## Health

The Otsuka Group is passionate about creating groundbreaking new products that can save lives and improve the quality of life for many people.

# **Addressing Unmet Needs**



Taiho Pharmaceutical: Anticancer drug research

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Otsuka Pharmaceutical is committed to helping patients with mental illness return to their regular activities. In the 1970s it began research into central nervous systems therapies, ultimately resulting in the launch in 2002 of ABILIFY, an antipsychotic and the world's first drug with dopamine system stabilizer action.\*1 It has been used to treat patients with various mental disorders in 60 countries and regions worldwide. Otsuka subsequently created and launched Abilify Maintena, a once-monthly injection developed to support long-term treatment of the condition. By developing this formulation, Otsuka is helping patients control their symptoms and live normal daily lives. In 2014, Otsuka acquired Avanir Pharmaceuticals Inc., a biopharmaceutical firm specializing in neurological disease to strengthen Otsuka's CNS portfolio.

Otsuka Pharmaceutical is also conducting research into tuberculosis, which is a major public health issue due to the increasing number of patients around the world. As of March 2014, no new anti-tuberculosis drug had been released in over 40 years, and there was a particularly strong need for new, effective drugs to treat multidrug-resistant tuberculosis (MDR-TB). Building on it's more than 30 years of research in this field and in an effort to improve the treatment of TB, Otsuka has developed Deltyba (delamanid) a drug for treating MDR-TB. Deltyba received regulatory approval and was launched in Europe and Japan in 2014.

Samsca (tolvaptan), the world's first aquaretic,\*<sup>2</sup> was developed by Otsuka Pharmaceutical over a period of 26 years, and is now being used in 20 countries and territories\*<sup>3</sup> worldwide. Autosomal Dominant Polycystic Kidney Disease (ADPKD)\*<sup>4</sup> is a rare kidney disease for which no drug treatment previously existed. Through ADPKD-focused R&D that began in 2004, Otsuka



Hospital TB ward

and external researchers found that tolvaptan inhibits proliferation and growth of renal cysts. As a result, in March 2014 an indication for Samsca (tolvaptan) in ADPKD was approved in Japan. Under the brand name JINARC, the drug was approved in Canada and the EU in 2015. Going forward, the company will file applications in multiple countries around the world and provide this encouraging new treatment to patients.

In the cancer field, the Otsuka Group continues to take on the challenge of developing new drugs to improve patients' quality of life. In 1974, when intravenous drip based treatment was the mainstay of cancer chemotherapy, Taiho Pharmaceutical, a member of the Otsuka Group, launched Futraful in Japan, an oral anticancer agent that provided a new method of treatment. Since then, Taiho Pharmaceutical has launched oncological products in Japan such as UFT in 1984, TS-1 in 1999, and Lonsurf in 2014.

While there has been enormous progress made in recent years in oncology, significant unmet medical needs remain. Therefore, Otsuka Group companies are committed to the research and development of new anticancer agents as well as drugs for supportive care, such as antiemetics and cancer pain relievers.

Otsuka Pharmaceutical, Taiho Pharmaceutical

- \*1: Dopamine D<sub>2</sub> receptor partial agonist
- \*2: A diuretic that causes the patient to excrete only water and not electrolytes
- \*3: Japan, China, South Korea, the Philippines, Indonesia, Hong Kong, Taiwan, Thailand, U.K., Denmark, Australia, Germany, Italy, Norway, Spain, Sweden, Finland, Turkey, U.S., and Canada
- \*4: Autosomal Dominant Polycystic Kidney Disease: A genetic disease in which the kidneys become enlarged due to proliferation of fluid-filled cysts, causing renal function to eventually decline



#### **Co-development of Medical Devices**

As Japan's population grows old, like that in the rest of the world, Otsuka continues to invest aggressively in disease areas that are of importance to aging societies, such as orthopedics, osteoporosis, and spinal and urological diseases. That is why Otsuka Medical Devices is carrying out development of an innovative spinal implant in an international joint research project based primarily in France. In urologic care, Otsuka is co-developing with a company in Japan that employs a non-invasive technology to detect the amount of urine in the bladder.

Otsuka Medical Devices

## Support Ranging from Basic IV Solutions to Eating Solid Food

Otsuka Pharmaceutical Factory is engaged in the development of products that comprehensively support the nutritional management of patients throughout their convalescence period. The company developed the world's first IV solution bag (quad bag), used to provide basic nutrition, which reduces the risk of infection and increases convenience. Otsuka also provides products designed for patients that require enteral feeding or have difficulty swallowing.

EN Otsuka Pharmaceutical develops and markets the iEat range, which are foods that are nourishing, tasty, and easy to eat for people who are still regaining their appetite. Using a proprietary technique, iEat foods after preparation are soft enough to break down in the mouth with just the use of the tongue, but retain the same shape, color, and, nutritional content as regular food. These products support health by providing nutritional food that even elderly persons requiring nursing care can find easy to eat.

Otsuka Pharmaceutical Factory. EN Otsuka Pharmaceutical

#### Opening of the Medical Foods Research Institute

Otsuka Pharmaceutical Factory has positioned medical foods as a strategic growth area. In May 2014, the Medical Foods Research Institute was opened at its headquarters site in Naruto, Tokushima. The institute is focusing on the development of products for the global market, especially Asia.

By consolidating in one location the previously separated research and formulation development functions, an R&D structure is in place to rapidly develop new products.

Otsuka Pharmaceutical Factory has developed and marketed a range of medical foods, including the oral rehydration solution OS-1. Going forward, the company will accelerate development of products that contribute to people's health worldwide, increasingly turning its sights beyond Japan to the global market.

Otsuka Pharmaceutical Factory

#### Women's Health

Otsuka Pharmaceutical developed a functional food containing equol, an ingredient derived from soybeans, that functions very similarly to the female hormone estrogen. Since the launch in 2014, the product has been marketed to middle-aged women experiencing a variety of symptoms due to hormonal fluctuations. Earlier, here were also high expectations for another family of compounds from soy, isoflavones, which have similar functions to equol. However, it was found that about 50%\* of Japanese women tended not to benefit from them. Otsuka Pharmaceutical is committed to contributing to women's health through its world-leading investigations into the efficacy and safety of equol.

Otsuka Pharmaceutical

Health





Otsuka Pharmaceutical Factory: Total support throughout convalescence



EN Otsuka Pharmaceutical: iEat food to support recovery to normal eating

\* Journal of the Japan Society for Menopause and Women's Health, 20: 313-332, 2012