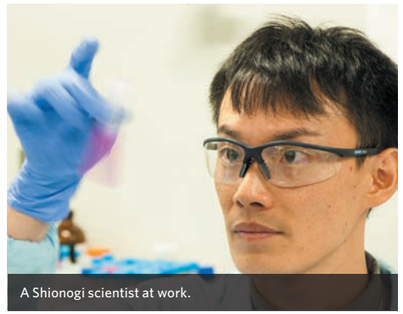
# Working together to create better vaccines

Two major players in the Japanese pharmaceutical industry are DEVELOPING THE NEXT GENERATION OF VACCINES.

A bioreactor used to produce vaccines at UMN's Akita plant.

A UMN employee checking the upstream processing of vaccines.



A Shionogi scientist at work.

**Japanese pharmaceutical companies Shionogi & Co., Ltd. and UMN Pharma Inc.** recently announced their plan to join forces in bringing cutting-edge vaccines to the marketplace. First up, the companies will tackle some of the most infectious human diseases with pandemic or epidemic potential.

**THE FOCUS OF COLLABORATION WILL BE DEVELOPMENT OF NEXT-GENERATION LOGICAL VACCINES**

**A history of success**

While the two organizations have shared goals, they have very different histories.

Shionogi was established in 1878, and over the last 140 years has built a name for itself as an industry leader in the development and production of 'classic' small-molecule drugs.

In addition to a strong pipeline of therapeutics in development, the company boasts a diverse drug portfolio covering their core areas of central nervous system diseases, pain, and infectious diseases. One of Shionogi's most promising drug pipelines is cefiderocol, an antibiotic that has shown efficacy against some carbapenem-resistant bacteria. Carbapenem antibiotics are regarded as one of the last lines of defence against bacterial infections, and carbapenem resistance is a critically important public health danger. Another drug is dolutegravir, a best-in-class antiretroviral HIV medicine. And, using the knowledge gained in dolutegravir's development, the company developed the breakthrough influenza treatment Xofluza, which made the headlines of the *Wall Street Journal* this year after it was approved for use in Japan. In the *WSJ,* Shionogi announced the medication can kill the flu virus in 24 hours.

Shionogi's long-standing success in developing several globally successful innovative drugs is thanks to the company's expertise in small-molecule drug discovery, says Takeshi Shiota, the company's senior vice president of the Pharmaceutical Research Division. Shionogi's chemists and scientists who have extensive experience in pharmacology, drug metabolism and pharmacokinetics, safety and other areas, have long been a driving force behind the company's success, Shiota notes. The team is now looking to expand these capabilities into medium-sized molecule therapeutics, which include nucleic acid- and peptide-based therapies. At the vanguard of this are Shionogi's cancer peptide vaccines, which are undergoing clinical trials.

Going forward, Shiota believes infectious diseases will become Shionogi's prioritized therapeutic area, and that the partnership with UMN will enable them to expand their capacities in this field. "UMN has deep know-how regarding vaccine production technology," Shiota says, adding that UMN's multifaceted experience in vaccine development and its deep connections to the Japanese vaccine research community make it an ideal business partner.

**Research with resilience**

UMN's wide-ranging network and expertise are even more impressive considering its short history. Originally established to commercialize research originating from universities, UMN was incorporated in 2004 and wasted no time in developing multiple partnerships in the development of an ambitious new influenza vaccine. While the vaccine candidate fell short of reaching the market, UMN gained keen research skills and knowledge of the challenges that pharmaceutical companies undergo in order to produce new vaccines. Owing to its stringent regulations, Japan is a particularly difficult arena in which to launch new prophylactics, says UMN's director of Research & Development, Fumihisa Nakata. UMN's history, he believes, will help them to navigate the collaboration's future vaccines over the regulatory hurdles.

**Future vaccines**

The focus of the UMN-collaboration will be the development of next-generation 'logical vaccines', says Nakata — a comprehensive system that comprises immunogenic, pathogen-emulating proteins together with an immunity-boosting adjuvant and a drug-delivery technology that, in combination, induce an "optimized immune response against a targeted infectious disease". This method cherry-picks the parts of a virus or bacteria that are most readily recognized by the human immune system and develops them into a therapeutic that primes the patient against future infection.

As logical vaccines use pathogen-derived proteins instead of the pathogens themselves, they are safer and easier to optimize, says Nakata. He adds that the drug delivery technology may use non-invasive dermal patches rather than traditional injections.

Alongside the delivery mechanism and the immunogenic protein, the adjuvant — a vaccine component often included in the formulation to provoke a greater immune response against the pathogen — is a "key element" of the logical vaccine, says Nakata. It's one that deepens the collaboration with Shionogi, which has its own promising adjuvant research including a new unique adjuvant molecule, currently undergoing pre-clinical research. In parallel, UMN has a separate research partnership with Ken Ishii, from Japan's National Institutes of Biomedical Innovation, Health and Nutrition, which is also pursuing an optimal adjuvant for UMN's vaccine candidates.

Just as vaccines and adjuvants work together to induce robust immunity against pathogens, Shionogi and UMN are pouring their wealth of expertise into their forward-facing partnership. It's early days, but Shiota notes that Shionogi and UMN have already overhauled a protein production system used in the creation of vaccines. In the near future, the two organizations will work to intensify their relationship and the research into their vaccine candidates. Nakata notes that they hope to launch their first joint vaccine by 2024. ■

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