PRESS RELEASE

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## Further Expanding the Regenerative Medicine Business Ajinomoto Co., Inc. Supplies Japan's First Growth Factor for Clinical Research to Research Facilities Obtained Written Confirmation of Raw Material Eligibility from

Pharmaceuticals and Medical Devices Agency

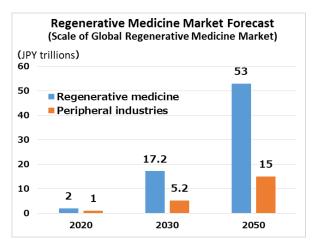
**TOKYO, November 29, 2018** – Ajinomoto Co., Inc. ("Ajinomoto Co.") obtained written confirmation from the Pharmaceuticals and Medical Devices Agency ("PMDA"), the pharmaceutical regulatory and review agency of Japan's Ministry of Health, Labour and Welfare, that Ajinomoto Co.'s "Recombinant human activin A", which is a growth factor<sup>1</sup> that is indispensable for cell differentiation<sup>2</sup> in regenerative medicine, does not contain any raw materials to which the Standards for Biological Ingredients are applicable. Thereafter, Ajinomoto Co. made this growth factor available to research facilities as the first in Japan for clinical research applications. By supplying a growth factor that has a high level of safety and enables cell differentiation to regenerative medicine research facilities for clinical research applications, Ajinomoto Co. aims to contribute to regenerative medicine, a field where considerable growth in demand is expected, and to expand its advanced biopharmaceuticals business.

1. A general term for proteins that promote proliferation and differentiation of specific cells in humans and animals

2. Causing iPS/ES cells to change into the cells of various tissue and organ cells that make up the body

As a result of advances in clinical research into regenerative medicine and its practical application, the global market for regenerative medicine is expected to grow to about JPY 17 trillion in 2030 and about JPY 53 trillion in 2050 (source: "Report on Application and Industrialization of Regenerative Medicine," Ministry of Economy, Trade and Industry). The market for industries peripheral to regenerative medicine, including materials such as the cell culture media and growth factors indispensable for cell proliferation and differentiation, and the equipment, consumables and services necessary for practical applications, has been forecast to reach JPY 5.2 trillion in 2030 and 15 trillion in 2050 (source: ibid.), and in this area demand is particularly rising for materials with a high level of safety.

Ajinomoto Co. was a global pioneer in the development of a method for producing activin A, a growth factor that promotes cell differentiation, and has been supplying it to prominent basic research institutions. Amid demand for the provision of growth factors that are free of animal- and human-derived components for clinical research applications associated with advances in regenerative medicine in recent years, Ajinomoto Co. manufactured "Recombinant human activin A" growth factor using its original biotechnologies for producing recombinant proteins<sup>3</sup> with a higher level of safety and launched it for testing and research applications in March 2018. Thereafter, Ajinomoto Co. applied to the PMDA for a consultation on raw material eligibility for regenerative medicine and other products and in





obtained written confirmation of raw material eligibility from the PMDA

October 2018 obtained the first written confirmation in Japan stating that "Recombinant human activin A" does not contain any raw materials to which the Standards for Biological Ingredients are applicable. Upon receipt of the confirmation, Ajinomoto Co. started supplying this growth factor to regenerative medicine research facilities for clinical research applications.

3. Proteins produced by microorganisms into which human genes are introduced

In its FY2017-2019 Medium-Term Management Plan, Ajinomoto Co. has been working to cultivate its advanced biopharmaceuticals business as a new growth driver, and it has strengths in development technologies for cell culture medium raw materials, components and other substances accumulated through its development of enteral nutrition products, serum-free culture media and other products, as well as its many years of amino acid nutrition research and biotechnologies. Using these strengths, Ajinomoto Co. has been promoting the development of its *StemFit*® culture medium for iPS/ES cells with the Center for iPS Cell Research and Application, Kyoto University. In 2018, Ajinomoto Co. also entered the contract development and manufacturing organization (CDMO) business for clinical-use cell culture media for regenerative medicine with the establishment of Japan's first such CDMO through a joint venture with Kohjin Bio Co., Ltd.<sup>4</sup>

4. https://www.ajinomoto.com/en/presscenter/press/detail/g2018\_05\_22.html

By strengthening the development of its advanced biopharmaceuticals business, Ajinomoto Co. will continue to contribute to the realization of regenerative medicine and to consumers' health and welfare.

## About Ajinomoto Co.

Ajinomoto Co. is a global manufacturer of high-quality seasonings, processed foods, beverages, amino acids, pharmaceuticals and specialty chemicals. For many decades Ajinomoto Co. has contributed to food culture and human health through wide-ranging application of amino acid technologies. Today, the company is becoming increasingly involved with solutions for improved food resources, human health and global sustainability. Founded in 1909 and now operating in 35 countries and regions, Ajinomoto Co. had net sales of JPY 1,150.2 billion (USD 10.36 billion) in fiscal 2017. For more about Ajinomoto Co. (TYO: 2802), visit <u>www.ajinomoto.com</u>.

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