Helix BioPharma Corp. and Moffitt Cancer Center to investigate L-DOS47 and checkpoint blockade

L-DOS47 therapy provides an alternative pharmacologic approach to neutralizing tumor acidity that may improve the response of immune checkpoint inhibitors

(Toronto, Ontario) – Helix BioPharma Corp. (TSX, FSE: “HBP”) (“Helix” or the “Company”), an immuno-oncology company developing innovative drug candidates for the prevention and treatment of cancer, today announced that it has entered into a collaboration agreement with Moffitt Cancer Center to perform basic research studies to further investigate the pharmacodynamics of L-DOS47 and determine the potential benefits of combining L-DOS47 with immune checkpoint inhibitors.

Cancer immunotherapies, such as immune checkpoint blockade or adoptive T-cell transfer, can lead to durable responses in the clinic. However the effectiveness of these therapies can be influenced by a number of factors unique to the tumor's microenvironment. Work conducted by Moffitt Cancer Center determined that an acidic pH tumour microenvironment is one of those factors that may lower the efficacy of these therapies. Neutralizing tumour acidity impaired the growth of some cancer types in mice where it was associated with increased T cell infiltration. As a result, raising intratumoral pH may improve responses to immunotherapy. Urease, the active component of L-DOS47, alters the pH of the local tumour milieu resulting in alkalinization of the local tumour environment.

“Our own experiments suggest that tumour acidity can be a ‘barrier’ against immunotherapies” said Heman Chao, Ph.D., Chief Executive & Scientific Officer of Helix. “Urease, the active component of L-DOS47, alters the pH of the local tumour milieu resulting in alkalinization of the local tumour environment.”

“We have been showing for years that neutralization of tumor acidity with oral buffers can prolong life in mice bearing cancer and that it combines with checkpoint blockade therapies to improve response rates” said Dr. Robert Gillies, Director of Moffitt’s Cancer Imaging and Technology Center of Excellence and the Martin Silbiger Chair of Cancer Imaging and Metabolism, “However, our attempts to bring buffers to the clinic have not been successful as they are too cumbersome. We are extremely excited about Helix’s technology because it will directly neutralize tumour acidity in a very localized fashion and thus will not have the systemic and dosing problems that we encountered with buffers. We have high expectations that this first in class approach to treating cancer will be successful.”
Collaboration Overview

Under this research plan Moffitt Cancer Center will perform in vitro and in vivo research studies to study the pharmacodynamics of L-DOS47 and its effect when combined with check-point blockage agents using their unique tumor models.

About Helix BioPharma Corp.

Helix BioPharma Corp. is an immuno-oncology company specializing in the field of cancer therapy. The company is actively developing innovative products for the prevention and treatment of cancer based on its proprietary technologies. Helix’s product development initiatives include its novel L-DOS47 new drug candidate. Helix is currently listed on the TSX and FSE under the symbol “HBP”.

About Moffitt Cancer Center

Moffitt is dedicated to one lifesaving mission: to contribute to the prevention and cure of cancer. The Tampa-based facility is one of only 48 National Cancer Institute-designated Comprehensive Cancer Centers, a distinction that recognizes Moffitt’s excellence in research, clinical trials, prevention and cancer control. Moffitt is the No. 6 cancer hospital in the nation and has been listed in U.S. News & World Report as one of the “Best Hospitals” for cancer care since 1999. Moffitt devotes more than 2 million square feet to research and patient care. Moffitt’s expert nursing staff is recognized by the American Nurses Credentialing Center with Magnet® status, its highest distinction. With more than 5,600 team members, Moffitt has an economic impact in the state of $2.1 billion. For more information, call 1-888-MOFFITT (1-888-663-3488), visit MOFFITT.org, and follow the momentum on Facebook, Twitter and YouTube.

About L-DOS47

L-DOS47 is Helix’s first immunoconjugate based drug candidate in development based on the Company’s novel DOS47 platform technology, which is designed to use an innovative approach to modify the microenvironmental conditions of cancer cells in a manner that leads to their destruction.

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This news release may contain forward-looking statements and information (collectively, "forward-looking statements") within the meaning of applicable Canadian securities laws including, without limitation, those relating to Helix’s operations and strategy and its research and development activities. These statements generally can be identified by forward looking words such as “may”, “will”, “expect”, “estimate”, “anticipate”, “intends”, “believe”, “suggests”, “successful”, “high expectations” or “continue” or the negative thereof or similar variations.

Although Helix believes that the expectations reflected in such forward-looking statements are reasonable, such statements involve risks and uncertainties that may cause actual results or events to differ materially from those anticipated and no assurance can be given that these expectations will be realized, and undue reliance should not be placed on such statements. Factors that could cause actual results or events to differ materially from the forward-looking statements include, without limitation, risks inherent in Helix’s research and development activities and those risks and uncertainties affecting the Company, as more fully described in Helix’s most recent Annual Information Form, including under the headings “Forward-
Looking Statements” and “Risk Factors”, filed under Helix’s profile on SEDAR at www.sedar.com (together, the “Helix Risk Factors”). Certain material factors, estimates or assumptions have been applied in making forward-looking statements including, without limitation, the safety and efficacy of the Company’s drug product candidates; that sufficient financing will be obtained in a timely manner to allow the Company to continue operations and implement its clinical trials in the manner and on the timelines anticipated; the timely provision of services and supplies or other performance of contracts by third parties; future costs; the absence of any material changes in business strategy or plans; the timely receipt of required regulatory approvals and strategic partner support and that the factors described in the Helix Risk Factors will not cause the Company’s actual results or events to differ materially from the forward-looking statements. These cautionary statements qualify all such forward-looking statements.

Forward-looking statements and information are based on the beliefs, assumptions, opinions, plans and expectations of Helix’s management on the date of this news release, and the Company does not assume any obligation to update any forward-looking statement or information should those beliefs, assumptions, opinions, plans or expectations, or other circumstances change, except as required by law.