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Alpha Tau Receives FDA's Breakthrough Device Designation for the Treatment of Recurrent GBM

JERUSALEM, Oct. 8, 2021 -- Alpha Tau Medical, the developer of the innovative alpha-radiation cancer therapy Alpha DaRT™, is pleased to announce that it has received Breakthrough Device Designation for Alpha DaRT from the U.S. Food and Drug Administration (FDA) for the treatment of patients with recurrent glioblastoma multiforme (GBM). This is the second Breakthrough Device Designation that Alpha Tau has received from the FDA, following its announcement on June 8, 2021 of the receipt of the designation for the treatment of skin cancer without curative standard of cure.

GBM is an aggressive malignant brain tumor, with an average 5-year survival rate of less than 10%, and is the most common malignant tumor of the brain or central nervous system. According to the designation, Alpha DaRT is proposed for use in treating recurrent GBM as an adjunct to standard medical therapies or as a standalone therapy after standard medical therapies have been exhausted.

“As GBM is such a terrible disease, it is critical that we find new solutions for these patients, and we are thrilled that receipt of the FDA’s Breakthrough Device Designation will allow us to expedite our clinical collaborations with leading cancer centers in the U.S. and across the world, and to bring new hope for GBM patients. I am very proud of our team and our collaborators who have worked hard to extend the use of Alpha DaRT to GBM and have already accomplished so many amazing things,” said Alpha Tau CEO Uzi Sofer. “This is fantastic news for Alpha Tau and fantastic news for so many GBM patients around the world.”

About Breakthrough Device Designation

Breakthrough Device is a category designed by the FDA to expedite the review process and to facilitate the clinical trial development of devices that treat life-threatening conditions. The designation is awarded when a device’s preliminary clinical data suggest it might be more effective than the current standard of care on clinically significant endpoints of efficacy, safety, or patient quality of life.

About Alpha DaRT

Alpha DaRT (Diffusing Alpha-emitters Radiation Therapy) enables highly potent and conformal alpha-irradiation of solid tumors. The treatment is delivered by intratumoral insertion of radium-224 impregnated sources. When the radium decays, its short-lived daughters are released from the source and disperse while emitting high-energy alpha particles that destroy the tumor. Since the alpha-emitting atoms diffuse only a short distance, Alpha DaRT mainly affects the tumor, sparing the healthy tissue around it.

About Alpha Tau Medical, Ltd.

Founded in 2016, Alpha Tau Medical Ltd. is an Israeli medical device company that focuses on research, development, and commercialization of the Alpha DaRT for the treatment of solid tumors. The technology was initially developed by Prof. Itzhak Kelson and Prof. Yona Keisari from Tel Aviv University.

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SOURCE Alpha Tau Medical

Forward-Looking Statements

This press release includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. When used herein, words including “anticipate,” “being,” “will,” “plan,” “may,” “continue,” and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon Alpha Tau’s current expectations and various assumptions. Alpha Tau believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. Alpha Tau may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation, Alpha Tau’s ability to receive regulatory approval for its Alpha DaRT technology or any future products or product candidates; its limited operating history; its incurrence of significant losses to date; its need for additional funding and ability to raise capital when needed; its limited experience in medical device discovery and development; its dependence on the success and commercialization of the Alpha DaRT technology; the failure of preliminary data from its clinical studies to predict final study results; failure of its early clinical studies or preclinical studies to predict future clinical studies; its ability to enroll patients in its clinical trials; undesirable side effects caused by Alpha Tau’s Alpha DaRT technology or any future products or product candidates; its exposure to patent infringement lawsuits; its ability to comply with the extensive regulations applicable to it; impacts from the COVID-19 pandemic; its ability to commercialize its Alpha DaRT technology; and the other important factors discussed under the caption “Risk Factors” in Alpha Tau’s Registration Statement on Form F-4 dated August 19, 2021 (the “Registration Statement”) and other filings that Alpha Tau may make with the United States Securities and Exchange Commission. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. While Alpha Tau may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing Alpha Tau’s views as of any date subsequent to the date of this press release.

Additional Information and Where to Find It

On July 8, 2021, Alpha Tau Medical Ltd. announced that it had entered into a definitive merger agreement (the “Merger Agreement”) with Healthcare Capital Corp. (Nasdaq: HCCC) (“HCCC”), a special purpose acquisition company, pursuant to which Alpha Tau Medical Ltd. (“Alpha Tau”) would consummate a business combination transaction (the “Business Combination”) with HCCC and become a Nasdaq-listed public company.

For additional information on the Business Combination, see HCCC’s Current Report on Form 8-K, which was filed with the Securities and Exchange Commission (“SEC”) on July 8, 2021.

In connection with the proposed transaction with HCCC, Alpha Tau Medical Ltd. has filed a Registration Statement on Form F-4, which includes a preliminary proxy statement/prospectus of HCCC.

Investors and security holders of HCCC are advised to read, when available, the preliminary proxy statement, and amendments thereto, and the definitive proxy statement in connection with HCCC’s solicitation of proxies for its special meeting of stockholders to be held to approve the proposed Business Combination because the proxy statement/prospectus will contain important information about the proposed transaction and the parties to the proposed transaction. The definitive proxy statement/prospectus will be mailed to stockholders of HCCC as of a record date to be established for voting on the proposed Business Combination.

Stockholders will also be able to obtain copies of the Registration Statement, proxy statement/prospectus, and Form 8-K, without charge at the SEC’s website at www.sec.gov.

No Offer or Solicitation

This announcement is for informational purposes only and is neither an offer to purchase, nor a solicitation of an offer to sell, subscribe for or buy any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed Business Combination or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Participants in the Solicitation

HCCC and Alpha Tau Medical Ltd. and their respective directors, executive officers, other members of management, and employees, under SEC rules, may be deemed to be participants in the solicitation of proxies of HCCC’s stockholders in connection with the proposed Business Combination between HCCC and Alpha Tau. Investors and security holders may obtain more detailed information regarding the names and interests in the proposed transaction of HCCC’s directors and officers HCCC’s and Alpha Tau’s filings with the SEC, including the Registration Statement.

Forward-Looking Statements

Certain statements made herein are not historical facts but are forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. These statements are based on the current expectations and estimates and assumptions that, while considered reasonable by HCCC and its management and Alpha Tau and its management, are not predictions of actual performance and are inherently uncertain. These statements are subject to a number of risks and uncertainties regarding HCCC’s and Alpha Tau’s businesses and the transaction, and actual results may differ materially. These risks, uncertainties, assumptions and other important factors include, but are not limited to: (1) the occurrence of any event, change or other circumstances that could give rise to the termination of the Merger Agreement and the proposed Business Combination contemplated thereby; (2) the risk that the proposed transactions disrupt current plans and operations of Alpha Tau as a result of the announcement and consummation of the transaction described herein; (3) the ability to recognize the anticipated benefits of the proposed Business Combination, which may be affected by, among other things, competition, the ability of the combined company to grow and manage growth profitably, maintain relationships with customers and suppliers and retain its management and key employees; (4) costs related to the proposed Business Combination; (5) the post-Business Combination entity’s ability to identify and integrate acquisitions; and (6) other risks and uncertainties indicated from time to time in the Registration Statement, including those under “Risk Factors” therein, and other documents filed or to be filed with the SEC by HCCC or Alpha Tau. There may be additional risks that HCCC presently does not know or that HCCC currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements provide the HCCC’s expectations, plans or forecasts of future events and views as of the date of this communication. However, while HCCC may elect to update these forward-looking statements at some point in the future, HCCC specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing HCCC’s assessments as of any date subsequent to the date of this communication.