

HaemaLogiX and Lonza Collaborate to Manufacture KappaMab, a Multiple Myeloma Drug Candidate

- Lonza to manufacture drug substance for clinical supply of HaemaLogiX's lead multiple myeloma drug candidate, KappaMab, at its new state-of-the-art facility in Guangzhou (CN)
 - HaemaLogiX will leverage Lonza's regulatory expertise, global manufacturing footprint, and extensive experience in manufacturing monoclonal antibodies
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Basel, Switzerland and Sydney, Australia, 27 January 2022 – HaemaLogiX Ltd (HaemaLogiX), the clinical-stage biotechnology company developing novel monoclonal antibody therapies for multiple myeloma, and Lonza, a global development and manufacturing partner to the pharma, biotech and nutrition industries, have entered into an agreement to manufacture the next clinical batch (cGMP) of HaemaLogiX's lead multiple myeloma drug candidate, KappaMab.

KappaMab is a monoclonal antibody which binds to a cell surface target called kappa myeloma antigen (KMA) that is only found on myeloma cancer cells and not on normal plasma cells. Specific binding of KappaMab to the myeloma cell enables the patient's immune system to recognize the cell as abnormal, triggering the natural response to attack and kill the myeloma cell. As a result, only the cancer cells are depleted and normal healthy plasma cells are spared from the patient's immune system attack.

To date, KappaMab has been tested in three clinical trials where it showed a good safety profile with no dose-limiting toxicities following single and multiple doses^{1,2,3}. In a recent phase 2b clinical trial, KappaMab synergized with the immune modulator drug (IMiD) lenalidomide in combination with dexamethasone to produce more disease responses and improved quality of response versus case-matched lenalidomide plus dexamethasone alone in patients with relapsed, refractory multiple myeloma².

¹ Spencer A, Walker P, Asvadi P, et al. A preliminary study of the anti- κ myeloma antigen monoclonal antibody KappaMab (MDX-1097) in pretreated patients with κ -restricted multiple myeloma. *Blood Cancer J.* 2019; 9(8):58.

² Kalff A, Shortt J, Yuen F, et al. A Sequential Cohort Study Comparing Kappamab Alone to Kappamab, Lenalidomide and Low Dose Dexamethasone in Kappa-Restricted Relapsed Refractory Multiple Myeloma (AMaRC 01-16). *Blood.* 2019; 134(Supplement_1): 3144-3144.

³ Spencer A, Augustson B, Mollee P, Copeman M, Asvadi P, Dunn R. Phase 2a, open-label, multi-dose study of the anti-kappa monoclonal antibody, MDX-1097, in relapsed kappa-chain restricted multiple myeloma with stable measurable disease. The European Hematology Association (EHA). Stockholm, Sweden; 2013.

Bryce Carmine, Chairman and CEO, HaemaLogiX, commented: "Multiple myeloma is the second most common haematological cancer worldwide, with an estimated 32,000 new cases and over 12,500 deaths annually in the US alone (2019), and a European incidence roughly equivalent. The incurable nature of multiple myeloma makes it necessary to expand treatment options available to patients. We look forward to taking KappaMab back into the clinic alongside standard of care, and this Lonza agreement is an important step toward providing the drug product for our upcoming trial."

According to the terms of the agreement, Lonza will manufacture drug substance of KappaMab for clinical supply at Lonza's new state-of-the-art cGMP mammalian manufacturing facility in Guangzhou (CN), which houses two 1,000-liter and two 2,000-liter single-use bioreactors. HaemaLogiX will leverage Lonza's regulatory expertise, global manufacturing footprint, and extensive experience in manufacturing monoclonal antibodies.

Jeetendra Vaghjiani, Executive Director, Clinical Development & Strategic Marketing, Lonza, commented: "We are looking forward to building a collaboration with HaemaLogiX to help advance their multiple myeloma candidate towards commercial launch. We will leverage our unique flexible offering and state-of-the-art expertise in manufacturing monoclonal antibodies at our site in Guangzhou (CN)."

The target completion date for the drug product is Q4 2022. The drug product will then be used in Australian-based clinical trials, currently scheduled to begin in late 2022.

About Lonza

Lonza is the preferred global partner to the pharmaceutical, biotech and nutrition markets. We work to enable a healthier world by supporting our customers to deliver new and innovative medicines that help treat a wide range of diseases. We achieve this by combining technological insight with world-class manufacturing, scientific expertise and process excellence. Our unparalleled breadth of offerings enables our customers to commercialize their discoveries and innovations in the healthcare sector.

Founded in 1897 in the Swiss Alps, today, Lonza operates across five continents. With approximately 15,000 full-time employees, we comprise high-performing teams and individual talent that make a meaningful difference to our own business, as well as to the communities in which we operate. The company generated sales of CHF 2.5 billion with a CORE EBITDA of CHF 847 million in H1 2021. Find out more at www.lonza.com.

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About HaemaLogiX Ltd - www.haemalogix.com:

Formed in 2014, HaemaLogiX is a public unlisted biotech company researching antibody therapies for multiple myeloma. Multiple myeloma is a haematological (blood) cancer of plasma cells (B cells) that can cause focused damage to a patient's bone marrow. Multiple myeloma is considered treatable but generally incurable. The HaemaLogiX team has a wide range and depth of experience in antibody research, nonclinical & clinical development, manufacturing and commercialisation. The Scientific Advisory Board (SAB) members are internationally recognised experts in monoclonal antibody therapies and haematology. Our current research and clinical trial partners are global leaders in Multiple Myeloma and AL Amyloidosis therapy. HaemaLogiX is located in Sydney, Australia.

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