Hemogenyx Pharma Plc - Operations Update

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Hemogenyx Pharmaceuticals PLC

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Hemogenyx Pharmaceuticals plc
("Hemogenyx" or the "Company")

Operations Update

Hemogenyx Pharmaceuticals plc (LSE: HEMO) is pleased to provide the following update on its development activities. The Directors believe that, taken together, the recent progress made across the full range of its activities represents a significant step forward for the Company considerably broadening the scope of its development activities.

Highlights

CDX Antibodies

- In February 2018, the Company announced its CDX Antibodies can attack and eliminate the blood cancer Acute Myelogenous Leukemia ("AML") *in vitro*
- Development Agreement with global pharmaceutical company (announced May 2018) progressing well, discussion regarding licensing deal expected to commence in early 2019
- Expanded use of CDX antibodies to improve the efficacy of already approved drugs as well as those still in clinical trials for AML
- Progress continues toward the submission of an Investigational New Drug ("IND") application

Advanced Hematopoietic Chimeras ("AHC")

- Originally developed to improve the testing of the Company's own products *in vivo,* AHC, or humanized mice, is evoking much wider interest across the bio-pharmaceutical industry
- Potential application of these mice in disease modelling and drug discovery as AHC

possess a seemingly fully functional human immune system

- Announced collaborations with Janssen Research & Development, LLC, and Orgenesis, Inc., to advance opportunities presented by AHC with an initial $1 million invested into the project by convertible loan at a project valuation of $8 million

Hu-PHEC products

- Steps taken to bring forward Human Postnatal Hemogenic Endothelial Cell ("Hu-PHEC") based suite of product candidates
- Hemogenyx-Cell SA, a Belgian registered subsidiary wholly-owned by the Company has entered into a collaboration agreement with Orgenesis, Inc., to further develop and commercialise the Hu-PHEC technology with an initial $1 million invested into the project by convertible loan at a project valuation of $12 million
- Hemogenyx-Cell will engage in preclinical development of the Hu-PHEC technology, and will be eligible for significant financial support from the Belgian government in the form of non-dilutive matching grants

Appointments

- In March 2018, H. Michael Shepard, Ph.D., a pioneer in modern cancer research, was appointed to the Scientific Advisory Board
- In April 2018, Sir Marc Feldmann, AC, FRS, a pre-eminent medically trained immunologist at the University of Oxford, was appointed Executive Chairman of the Board

CDX Antibodies

Progress continues toward the submission of an Investigational New Drug ("IND") application to the US Food and Drug Administration or to a UK or European regulatory agency for the Company's lead product candidate, CDX antibodies, and pre-clinical evaluations of additional clones of CDX antibodies to use in combination with other blood cancer treatments are now completed.

In February 2018, the Company announced that its CDX antibodies attacked and eliminated the blood cancer Acute Myelogenous Leukemia ("AML") *in vitro* (test tube experiments) (**https://goo.gl/fa7u45**). Since then, the Company has established a new in vivo model of human AML in its AHC mice that will be used to test CDX antibodies for their potential ability to eliminate AML *in vivo*. If these tests are successful, the Company will most likely be able to use CDX antibodies not only to condition patients for bone marrow transplantation, but also to eliminate refractory and/or relapsed AML in patients who might otherwise qualify for bone marrow transplantation. The AML market across seven developed countries (US, France, Germany, Italy, Spain, the UK, and Japan) is projected to increase to $1.5B by 2026. The Directors consider the expansion of the use of CDX antibodies to treat AML to be a significant opportunity for the Company that may allow it to potentially double revenues from the CDX antibodies when approved for sale and, of equal importance, save more lives.

In May 2018, the Company announced a Development Agreement ("Agreement") with a global biopharmaceutical company for the development of the Company's CDX antibodies (**https://goo.gl/6hWaUS**). The Company is pleased to report that the development of CDX antibodies under the Agreement is progressing well, and hence the Company is planning to initiate preliminary discussions with the partner in January 2019 regarding a potential licensing deal.

Under the Agreement, Hemogenyx will receive on a cost-free basis: technical support access to advanced methods of discovering, developing and engineering antibodies; and certain intellectual

property which is expected to assist the successful preclinical development of the Hemogenyx's lead candidate bi-specific CDX antibodies. This will complement the Company's own development work currently being undertaken.

Also, Hemogenyx will grant the global pharmaceutical company a research license for anything jointly developed under the Agreement, as well as an option for an exclusive worldwide license to commercially exploit CDX antibodies or any variants, which will be jointly developed. If such option is not exercised by the global pharmaceutical company, the Company has the option to license the jointly developed CDX antibodies or any variants.

Hemogenyx is already benefitting from the Agreement as its partner has produced good bi-specific antibodies which appear to be clinical grade, and discussions in 2019 will clarify their intentions. Either way, Hemogenyx benefits considerably.

The Company is expanding the use of its CDX antibodies to improve the efficacy of already approved drugs as well as those still in clinical trials for AML. Hemogenyx's goal is to significantly improve the outcomes of treatments using these drugs without a risk of compromising the standard of care. The Directors believe that the ability to use CDX antibodies to improve the performance of existing drugs without any risk of a negative impact on treatment outcomes will be very attractive to major pharmaceutical companies. Consequently, the Company has filed a provisional patent application covering the composition matter of additional clones of CDX antibodies and their combination with a wide class of novel compounds that are currently undergoing clinical development by a number of other companies. The purpose is to create a new paradigm of combination treatment for patients with AML and possibly other types of blood cancers. The Company is in exploratory talks with a number of potential pharmaceutical partners about these opportunities.

The consequences of these developments in the CDX project are extensive. Hemogenyx may no longer need to spend money and use staff resources to make its own antibodies, because the preferred strategy now is to work with its partner which has already made a suitable antibody. With the availability of a new patented combination therapy strategy, it is likely that this or potentially other biopharmaceutical companies will decide to in-license CDX.

Advanced Hematopoietic Chimeras

The Company continues to be encouraged by the interest generated by its new type of humanized mice - Advanced Hematopoietic Chimeras or "AHC" - and the potential application of these mice in disease modelling and drug discovery. AHC possess a seemingly fully functional human immune system. This is a crucial advantage that the Directors believe makes AHC unique among other types of humanized mice currently available.

The Company initially developed AHC in order to have an improved means of testing its own products *in vivo,* but has now found that the AHC platform is evoking much wider interest across the bio-pharmaceutical industry and beginning to provide significant immediate levels of revenue for the Company. To fully exploit this newly created opportunity, the Company is forming strategic collaborations with major bio-pharmaceutical companies to expand the use of AHC and to open new venues to increase its own product portfolio.

To take full advantage of opportunities presented by AHC, the Company established a wholly owned subsidiary, Immugenyx, LLC ("Immugenyx"), which is dedicated to the development and commercialization of AHC as an *in vivo* platform for disease modelling and drug development and testing. In addition, Immugenyx itself is leveraging the unique properties of AHC to discover and

develop novel treatments for autoimmune diseases.

The value of AHC as an *in vivo* platform for disease modelling and drug development, as well as a source of revenue for the Company, has been evidenced not only by two previously announced ongoing collaborations with major biopharmaceutical companies, but also by the interest shown by a number of other biopharmaceutical companies that are currently in talks with the Company about entering into collaborations. The Company will be able to update shareholders as these talks progress.

The first announced collaboration with a major US biotechnology company to use the Company's AHC as a tool for drug development and testing has progressed well and is expected to generate up to US$377,000 in revenue at the conclusion of the current phase of collaboration (**https://goo.gl/M1oKAP**). Although confidentiality restrictions prevent Hemogenyx from disclosing the results of the collaboration, the Company is confident that it has been successful to date and that there is the potential to extend it and to generate additional revenue.

The second announced collaboration with Janssen Research & Development, LLC ("Janssen"), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, is centred on the development of a model of systemic lupus erythematosus ("SLE", also known as Lupus) using AHC. Lupus is a systemic autoimmune disease wherein patients' immune systems attack their own organs including the skin, kidneys, blood cells, brain, heart and lungs. Lupus is often a life-long disease that currently has no cure. Establishing a human Lupus model is very important for understanding the emergence and development of the disease. In addition, if successful, the Lupus model will provide the opportunity not only to test therapeutics that are currently under development, but also potentially to discover fundamentally new therapeutic approaches for treatment of the disease. For a more detailed description of the terms of the collaboration please see the full announcement (**https://goo.gl/rsoqKS**)

The Company has also announced that its wholly owned subsidiary Immugenyx has entered into a collaboration agreement with Orgenesis, Inc ("Orgenesis") to further develop and commercialize its AHC. Orgenesis will advance to Immugenyx a convertible note in an amount of not less than US$1,000,000 that can be converted into shares of Immugenyx at a price per share based on a pre-money valuation of US$8,000,000 with an option to increase the convertible note by up to an additional $1,000,000. For a more detailed description of the terms of the transaction please see the full announcement (**https://goo.gl/RKoTpf**). This collaboration represents additional validation of the potential value of the AHC platform. The Directors believe that the participation of Orgenesis in the business development and commercialization of AHC may significantly expand and speed up the platform's adoption as a standard tool for drug discovery, testing, and disease modeling by a wide variety of pharmaceutical and biotechnology companies around the world as well as providing access to Orgenesis' marketing resources

The research collaboration with Rockefeller University, which focuses on auto-immune disease modelling to develop new treatments for diseases such as Lupus, is still in its early stages and continues to progress in line with the Company's expectations.

The collaborations above and the broad interest currently being shown by other potential

collaborators reinforces the additional value that AHC can potentially unlock.

Hu-PHEC products

The Company has in recent months focused its attention on the CDX Antibodies product candidate but has also taken clear steps to bring forward its Human Postnatal Hemogenic Endothelial Cell ("Hu-PHEC") based suite of product candidates.

To that end, because the technical requirements are different and costly the Company is in the process of establishing a wholly owned subsidiary, Hemogenyx-Cell SA ("Hemogenyx-Cell"), and has entered into a collaboration agreement with Orgenesis to further develop and commercialise its Hu-PHEC technology. Hemogenyx-Cell will engage in preclinical development of the Hu-PHEC technology, and as a Belgian company will be eligible for significant financial support from the Belgian government in the form of non-dilutive matching grants.

Hu-PHEC is a cell replacement product candidate that is being developed by the Company to generate cancer-free, patient-matched blood stem cells after transplantation into the patient. Orgenesis will advance to Hemogenyx-Cell a convertible note in an amount of not less than US$1,000,000 that can be converted into shares of Hemogenyx-Cell at a price per share based on a pre-money valuation of US$12,000,000 with an option to increase the convertible note by up to an additional US$1,000,000. For a more detailed description of the terms of the transaction please see the full announcement (**https://goo.gl/xgCQQY**). The Directors believe that this collaboration is especially important for the Company as it has the potential to drastically speed up development of its Hu-PHEC product candidate without reducing progress on other projects.

Appointments

The Company has made two significant appointments to its leadership and advisory team. In March 2018, the Company appointed H. Michael Shepard, Ph.D. to its Scientific Advisory Board (**https://goo.gl/jfQ37L**). Dr. Shepard is a pioneer in modern cancer research. His work has led to the discovery and development of many successful cancer treatments, most notably leading the development of Herceptin/trastuzumab, an antibody used to treat breast cancer patients. Sales of Herceptin and its biosimilars currently exceed $6.5 billion worldwide. In his Advisory Board role, Dr. Shepard draws on his many years of experience advancing antibody-based therapeutics from the development phase, through clinical studies and FDA approval, to commercial launch.

In April 2018 Sir Marc Feldmann, AC, FRS, a pre-eminent medically trained immunologist at the University of Oxford, was appointed Chairman of the Board (**https://goo.gl/Qo49qJ**). Sir Marc was the Head of the Kennedy Institute of Rheumatology until 2014 and is now an Emeritus Professor. Sir Marc shares the academic credit for inventing and developing anti-TNF therapy for rheumatoid arthritis, the first major use of monoclonal antibodies in a common disease. Centocor, Inc licensed Sir Marc's key patent, and developed Infliximab, ultimately branded as Remicade. Remicade was the main driver of the $4.9 billion acquisition of Centocor by Johnson and Johnson in 1999 and is still J&J's best-selling drug. Since 2012 Anti-TNF therapy has become the world's largest drug class with sales in 2016 exceeding US$36 billion, all based on Feldmann's research. Sir Marc has broad experience in drug development , having worked through all stages from developing new concepts of how diseases emerge, through testing ideas and early clinical development, leading clinical trials, approval, registration and commercial execution.

Conclusion

The Company has made significant progress in widening its suite of products (e.g., its collaborations pertaining to AHC) and their potential applications (e.g., the application of CDX antibodies to treat AML) and providing important partnerships and finance for all of its product

suites. The Directors believe that investment in the diversification of the Company's product suites and their application to additional disease markets de-risks the business and maximizes overall potential shareholder value.

Overall the Board is very pleased with the progress being made, in particular the unlocking of opportunities for CDX antibodies, as well as the potential value that can be created through the Company's new type of humanized mice.

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About Hemogenyx Pharmaceuticals plc

Hemogenyx Pharmaceuticals plc is a publicly traded company (LSE: HEMO) headquartered in London, with its wholly owned US operating subsidiary, Hemogenyx LLC, located in New York City at its state-of-the-art research facility ("Hemogenyx").

Hemogenyx is a pre-clinical stage biopharmaceutical group developing new medicines and treatments to bring the curative power of bone marrow transplantation to a greater number of patients suffering from otherwise incurable life-threatening diseases. Hemogenyx is developing two distinct and complementary products, as well as a platform technology that it uses as an engine for

novel product development.

For more than 50 years, bone marrow transplantation has been used to save the lives of patients suffering from blood diseases. The risks of toxicity and death that are associated with bone marrow transplantation, however, have meant that the procedure is restricted to use only as a last resort. Hemogenyx's technology has the potential to enable many more patients suffering from devastating blood diseases such as leukemia and lymphoma, as well as severe autoimmune diseases such as multiple sclerosis, aplastic anemia and systemic lupus erythematosus (Lupus), to benefit from bone marrow transplantation.

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