), a contribution auditor will be appointed by order of the President of the Commercial Court of Montpellier. The mission of the contribution auditor will be extended to the assessment of the fairness of the remuneration of the

⁶ Methicillin-resistant *Staphylococcus aureus* (MRSA)

⁷ Burden of *Clostridium difficile* Infection in the United States - Fernanda C. Lessa, The New England Journal of Medicine, 2015

contributed BIOVERTIS shares and options. This contribution-in-kind transaction and the related capital increase will be submitted to the approval of DEINOVE's shareholders' meeting rescheduled to 23 May 2018.

Following the contribution, the 500,001 new shares issued as part compensation for this contribution will represent 4.06% of DEINOVE's capital after the transaction.

The 8 million warrants, entitling the holder to a maximum of 8 million new DEINOVE shares, will only be exercisable by their holders in the event of reaching various milestones in the development of the drug candidate. Therefore, the exercise of the warrants is conditional on achieving highly value creating milestones for DEINOVE alongside the development of the targeted antibiotic compound.

Subject to certain exceptions, the warrants will entitle the holders to receive new DEINOVE shares as follows:

- 500,001 new shares upon the beginning of the Project's next clinical trial (first patient in);
- 2,300,000 new shares upon the start of the Project's phase IIb/III pivotal trial or phase III (first patient in);
- 2,300,003 new shares upon the end of the Project's positive phase IIb/III pivotal trial or phase III. For the sake of clarity, "positive" shall mean that all primary efficacy clinical endpoints together with at least one secondary endpoint and safety objectives supporting registration have been met;
- 1,399,998 new shares upon the FDA acceptance of regulatory filing for the first marketing approval of the Project at least in the USA or any other country or countries which alone or taken together actually represent the same number of qualified patients and, as a consequence, the same commercial value as in the USA;
- 1,499,998 new shares upon the first marketing approval of the Project at least in the USA (New Drug Application) or any other country or countries which alone or taken together actually represent the same number of qualified patients and, as a consequence, the same commercial value as in the USA.

As part of the transaction, the contributors, they have agreed, as from the date they come to hold the new shares, to a lock-up period of six months for all new shares transferred to them.

For as long as the contributors collectively hold shares in DEINOVE that represent 5% or more of the issued share capital of DEINOVE or for the duration of the development of the Project through marketing authorization in the USA or Europe, TVM Capital shall have the right to nominate one representative only to the board of directors of DEINOVE.

Finally, DEINOVE has made a commitment to have sufficient financial resources to ensure its going concern as well as that of its subsidiaries. In this context, DEINOVE could soon proceed with the raising of funds, notably but not only, through a capital increase.

"The MCB3837 program has the potential to address the major health challenge of Clostridium difficile infections, a rapidly growing epidemic. We are pleased to entrust DEINOVE, which has set the search

for new antibiotics as its top priority, with its continued development. We will support DEINOVE in the next stages of development and, in this respect, we are already committed to making a substantial contribution to its future financing needs," said Dr. Hubert BIRNER, Managing Partner, TVM Capital.

Emmanuel PETIOT, CEO of DEINOVE, added: "With this transaction, we are significantly strengthening our portfolio of antibiotics in development and our health activities. With the entry into our capital of TVM, a European investment fund specialized in health innovation, along with its commitment to participate in our financing needs, we find ourselves with a new high-quality shareholder that supports our development strategy."

For further information, a meeting will be held on 26 April 2018 at 10am in Paris at the SFAF (French Society of Financial Analysts) facilities.

ABOUT CLOSTRIDIUM DIFFICILE INFECTIONS⁸

Clostridium difficile infections include a broad spectrum of clinical conditions of varying severity ranging from mild diarrhea to fulminant colitis that can progress to septic shock and death. 40% of patients have severe forms, with mortality rates as high as 50%. Over the past 20 years, *Clostridium difficile* infections (CDI) have had a strong tendency to increase in incidence and severity, particularly due to the development of new, hyper virulent strains, some of which are resistant to existing antibiotics.

About 25% of patients relapse within two months of the first episode, regardless of treatment. Half of the cases are due to the persistence in the digestive tract of the same *C. difficile* strain in the sporulated form, and the other half to reinfection (infection with a new strain, most often acquired during hospitalization).

The treatment of CDI represents a real therapeutic challenge.

The main factors associated with CDI are: an age over 65 years, hospitalization, and taking medication affecting the intestinal flora. The risk of renewed infection increases with the number of recurrences: 45% after the second and 65% after the third.

ABOUT TVM CAPITAL LIFE SCIENCE

TVM Capital Life Science is a group of independent investment advisories and fund managers for Venture Capital funds, investing into innovative biotech, pharmaceutical, and medtech companies, with teams based in Munich and Montreal. Since 1984, TVM Capital Life Science has invested in more than 130 life science companies in Europe, Canada and the United States, currently managing in excess of €900 million from more than 50 investors.

Notably, TVM Capital Life Science was the Series A lead investor in the following publicly listed companies with market capitalizations that at some point were or still are greater than €1 billion: Qiagen, Sequenom, Actelion, Intercell, Evotec and most recently Colucid.

⁸ Récidives d'infection à *Clostridium difficile* : l'importance du microbiote intestinal – MC Zanella Terrier et al. Revue Médicale Suisse, 2013

ABOUT DEINOVE

DEINOVE (Euronext Growth Paris: ALDEI) is a biotech company that discovers, develops and produces high added-value compounds from rare microorganisms for use in the fields of health, nutrition and cosmetic markets. To do so, DEINOVE draws on two key assets:

- a unique library of 6,000 rare or unexploited bacterial strains;
- a metabolic and fermentation engineering platform capable of leveraging these natural "micro-factories" to turn them into new industrial standards.

Based in Montpellier, DEINOVE employs approximately 55 employees and has nearly 130 international patents. The Company has been listed on Euronext Growth since April 2010.

Contacts

Emmanuel Petiot

Chief Executive Officer

Tel : +33 (0)4 48 19 01 28

emmanuel.petiot@deinove.com

Coralie Martin

Communication, Marketing and Investor Relations

Tel : +33 (0)4 48 19 01 60

coralie.martin@deinove.com

ALIZE RP, Press Relations

Caroline Carmagnol / Aurore Gangloff

Tel : +33 (0)1 44 54 36 66

deinove@alizerp.com

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