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Destiny Pharma PLC
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Destiny Pharma PLC

Exclusive collaboration and co-development agreement for NTCD-M3 with Sebela Pharmaceuticals® worth up to $570m plus royalties

Partnership with Sebela will finance the future clinical development and commercialization costs of NTCD-M3 in North America

Destiny Pharma retains majority rights for Europe and ROW

Key strategic target achieved for NTCD-M3

Brighton, United Kingdom - 24 February 2023 -Destiny Pharma plc (AIM: DEST), a clinical stage innovative biotechnology company focused on the development of novel medicines that can prevent life-threatening infections, is pleased to announce that it has signed an exclusive collaboration and co-development agreement for the North American (U.S., Canada and Mexico) rights of NTCD-M3, its lead asset for the prevention of*Clostridioides difficile infection* (CDI) recurrence, with Sebela Pharmaceuticals®, a U.S. pharmaceutical company with a market-leading position in gastroenterology.

Under the terms of the deal, it is anticipated that Sebela will lead and finance the future clinical development and commercialisation activities of NTCD-M3 in North America. The Company retains the majority of rights for Europe and Rest of the World and Sebela has a minority interest in any income generated in these non-North American territories based on the clinical studies it is funding.

The agreement, which could be worth up to $570m to Destiny Pharma in milestones alone, includes;

- an initial upfront payment of $1m;
- success-based development milestones of $19m;
- sales revenues-based milestone payments up to $550m; and
- tiered, double-digit royalties.

Destiny Pharma has the obligation to continue its current plan to complete the ongoing manufacture of all clinical trial supplies needed to undertake the required clinical studies. It is anticipated that Phase 3 studies will commence in 2024.

About NTCD-M3

NTCD-M3 was originally in-licensed by Destiny Pharma in November 2020 and is a naturally occurring non-toxigenic strain of *C. difficile* which lacks the genes that can express *C. difficile* toxins. It is an oral formulation of NTCD-M3 spores and patients who have taken NTCD-M3 were found to be protected from toxic strains of CDI. NTCD-M3 acts as a safe "ground cover" preventing toxic strains of *C. difficile* proliferating in the colon after antibiotic treatment. NTCD-M3 temporarily colonises the human gut without causing any symptoms and the gut microbiome returns to normal a few weeks after treatment.

About *C. difficile*

C. difficile is one of the leading causes of hospital acquired infection in the U.S. and poor treatments from antibiotics lead to cycles of repeated recurrence in many patients. In the U.S., there are approximately 500,000 cases of CDI each year; 25% of these initial cases then recur and there are approximately 29,000 deaths per year. Current CDI treatment options are limited, with lower efficacy observed when patients are retreated with the same antibiotic for recurrence of CDI.

About Sebela Pharmaceuticals®

Sebela Pharmaceuticals is a U.S. pharmaceutical company with a market leading position in gastroenterology and a focus on innovation in women's health. Braintree Laboratories, Inc., a part of Sebela Pharmaceuticals, has been the market leader in colonoscopy screening for over 35 years, having invented, developed and commercialised a broad portfolio of innovative prescription colonoscopy preparations and multiple gastroenterology products. Braintree also has multiple gastroenterology programs in late-stage clinical development, including Tegoprazan, a novel potassium-competitive acid-blocker (P-CAB), in phase 3 trials in the US for the treatment of erosive esophagitis and non-erosive reflux disease. In addition, Sebela Women's Health has two next generation intra-uterine devices (IUDs) for contraception in the final stages of clinical development. Sebela Pharmaceuticals has offices/operations in Roswell, GA; Braintree, MA; and Dublin, Ireland; has annual net sales of approximately $200 million; and has grown to over 340 employees through strategic acquisitions and organic growth. Please visit sebelapharma.com for more information.

Commenting on the announcement, Neil Clark, Chief Executive Officer of Destiny Pharma, said:

"We are very pleased to have reached this agreement with Sebela, a high quality, GI specialist company which has the necessary clinical development and commercialisation expertise to take NTCD-M3 through to launch. Such partnering deals are in line with our stated strategy of finding pharma partners to undertake the required Phase 3 clinical studies of our lead assets thus reducing the funding requirements of the Company.

"This deal is not only great news for the many thousands of patients that suffer from *C. difficile* infections each year but is also a tremendous endorsement of Destiny Pharma's approach. In a little over two years since acquisition, we have managed to re-activate NTCD-M3 as a very exciting and valuable clinical candidate and find a commercialisation partner in Sebela with the capabilities to implement and fund all further clinical development costs as well as funding NTCD-M3's launch and commercialisation in the key U.S. market. Destiny retains control over the rights for Europe and the Rest of the World (excluding China region), which we believe, together with our XF-73 programs, contain significant value potential."

Commenting on the announcement, Alan Cooke, President and Chief Executive Officer of Sebela Pharmaceuticals said:

"We are delighted to partner with Destiny Pharma to advance NTCD-M3 to Phase 3 and plan for commercialization in the U.S. NTCD-M3 provides a unique and differentiated approach to prevent the recurrence of*C. difficile* infection and represents a significant addition to our valuable development pipeline."

Investor Meet Presentation

DESTINY PHARMA PLC is pleased to announce that **Neil Clark** and **Shaun Claydon** will provide a live presentation via the Investor Meet Company platform on **27th Feb 2023 at 10.00am GMT.**

The presentation is open to all existing and potential shareholders.

Investors can sign up to Investor Meet Company for free and add to meet **DESTINY PHARMA PLC** via:

https://www.investormeetcompany.com/destiny-pharma-plc/register-investor

Investors who already follow **DESTINY PHARMA PLC** on the Investor Meet Company platform will automatically be invited.

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The information communicated in this announcement contains inside information for the purposes of Article 7 of the Market Abuse Regulation (EU) No. 596/2014.

About Destiny Pharma

Destiny Pharma is a clinical stage, innovative biotechnology company focused on the development of novel medicines that can prevent life-threatening infections. Its pipeline has novel microbiome-based biotherapeutics and XF drug clinical assets including NTCD-M3, a Phase 3 ready treatment for the prevention of*C. difficile* infection (CDI) recurrence which is the leading cause of hospital acquired infection in the US and also XF-73 nasal gel, which has recently completed a positive Phase 2 clinical trial targeting the prevention of post-surgical staphylococcal hospital infections including MRSA. It is also co-developing SPOR-COV™, a novel, biotherapeutic product for the prevention of COVID-19 and other viral respiratory infections and has earlier grant funded XF drug research projects.

For further information on the company, please visit www.destinypharma.com

Forward looking statements

Certain information contained in this announcement, including any information as to the Group's strategy, plans or future financial or operating performance, constitutes "forward-looking statements". These forward-looking statements may be identified by the use of forward-looking terminology, including the terms "believes", "estimates", "anticipates", "projects", "expects", "intends", "aims", "plans", "predicts", "may", "will", "seeks" "could" "targets" "assumes" "positioned" or "should" or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These forward-looking statements include all matters that are not historical facts. They appear in a number of places throughout this announcement and include statements regarding the intentions, beliefs or current expectations of the Directors concerning, among other things, the Group's results of operations, financial condition, prospects, growth, strategies and the industries in which the Group operates. The directors of the company believe that the expectations reflected in these statements are reasonable but may be affected by a number of variables which could cause actual results or trends to differ materially. Each forward-looking statement speaks only as of the date of the particular statement. By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future or are beyond the Group's control. Forward-looking statements are not guarantees of future performance. Even if the Group's actual results of operations, financial condition and the development of the industries in which the Group operates are consistent with the forward-looking statements contained in this document, those results or developments may not be indicative of results or developments in subsequent periods.

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