

APTAHEM

Malmö August 29, 2018

PRESS RELEASE

Apta-1 has in the ongoing toxicology program indicated a good safety profile that resulted in a greater substance need, which delays the program

Aptahem AB (publ) announce today that the company's ongoing pre-clinical toxicology development program is delayed pending the manufacturing of more Apta-1.

The drug candidate Apta-1 has in the company's ongoing toxicology program indicated a good safety profile, which has resulted in a greater substance need (Apta-1) than expected. The results also indicate that the dosages can be increased in the ongoing efficacy study in NHP (Non Human Primate), which warrant us to test higher dosages and lead to an extension of the study. The time required for the manufacturing of new substance causes a delay of the start of the regulatory GLP toxicology, which is expected to postpone the planned start of clinical trials to the third quarter 2019.

Aptahem is currently conducting a regulatory-controlled pre-clinical safety program comprising non-regulated GLP (Good Laboratory Practice) toxicology studies in rat and primate (NHP). The results, thus far, suggest a good safety profile, which has resulted in a greater substance need than estimated. This means that there will not be enough manufactured substance to start the next part of the toxicology program on time. Additional non-GMP substance (Good Manufacturing Practice), therefore, needs to be manufactured to start the regulatory GLP program.

The process development work in order to produce a GMP-batch for the company's planned clinical trials is ongoing in parallel. Discussions are ongoing with the contract manufacturer to ensure satisfactory purity. Aptahem has been informed by the contract manufacturer that the process development is, thus, extended but it should not contribute to the overall delay.

Aptahem's CEO, Mikael Lindstam, comments, "Aptahem has come into a somewhat paradoxical situation where our pre-clinical studies indicate that Apta-1 has a good safety profile, but where the same conclusion leads to a delay. We are, of course, happy to see a good safety profile but are disappointed to announce the consequences on our timeline."

In parallel, an NHP efficacy study is testing the therapeutic efficacy of Apta-1. Based on the above knowledge, the NHP efficacy study will, therefore, be extended to a study where more and higher doses are administered. Overall, the extension means that a more comprehensive statistical data sample can be collected, which has been requested in discussions with big pharmaceutical companies.

The overall situation means that the planned start of the clinical trials is estimated to the third quarter 2019.

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This information is information that Aptahem AB is obliged to make public according to the EU Market Abuse Regulation. The information was provided through the agency of the contact persons above, for publication on August 29, 2018.

Forward-looking statements

This communication contains forward-looking statements, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as of the date they are made and are, by their nature, as is research and development work in the biotechnology segment, associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios as 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.