

## **FDA Grants Hoth Therapeutics Pre-IND Meeting Regarding Proposed Drug Development Plan for HT-001 Treatment for Cancer Patients**

NEW YORK, Jan. 13, 2021 /PRNewswire/ -- Hoth Therapeutics, Inc. (NASDAQ: HOTH), a biopharmaceutical company, today announced the Pre-IND meeting [requested on 22 December 2020](#) for HT-001 with the U.S. Food and Drug Administration (FDA) Division of Dermatology and Dental Products has been granted to receive written responses only from FDA that are targeted for delivery on February 22, 2021.

[HT-001](#) is a topical formulation under development for the treatment of rash and skin disorders associated with initial and repeat courses of tyrosine kinase inhibitor/epidermal growth factor receptor (EGFR) inhibitor therapy for patients undergoing treatment for cancer.

The Pre-IND meeting topics include the acceptability of the overall proposed drug development program for HT-001 including requirements for nonclinical, clinical pharmacology, clinical, chemistry, and manufacturing controls. The proposed clinical trial designs for the first clinical studies (phase 2) in the HT-001 program are also included in the Pre-IND meeting topics to receive FDA feedback.

"We are looking forward to receiving feedback from FDA to continue advancing the HT-001 development program towards the clinic as efficiently as possible," stated Robb Knie, Chairman and CEO of Hoth Therapeutics. "Receiving feedback from FDA in February positions us well to achieve our planned IND-enabling development activities on time with the eventual goal of initiating the first HT-001 clinical trial in patients."

### **About Hoth Therapeutics, Inc.**

Hoth Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing new generation therapies for dermatological disorders. Hoth's pipeline has the potential to improve the quality of life for patients suffering from indications including atopic dermatitis, chronic wounds, psoriasis, asthma and acne and other immunological disorders. Hoth has also recently entered into two different agreements to further the development of two different therapeutic prospects to prevent or treat COVID-19. To learn more, please visit [www.hoththerapeutics.com](http://www.hoththerapeutics.com).

### **Forward-Looking Statement**

This press release includes forward-looking statements based upon Hoth's current expectations which may constitute forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995 and other federal securities laws, and are subject to substantial risks, uncertainties and assumptions. These statements concern Hoth's business strategies; the timing of regulatory submissions; the ability to obtain and maintain regulatory approval of existing product candidates and any other product candidates we may develop, and the labeling under any approval we may obtain; the timing and costs of clinical trials, the timing and costs of other expenses; market acceptance of our products; the ultimate impact of the current Coronavirus pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole; our intellectual property; our reliance on third party organizations; our competitive position; our industry environment; our anticipated financial and operating results, including anticipated sources of revenues; our assumptions regarding the size of the available market, benefits of our products, product pricing, timing of product launches; management's expectation with respect to future acquisitions; statements regarding our goals, intentions, plans and expectations, including the introduction of new products and markets; and our cash needs and financing plans. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. You should not place reliance on these forward-looking statements, which include words such as "could," "believe," "anticipate," "intend," "estimate," "expect," "may," "continue," "predict," "potential," "project" or similar terms, variations of such terms or the negative of those terms. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee such outcomes. Hoth may not realize its expectations, and its beliefs may not prove correct. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, without limitation, market conditions and the factors described in the section entitled "Risk Factors" in Hoth's most recent Annual Report on Form 10-K and Hoth's other filings made with the U. S. Securities and Exchange Commission. All such statements speak only as of the date made. Consequently, forward-looking statements should be regarded solely as Hoth's current plans, estimates, and beliefs. Investors should not place undue reliance on forward-looking statements. Hoth cannot guarantee future results, events, levels of activity, performance or achievements. Hoth does not undertake and specifically declines any obligation to update, republish, or revise any forward-looking statements to reflect new information, future events or circumstances or to reflect the occurrences of unanticipated events, except as may be required by applicable law.

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