



HELIXBIOPHARMA

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Press Release

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## Helix BioPharma Corp. and Moffitt Cancer Center extend collaboration on immunotherapy, including study of L-DOS47 with PD-1/PD-L1 inhibitors

RICHMOND HILL, ONTARIO- Helix BioPharma Corp. (TSX: HBP), (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 extended its collaboration agreement with Moffitt Cancer Center for an additional year.

During the first year of the collaboration, a new pancreatic adenocarcinoma mouse model suitable for testing L-DOS47 in combination with immunotherapy was developed. Preliminary studies in this model showed that L-DOS47 may increase the activity of a PD-1/PD-L1 inhibitor in treating pancreatic cancer. In addition, work was initiated to demonstrate that certain imaging techniques may be useful in directly measuring tumor acidity. Helix is hoping to use this non-invasive technique in the clinic soon.

In year two of the project, work will include not only the study of L-DOS47 in combination with PD-1/PD-L1 inhibitors, but also in combination with other drugs in the pancreatic model. Analysis of the immune response that is occurring in the tumor upon L-DOS47 combination treatment will also be characterized. Results from these studies will add to the current understanding of how tumor acidity affects the tumor immune response. Data from these studies will also support Helix’s plan to increase the clinical application of L-DOS47 with various combination treatments, including immunotherapies with checkpoint inhibitors.

“We are strongly encouraged by our preliminary data that this may be an effective approach to improving outcomes to a variety of therapies” said Dr. Robert Gillies, Martin Silbiger Endowed Chair, Moffitt Cancer Center. “We know that tumor acidity is an important contributor to therapy resistance, and thus neutralizing acidity with L-DOS47 should have a positive effect in combination with chemotherapies and immune checkpoint blockade”.

“This years’ Nobel prize in Physiology or Medicine was awarded for the discovery of cancer therapy by inhibition of negative immune regulation.” said Heman Chao, Ph.D., Chief Executive & Scientific Officer of Helix. “We are very excited to work with the Moffitt team in applying L-DOS47 in immunotherapy and we look forward to using L-DOS47 with PD-1/PD-L1 inhibitors in the clinic which could result in significant benefits to patients.”

### **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 and Chimeric Antigen Receptor (“CAR”) based cell therapies. Helix is currently listed on the TSX and FSE under the symbol “HBP”.

## **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.

## **Investor Relations**

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## **Cautionary Statements**

*This news release may contain forward-looking statements and information (collectively, "forward-looking statements") within the meaning of applicable Canadian securities laws. Forward-looking statements are statements and information that are not historical facts but instead include financial projections and estimates; statements regarding plans, goals, objectives, intentions and expectations with respect to Helix's future business, operations, research and development, including Helix's activities relating to its drug development program, the anticipated timelines for the commencement or completion of certain activities, including enrolment of patients, the expansion of the DOS47 platform into other compounds and indications and other information in future periods. Forward-looking statements, which may be identified by words including, without limitation, "may", "improve", "planned", "possible", "postulated", "enhances", "potential", "development", "unique", "expects", "plans", "will", "intends", "pending", "objective", "exploring", "projected", and other similar expressions, are intended to provide information about management's current plans and expectations regarding future operations.*

*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. Risk factors that could cause actual results or events to differ materially from the forward-looking statements include, without limitation: (i) Helix's ability to operate as a going concern being dependent mainly on securing sufficient additional financing in order to fund its ongoing research and development and other operating activities; (ii) the generally inherent uncertainty involved in scientific research and drug development and those specific to Helix's pre-clinical and clinical development programs (DOS47, L-DOS47, V-DOS47 and CAR-T); (iii) difficulties in predicting accurate timelines for the commencement or completion of certain activities including those in support of ongoing clinical trials; (iv) positive preliminary results from early-stage clinical trials may not be indicative of the final results from the trial or be indicative of favorable outcomes in later-stage clinical trials; (v) delays or inability to complete clinical trials successfully and the long lead-times and high costs associated with obtaining regulatory approval to market any product which may result from successful completion of such trials; (vi) clinical data may not demonstrate adequate efficacy and safety to result in regulatory approval to market any of Helix's product candidates in any jurisdiction; (vii) economic and market conditions may become worse and market shifts may require a change in strategic focus; and (viii) those risks and uncertainties affecting Helix 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](http://www.sedar.com) (together, the "Helix Risk Factors"). Certain material factors and assumptions are applied in making the forward-looking statements, including, without limitation, that sufficient financing will be obtained in a timely manner to allow Helix to continue operations and implement its clinical trials in the manner and on the timelines anticipated and that the Helix Risk Factors will not cause Helix'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.*