



## PRESS RELEASE

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### **Amarna Therapeutics Receives Constructive Feedback from FDA INTERACT Meeting for AM510 Gene Therapy Development Targeting Type 1 Diabetes**

**Leiden, The Netherlands, 27<sup>th</sup> August 2024 - Amarna Therapeutics**, ("Amarna" or "the Company"), a privately held biotechnology company specializing in transformative gene therapies, today announced the successful completion of an FDA INTERACT meeting held on July 31, 2024. The meeting focused on the development plans for AM510, an innovative gene therapy targeting Type 1 Diabetes Mellitus (T1D). The Initial Targeted Engagement for Regulatory Advice (INTERACT) meeting, requested on April 26, 2024, was a collaborative effort involving Amarna's teams in Leiden and Seville, regulatory consultants from Veristat, and some of the key members of Amarna's T1D Scientific Advisory Board. During the meeting, Amarna had an in-depth discussion of the FDA's preliminary feedback in a productive virtual session.

#### **Key discussion points:**

Amarna received extensive feedback on the overall development program, and especially the manufacturing and controls (CMC) program, nonclinical program, and the safety aspects of our clinical trial design. The FDA's insights will be instrumental as we refine our approach to ensure the safety and efficacy of AM510 for T1D patients currently relying on insulin therapy. Amarna looks forward to implementing the guidance received and continuing our collaboration with the FDA as we advance this innovative treatment towards our IND application.

#### **Henk Streefkerk, CEO & Medical Director of Amarna Therapeutics, commented:**

*"Our AM510 tolerance induction program for T1D just hit a major milestone with the FDA INTERACT meeting. We received extremely valuable feedback, confirming our integrated development strategy and outlining a clear regulatory path. We're eager to push forward with our preclinical work towards a successful pre-IND meeting, because we want to start treating and hopefully curing T1D patients as soon as possible"*

The INTERACT meeting was characterized by open dialogue and constructive feedback, which has laid a strong foundation for Amarna's continued development process and future regulatory submissions. Amarna aims to engage again with the FDA in a pre-IND meeting within the next 2 years. Amarna greatly appreciates the FDA's input, as the INTERACT format has proven to be an effective catalyst for advancing early drug development.

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### **About T1D**

T1D is a debilitating disease occurring in millions of patients globally, with rising incidences each year, where despite advancements in therapy the life expectancy remains lower than the general population. Diabetes is an autoimmune disease where self-reactive T lymphocytes selectively attack and destroy insulin-producing  $\beta$  cells lodged within the pancreas, leaving the patient unable to maintain glucose homeostasis. To date, T1D cannot be cured, and glucose homeostasis can only be maintained using daily insulin injections. In addition, secondary complications of the current therapy are considerable and can lead to significant morbidity and mortality. Using Nimvec™ AM510 Amarna intends to restore the immune tolerance to insulin and potentially cure the patients.

### **About Nimvec™ AM510**

The development of AM510 is based on our proprietary Nimvec™ platform, which has demonstrated exceptional promise in preclinical studies. Unlike other gene therapies that induce a strong immune response, limiting the possibility for repeat dosing and efficacy, Nimvec™ does not trigger such immune responses. Instead, it moderates the immune system to induce tolerance, making it an ideal vehicle for our therapeutic approach. Our preclinical data with Nimvec™ AM510 showcases its protective effects in delaying the onset of hyperglycemia and preventing the development of T1DM in relevant animal models.

### **About Amarna Therapeutics**

Amarna Therapeutics is at the forefront of developing groundbreaking immuno modulating gene therapies for rare and prevalent autoimmune diseases and genetic diseases. The company's proprietary Nimvec™ platform is designed to deliver transformative treatments with exceptional promise in preclinical studies. Amarna is committed to pioneering treatments for Type 1 Diabetes Mellitus and enhancing patient outcomes.

More information on [www.amarnatherapeutics.com](http://www.amarnatherapeutics.com)

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### **For further inquiries please contact:**

#### **Amarna Therapeutics**

Henk Streefkerk, CEO

E-mail: [info@amarnatherapeutics.com](mailto:info@amarnatherapeutics.com)

#### **LifeSpring Life Sciences Communication, Amsterdam**

Léon Melens

Tel: +31 6 538 16 427

E-mail: [lmelens@lifespring.nl](mailto:lmelens@lifespring.nl)