

APTACHEM

Malmö 10 August 2020

PRESS RELEASE

The first larger scale production campaign of Aptahem's lead candidate Aptahem-1 is now ready to start

Aptahem AB, a leading developer of aptamer-based drugs, announced today that the company is now starting large-scale manufacturing after LGC Bioresearch Technologies Inc. (LGC) completed the Process Development (PD) work enabling larger Pilot scale production campaigns of Aptahem-1.

This campaign is now the first larger scale production run of Aptahem-1 as a non-GMP material, intended for use in GLP toxicology studies. The preceding PD work also enables LGC to manufacture Aptahem-1 under GMP for use in the first in human clinical trial. However, continuous PD work will focus on optimization of manufacturing cost, thus lowering Cost of Goods (CoG), and to further improve process, such as yield and purity. The progress made in process optimization is also a result of a long and careful analytical development work by LGC and their sister company AxoLabs. This analytical development has been key to assess the set-up parameters necessary for the scale up and in process control.

“We are excited to announce that the collaboration with LGC as our long-term partner to scale up production of Aptahem-1 for our development program, now reached a first milestone in production settings,” says Mikael Lindstam, CEO of Aptahem, and continues: “We will not rest at this as together with LGC we will continue to optimize the process for forthcoming manufacturing but we have now reached a good starting point.”

Thomas Rupp, Subject Matter Expert on Nucleic Acid manufacturing, CMC consultant to Aptahem, says, “Because of its highly structured aptamer nature, the manufacturing and analytical characterization of Aptahem-1 proved expectedly challenging. Both, AxoLabs and LGC, have utilized their outstanding experience in the field of Nucleic Acids to deliver tremendous analytical and process development work facilitating the manufacturing of the Aptahem lead compound, whilst maintaining scalability and cost of the process.”

David Griffiths, Ph.D., Managing Director of LGC's Nucleic Acid Therapeutics Solutions business says, “Aptahem is a dynamic company and leader in an exciting and innovative field. The LGC team is delighted by the collaboration with Aptahem to develop the Aptahem-1 programme. Our core purpose is science for a safer world and we have applied all our specialist knowledge and capabilities to help Aptahem progress with their mission.”

For further information:

Aptahem AB

Mikael Lindstam, CEO

Tel: +46 (0)766-33 36 99

E-mail: ml@aptahem.com

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About LGC

LGC is an international leader in the extended life sciences sector, including human healthcare, agri-food & the environment. LGC provides a comprehensive range of reference materials, proficiency testing schemes, and genomics reagents, as well as research and measurement services. Its scientific tools and solutions enable organisations to advance research, develop new products and form an essential part of their quality and compliance procedures. For more information, please visit www.lgcgroup.com

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.