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ARCALIS, Inc.
Axcelead Drug Discovery Partners Inc.

ARCALIS and Axcelead DDP Announce Collaboration to Provide Integrated Drug Discovery Support Service for mRNA Therapeutics

TOKYO, JAPAN, 20 JULY 2022: ARCALIS Inc. (Head office: Kashiwa, Chiba; President & CEO: Tomoyuki Fujisawa; "ARCALIS") and Axcelead Drug Discovery Partners Inc. (Head office: Fujisawa, Kanagawa; President & CEO: Yoshinori Ikeura; "Axcelead DDP"), both are subsidiary of Axcelead Inc. (Head office: Minato-ku, Tokyo; President & CEO: Tomoyuki Fujisawa; "Axcelead"), today announced a collaboration to provide integrated drug discovery support service for mRNA vaccines and therapeutics.

This service enables the fastest and successful discovery of mRNA vaccines and therapeutics from scratch. ARCALIS, a contract development and manufacturing organization (CDMO) for mRNA pharmaceuticals, is in charge of mRNA design, synthesis, and evaluation, and Axcelead DDP, which has drug discovery platform capabilities, conducts the preparation of the lipid nanoparticle (LNP) formulation for mRNA transfection and *in vitro/in vivo* evaluations. Through this collaboration, it will be possible to provide lead mRNA-LNP formulations with confirmed *in vivo* expression in three months at the earliest. Once a candidate mRNA has been identified, Axcelead DDP supports research strategy planning and conducts pharmacological studies, pharmacokinetic studies, and toxicity studies for IND in consideration of project characteristics such as target molecules and potential indications. ARCALIS supports customers from CMC (Chemistry, Manufacturing and Control) development to cGMP-qualified drug substance manufacturing for both clinical development and commercial purposes.

Through this service, customers can instantly obtain the *in vivo* expression-proven mRNA-LNP and validate the concept (go/no-go decision) just by providing ARCALIS/Axcelead DDP with target information of interest.



Tomoyuki Fujisawa, President and CEO of Axcelead states, "Academic institutes and pharmaceutical companies around the world are now keen to enter the field of mRNA vaccines and therapeutics. However, in order to participate into this groundbreaking pharmaceutical modality, they must design and procure active pharmaceutical ingredient of mRNA, and formulate it in order to evaluate pharmacological efficacy and safety both in the cellular and animal models. As of today, we have never seen a non-clinical platform service provider in the world, which can provide fully-integrated service in early-stage mRNA drug discovery process. But now, through the collaboration between ARCALIS and Axcelead DDP, we will see a world-first, fully-integrated non-clinical platform service. This service is expected to strongly promote the efficient generation of future breakthrough vaccines and therapeutics using mRNA."

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About ARCALIS Inc.

ARCALIS is an mRNA vaccines and therapeutics contract development and manufacturing organization ("CDMO"), jointly established by Axcelead. and Arcturus Therapeutics Holdings, Inc. (NASDAQ: ARCT/hereafter, Arcturus). ARCALIS aims to develop the world's first mRNA vaccines and therapeutics CDMO business that promises a stable supply of high-quality mRNA medicines to all customers, including Arcturus, other pharmaceutical companies, biotech companies, and academic institutes worldwide. The new facility in the city of Minami-soma (Fukushima prefecture) will be equipped with state-of-the-art manufacturing and quality control systems that meet the cGMP standards for pharmaceuticals.

About Axcelead Drug Discovery Partners, Inc.

Axcelead DDP is the first integrated drug discovery solutions provider in the pharmaceutical industry in Japan, having succeeded the drug discovery research capabilities of Takeda Pharmaceutical Company Limited and started its business in July, 2017. The company provides integrated services, from discovery of drug targets to optimization of small- and medium-molecule drug candidates, in which the company has particular expertise, and to the process of bridging the gap to clinical development. For more information, please visit

<https://www.axcelead.com/en/>