

Enhancing the Contract Development and Production System from Early-Stage to Late-Stage Development and Post-Marketing Ajinomoto Co., Inc. to Establish a New Development and Production Base for Oligonucleotide Drug Substances

Introduction of the First Large-Scale Production Facility in Japan

TOKYO, November 29, 2017 – GeneDesign, Inc. (“GeneDesign”), a consolidated subsidiary of Ajinomoto Co., Inc. (“Ajinomoto Co.”), will establish a new development and production base for oligonucleotide drug¹ substances (oligonucleotides²) on the premises of its research institute in Ibaraki-shi, Osaka, Japan. As one of Japan’s largest production bases for oligonucleotides, the facility will substantially enhance GeneDesign’s oligonucleotide production capacity.

Development of oligonucleotide drugs is underway to enable applications for illnesses that have been difficult to treat, which has brought expectations of significant market growth in Japan and overseas. Moreover, along with advances in drug manufacturing technology, dependence on contract manufacturing companies with a high level of expertise in the development of manufacturing methods for and the manufacture of biopharmaceuticals and other products is increasing in the pharmaceutical industry. In recent years, the number of development projects at the clinical research stage has risen significantly, and the contract manufacturing market for oligonucleotides is projected to grow to around JPY 60 billion by 2020 (about 3 times compared with 2015) (Source: Seed Planning, Inc., 2015).

GeneDesign, which was established in 2000, is a major Japanese contract development and manufacturing organization (CDMO)³ for oligonucleotides. By making GeneDesign a consolidated subsidiary in April 2017, Ajinomoto Co. enabled integrated contract development and manufacturing of oligonucleotides from high-mix, low-volume production of oligonucleotides using solid-phase synthesis at GeneDesign (for early-stage development) to mass production with liquid-phase synthesis (*AJIPHASE*^{®4} technology) at Ajinomoto Co. (for late-stage development and post-marketing).

With the establishment of this new base, production volume will increase to a scale of kilograms (kg) per lot for the first time in Japan, thus raising GeneDesign's oligonucleotide production capacity to about 100 times its current level. Combining GeneDesign's production capacity and Ajinomoto Co.'s mass production technology (*AJIPHASE*[®] technology) will enable the creation of a system to flexibly and seamlessly supply from micrograms (µg) to over 100 kg. Ajinomoto Co. aims to be the world's top contract manufacturer of oligonucleotides by 2025 by responding to a wide range of requests from users such as pharmaceutical companies and research institutions.

Ajinomoto Co.'s FY2017-2019 Medium-Term Management Plan sets forth the key strategy of expanding the AminoScience business portfolio by establishing specialty businesses as new pillars. Ajinomoto Co. intends to expand its operations in areas related to advanced biopharmaceuticals, including the CDMO business for oligonucleotides, as it contributes to the health and well-being of consumers.



Overview of New Base

- (1) Name: Oligonucleotide Drug API Development Center
- (2) Location: Ibaraki-shi, Osaka
- (3) Total investment: Undisclosed
- (4) Production capacity: Tens of kilograms annually
- (5) Start of construction: February 2018 (scheduled)
- (6) Start of operation: February 2019 (scheduled)

Reference

Overview of GeneDesign, Inc.

- (1) Location: Ibaraki-shi, Osaka, Japan
- (2) Established: December 2000 (consolidated subsidiary of Ajinomoto Co., Inc. since April 2017)
- (3) Representative: Kazuhiko Yuyama, President (Founder)
- (4) Number of employees: 85 (as of November 2017)
- (5) Business description: Contract development and manufacture of oligonucleotides, oligonucleotide drug substances and oligonucleotide-related compounds, and sale of other synthesis equipment, etc.
- (6) Equity ownership: Ajinomoto Co., Inc. 95%, S.A. Ajinomoto OmniChem N.V. (wholly owned subsidiary of Ajinomoto Co., Inc.) 5%

Notes

1. Oligonucleotide Drugs

Drugs that use the genetic materials DNA (deoxyribonucleic acid) and RNA (ribonucleic acid) as their medicinal components. The main components of these drugs are made by designing the four types of bases that constitute oligonucleotides or their derivatives to have useful functions against disease targets, and linking them in a straight chain through chemical synthesis of a few to over a hundred nucleic acid constituents (oligonucleotides). A feature of oligonucleotide drugs is that they act directly on genes that cannot be targeted by small-molecule drugs or therapeutic antibodies, and because their targets and mechanisms of action are clear and highly specific, there are expectations for them as next-generation drugs with minimal side effects.

2. Oligonucleotides

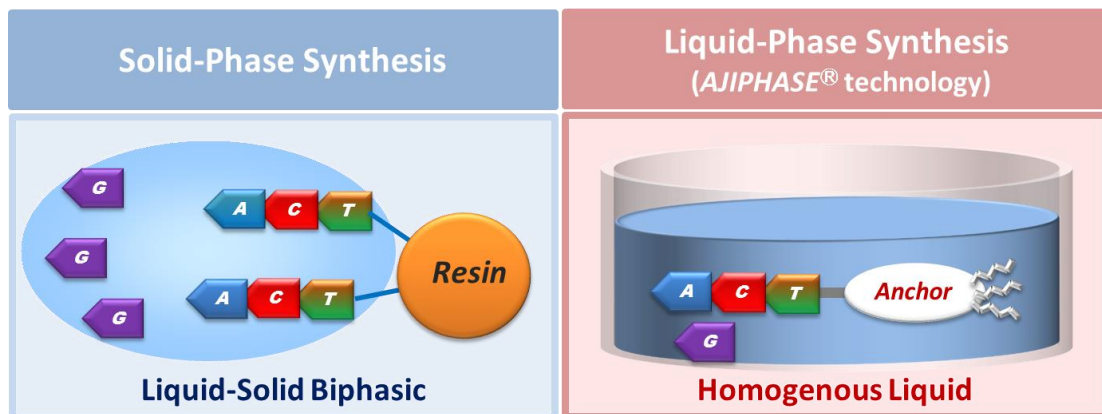
The main constituents of oligonucleotide drugs, linked in a straight chain through chemical synthesis of a few to over a hundred.

3. CDMO

Contract Development and Manufacturing Organization. A company providing contract process development and manufacturing services for drugs at the pre-clinical, clinical and/or commercial stage for pharmaceutical and other companies.

4. AJIPHASE[®]

A CDMO business for oligonucleotides and peptides that uses a kind of liquid-phase synthesis method developed by Ajinomoto Co. Liquid-phase synthesis is better for mass synthesis than conventional solid-phase synthesis.



The schematic diagrams above show solid-phase synthesis on the left and liquid-phase synthesis on the right. Generally, manufacture of oligonucleotides and peptides uses solid-phase synthesis in which nucleic acid (or amino acids) are caused to successively bond and grow on the solid-phase surface of polymer beads (resin) or other material. On the other hand, liquid-phase synthesis (*AJIPHASE[®]* technology) uses protecting group (anchor), which is highly soluble in an organic solvent, rather than the polymer beads used in solid-phase synthesis. Due to the use of an anchor, the solution remains homogeneous as the oligo chains (oligonucleotides, peptides) lengthen, resulting in highly efficient synthesis. Moreover, the characteristics of the anchor enable isolation and purification, resulting in high product purity. Liquid-phase synthesis, including *AJIPHASE[®]* technology, is suitable for mass production and does not require the special equipment necessary for solid-phase synthesis. On the other hand, solid-phase synthesis is suitable for high-mix, low-volume production.

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 30 countries and regions, Ajinomoto Co. had net sales of JPY 1,091.1 billion (USD 10.07 billion) in fiscal 2016. For more about Ajinomoto Co. (TYO: 2802), visit www.ajinomoto.com.

For further information, please contact:

Ajinomoto Co., Inc. Public Communications Department; pr_info@ajinomoto.com