26G-ISMS21 **Nucleic Acid Drugs Large Scale Manufacturing and Specification Assay– Equivalency Solid Phase versus AJIPHASE® and Oligonucleotide Sequences Confirmation for IND and NDA**

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Oligonucleotides which constitutes nucleic acid drug, are provided by chemical synthesis. We already have several track records of the GMP production of some nucleic acid drugs. All these batches were synthesized by solid phase synthesis which is well established organic chemistry but it is limited for scalability and cost effectivity. To overcome this issue, we have been co-developed liquid phase synthetic methodology of oligonucleotides called AJIPHASE® originated by AJINOMOTO. Comparison data between solid phase and AJIPHASE® showed that two methods are equivalent for impurity profile and purity. This result shows one of breakthrough of cost effective nucleic acid drug development. We believe nucleic acid drugs development is accelerated by AJIPHASE®.

On the other hand, in the analysis of nucleic acid drugs for specification, sequence confirmation examination is critical test of identification. We show example of sequence confirmation examination using MS different methodologies.

We can cope to IND and NDA by above-mentioned production technology and analysis technique.