

Malmö 17 May 2022

PRESS RELEASE

Aptahem enters agreement with international clinical CRO for phase 1 studies with Apta-1

Aptahem (publ) announces today that the company has signed an agreement with the clinical contract research organization (CRO) The Centre for Human Drug Research (CHDR) in the Netherlands to perform the upcoming phase 1 studies with Apta-1. By entering this agreement, which follows on the previous Start-Up Agreement, the plans for the phase 1 studies will continue and preparations for the application to the authorities can be initiated.

Aptahem is developing Apta-1 as an acute treatment to prevent organ and tissue damages in patients with sepsis or other inflammatory critical conditions. Sepsis is a condition which yearly affects 47-50 million people worldwide, whereof approximately 11 million die. There is no effective treatment for sepsis and septic shock today, which indicates a large unmet medical need.

The drug candidate Apta-1 has, in preclinical studies, shown to specifically recognize and deactivate thrombin without influencing on the active site of the enzyme and by this reducing the risk of blood clotting, slow down the body's uncontrolled inflammatory response, repair or inhibit tissue degradation and modulate the body's own immune response. All of these mechanisms are relevant in the fight against sepsis, a multi factorial condition which can be triggered by several diseases and by a simple infection.

This agreement follows on the initial start-up agreement which was signed in the beginning of the year to allow Aptahem to finalize all documentation and initiate the phase 1 studies according to plan.

Aptahem CEO Mikael Lindstam comments:

"We have had an ongoing dialogue with CHDR since we entered the start-up agreement and we have now finalized a solid as well as tailor made study design for the unique properties of Apta-1. CHDR has been an excellent partner who has contributed with their experience, expertise and key opinion leaders within the field. I am very pleased with entering this agreement to be able to continue our preparations according to the communicated timelines and to become a company in clinical phase."

CHDR CEO Koos Burggraaf comments:

"We are thrilled to solidify our partnership with Aptahem and move the Apta-1 program forward into the clinical phase. Our unique approach in early phase drug development that includes specific methodology for clinical research of inflammation and sepsis, will facilitate the efficient translation of Apta-1 into the clinic."

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.

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* Rudd KE, Johnson SC, Agesa KM, Shackelford KA, Tsoi D, Kievelan 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, 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, Apt-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.