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PRESS RELEASE

Aptahem receives full regulatory approval to start the FIH study with Apta-1

Aptahem AB (publ), a biotech company developing treatments for patients suffering from acute inflammatory diseases such as sepsis, has today received approval from the central ethics committee and the competent authorities in the Netherlands to start a clinical First in Human (FIH) study with its drug candidate Apta-1.

The planned randomized, placebo-controlled Phase 1 study will evaluate the safety, tolerability and pharmacodynamic effects of intravenous Apta-1 in healthy volunteers. The results will support the design for the upcoming Phase 2 study to evaluate Apta-1 in patients with sepsis. The planned FIH study will be conducted in collaboration with the Centre for Human Drug Research (CHDR) in Leiden, the Netherlands. CHDR is an independent clinical contract research organization (CRO) specialising in innovative early-stage clinical drug research. CHDR has a considerable expertise in advanced inflammation models that makes them well-suited for early clinical development work with Apta-1.

With this, Aptahem becomes a company in clinical phase with its lead candidate Apta-1. Years of top forefront development breaking new grounds of unique mode of action and effect with Apta-1 now makes it possible to take yet another step towards the market. Those stakeholders that would greatly benefit from the solution now can increase their hopes, specially those victims of sepsis and life threatening inflammatory conditions.

Dr Matthijs Moerland, Research Director Immunology and PI for the study, comments:

“We’re excited to collaborate with Aptahem on this important clinical project. Apart from a thorough investigation of Apta-1’s safety and tolerability, we think this project allows a deep mechanistic evaluation, based on CHDR’s inflammation methodology. Clinical characterization of the anti-inflammatory effects of Aptahem’s aptamer will not only provide insights into the potential therapeutic value of the compound, but also increase our understanding on the central role of thrombin in human physiology.”

CEO Mikael Lindstam comments:

“I am very pleased to receive the approval from the authorities and the ethical committee to be able to start the study. It is an important confirmation that our study design is correct and that the study protocol is well thought-through and elaborated. The team has worked hard to reach to goal to take Apta-1 into clinical phase, and it will be extremely exciting to follow the study and eventually take part of the results. The group at CHDR, lead by Principle Investigator Dr Matthijs Moerland, is very competent and experienced in this kind of clinical development activities and we are convinced that their methodology and models are the most well suited for our study.”

For further information:

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About Sepsis

Sepsis is today considered a world health problem and affects 49 million people worldwide each year, of which 11 million die. In Europe alone, over 1 million people are estimated to be affected by sepsis on a yearly basis*. There is currently no specific treatment for sepsis, but instead the underlying symptoms are treated with antibiotics, fluids and oxygen.

* Rudd KE, Johnson SC, Agesa KM, Shackelford KA, Tsoi D, Kievlan DR, Colombara DV, Ikuta KS, Kissoon N, Finfer S, Fleischmann-Struzek C, Machado FR, Reinhart KK, Rowan K, Seymour CW, Watson RS, West TE, Marinho F, Hay SI, Lozano R, Lopez AD, Angus DC, Murray CJL, Naghavi M. Global, regional,



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and national sepsis incidence and mortality, 1990-2017: analysis for the Global Burden of Disease Study. Lancet. 2020 Jan 18;395(10219):200-211. doi: 10.1016/S0140-6736(19)32989-7. PMID: 31954465; PMCID: PMC6970225.

Forward-looking statements

This press release contains forward-looking statements that constitute subjective estimates and forecasts about the future. Assessments about the future are only valid on the date they are made and are, by their nature, similar to research and development work in the biotech field, associated with risk and uncertainty. In light of this, actual outcomes may differ substantially from what is described in this press release.

About the Centre for Human Drug Research (CHDR)

The Centre for Human Drug Research (CHDR) is an independent institute located in Leiden, the Netherlands that specializes in cutting-edge early-stage clinical drug research. Combining innovative methods and technologies, state-of-the-art facilities, and talented, motivated researchers helps CHDR maximize their clients' success. In addition, CHDR places the highest priority on their subjects' comfort and safety, and they play an active role in helping educate the medical and clinical research communities (www.chdr.nl).

About Aptahem

Aptahem AB (APTA) is a biotechnology company that develops aptamer-based pharmaceuticals for the treatment of life-threatening conditions in which a combination of coagulation and inflammation are involved. The company's primary pharmaceutical candidate, Apta-1, is being developed with the aim of preventing the high mortality rate caused by organ and tissue damage in sepsis patients, among others. The company possesses patent protection in strategic target markets and actively seeks business development opportunities with potential collaborators.