

# Malmö 19 September 2022

### **PRESS RELEASE**

## Aptahem submit regulatory approval to initiate clinical phase 1 study

Aptahem AB (publ) announce today that applications to the regulatory authority and the central ethics committee in The Netherlands have been submitted for approval to initiate a clinical phase 1 study with its drug candidate Apta-1.

Aptahem develop Apta-1 to offer an emergency treatment to prevent the emergence of organ and tissue damage in patients suffering from sepsis or other critical inflammatory conditions. The applications to the regulatory authority, *Centrale Commissie Mensgebonden Onderzoek* (CCMO, and the responsible ethical committee in The Netherlands for approval to initiate a first-in-human study in healthy volunteers with Aptahem's drug candidate Apta-1 have now been submitted.

The study consists of 2 parts. The purpose of part A is to evaluate the safety and tolerability of Apta-1, while part B is to evaluate the response on systemic inflammation of Apta-1 in the participants who have been challenged with LPS (the bacterial toxin lipopolysaccharide). LPS is a well-established provocation model used to induce measurable symptoms for characterizing the early stages of septic inflammation.

#### **CEO Mikael Lindstam comments:**

"I am pleased to announce that we now have achieved the important milestone to submit the applications to the regulatory authority and the central ethical committee to initiate our first clinical phase 1 study with Apta-1. The team at Aptahem has made a great job to get all the pieces in place in close collaboration with our contract research organization CHDR. We are now looking forward to receiving a prompt response from the authority and the ethics committee, however within 60 days at most."

## For further information:

Aptahem AB Mikael Lindstam, CEO Tel: +46 (0)766-33 36 99 E-mail: ml@aptahem.com

### 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, 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 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.