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Axcelead Decided to Build an mRNA Drug Manufacturing Plant in Minamisoma City, Fukushima Prefecture — A worldwide mRNA Vaccine and Therapeutic Drug Substance Factory is Scheduled to Start Operations in 2023 —

Axcelead, Inc. (CEO, Tomoyuki Fujisawa, "Axcelead") announced today, that ARCALIS, Inc. ("ARCALIS"), a joint venture entity between Axcelead and Arcturus Therapeutics, Inc. ("Arcturus", Nasdaq: ARCT), have decided to build its mRNA manufacturing plant in Minamisoma City, Fukushima Prefecture.

ARCALIS is a company that develops a contract development and manufacturing organization (CDMO) focused on mRNA vaccines and therapeutics, which would provide manufacturing service to Arcturus and also to pharmaceutical and biotech companies over the world. ARCALIS plans to develop the one-stop integrated mRNA vaccines and therapeutics CDMO business, which promises a stable supply of high-quality mRNA drugs to a wide range of customers. The factory to be constructed in Minamisoma City is equipped with state-of-the-art manufacturing control and quality control systems that meet the current Good Manufacturing Practices (cGMP), and is equipped with mRNA vaccines and therapeutics for the entire world, mainly in Japan, the United States and Europe. We plan to manufacture medicines on a contract basis. As a first step, we plan to start operation of the API plant by the end of 2023.

Arcturus is a leading clinical-stage messenger RNA medicines company focused on the development of infectious disease vaccines and significant opportunities within liver and respiratory rare diseases. Arcturus's COVID-19 vaccine candidate, ARCT-021, is a single shot, lyophilized self-amplifying mRNA vaccine, which may show important differences from currently available mRNA vaccines.

"The efficacy and safety of mRNA vaccine, a new drug discovery modality, has already been demonstrated by Pfizer and Moderna products, and it is expected that the development of mRNA vaccine will continue to expand and the manufacturing needs for ARCALIS will continue to grow. We hope that we can contribute to the reconstruction of the earthquake as much as possible through the construction and start of operation of the plant," said Tomoyuki Fujisawa, CEO of Axcelead. "We believe that establishing a state-of-the-art pharmaceutical





production base in Minamisoma will make a significant contribution to the revitalization of the local economy. We will support this project, to make this enterprise invitation succeed" said Kazuo Monma, Mayor of Minamisoma.

Regarding to the relationship between this project and government efforts, this project can be positioned as contributing to the (1)"Fukushima Innovation Coast Concept" promoted by the government and (2)"strengthening the competitiveness of CDMO for biologics" to further improve the competitiveness of the Japanese biotechnology industry.

(1) This project is expected to be a pioneer of industrial agglomeration in the "medical related" category in Fukushima Innovation Coast Concept as a plan for priority promotion of efforts that contribute to the creation of new industries and the strengthening of the international competitiveness of industries in Fukushima Prefecture.

(2) Biologics requires special manufacturing technologies and know-how, different from conventional chemical synthesis, and has a problem that development and manufacturing costs are higher than those of conventional small molecule drugs. In addition, as the role of venture companies in the development of new drugs is increasing, cooperation with external businesses is indispensable in order to maximize the vitality of venture companies that have technological capabilities but lack financial resources. For these reasons, the government is working to strengthen the competitiveness of CDMOs such as biologics from the perspective of securing a domestic manufacturing base. This project is expected to be an advanced and pioneering example of CDMO for biologics.

Regarding the establishment of ARCALIS, it is a part of the project described in "Axcelead Launches ARCALIS, a Joint Venture to Manufacture mRNA Therapeutics" reported by Axcelead on April 27. This project is described in the joint report by Hitachi, Ltd. and Axcelead on April 7, "Hitachi and Axcelead have agreed to start joint development of solutions contributing on more efficient of next-generation biopharmaceuticals" * 2.

*1Press Release URL :

<u>https://www.axcelead-hd.com/wp-content/uploads/2021/04/アクセリードmRNA医薬品CDMO合弁会社「Arcalis」を</u> 設立fin 2.pdf

*2Press Release URL :

https://www.axcelead-hd.com/wp-content/uploads/2021/04/20210407_AHDHITACHI_newsrelease_JP-1.pdf





About Axcelead, Inc.

Axcelead is a group of companies that develops a drug discovery platform business centered on Axcelead Drug Discovery Partners, Inc. (ADDP), Japan's first integrated drug discovery solution provider, which took over Takeda's drug discovery platform business in 2017. Axcelead, is the flagship portfolio company of Drug Discovery Gateway Fund, which was jointly established by Whiz Partners, Inc., and Takeda Pharmaceutical Company, Co., Ltd., in 2018, with the aim of promoting the drug discovery ecosystem in Japan and will make various contributions to healthcare broadly and globally. For more information on Axcelead and Whiz Partners, please visit the company's website at https://www.axcelead-hd.com/, and at http://www.axcelead-hd.com/, and

About Minamisoma city

Minamisoma City was born on January 1, 2006 by merging 1 city and 2 towns of the former Odaka Town, the former Kashima Town, and the former Haramachi City.

Minamisoma City is located in the northern part of Hamadori, Fukushima Prefecture, facing the Pacific Ocean, and has an area of 398.58 square kilometers. The distance from Tokyo is 292 kilometers, which is approximately halfway between Iwaki City in Fukushima Prefecture and Sendai City in Miyagi Prefecture.

Minami soma city is promoting town development through the "100 years based Minamisoma City Reconstruction Comprehensive Plan Late Basic Plan" formulated in 2019 with the aim of recovering from the Great East Japan Earthquake that occurred on March 11, 2011 and the accident at the Fukushima Daiichi Nuclear Power Station of Tokyo Electric Power Company. In addition, in line with the Fukushima Innovation Coast Initiative promoted by the government, we are implementing various initiatives such as attracting companies in priority fields such as medical care, the robot and drone field.

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