



Otsuka Pharmaceutical Co. Ltd.

Founded in 1964, Otsuka Pharmaceutical Co., Ltd. (Otsuka) is a global healthcare company with the corporate philosophy 'Otsuka-people creating new products for better health worldwide.' Otsuka researches, develops, manufactures and markets innovative and original products, with a focus on pharmaceutical products for the treatment of diseases and nutraceutical products for the maintenance of everyday health.

Otsuka is a wholly owned subsidiary of Otsuka Holdings Co., Ltd., the holding company for the Otsuka Group. The Otsuka Group has business operations in 25 countries and regions around the world, with consolidated net sales of USD 14.5 billion for fiscal year 2011.

RESEARCH & DEVELOPMENT

Otsuka leverages its network of research institutes and facilities in and outside of Japan to conduct research and development on pharmaceutical and consumer nutraceutical products.

The company enters untraveled paths and unopened scientific doors to develop pharmaceutical products that could only be imagined by Otsuka. As a result, in many cases we have achieved, or continue to strive for, first-in-class drugs in the areas of the central nervous system (CNS), oncology, cardiovascular, digestive and respiratory systems, infectious disease, ophthalmology and dermatology. The company is also making the most of its internal and external networks to pursue novel approaches to drug discovery, diagnostics and prevention.

- **Examples of Otsuka's unique drug development**
ABILIFY, in the CNS therapy area, is one. Most antipsychotics to date have been based on suppression of dopamine, but Otsuka took a new idea and, through trial and error, created a partial agonist to control the amount of dopamine. On another occasion, a professor at a local university spoke of the need for a diuretic that increases the excretion of free water only. This led to the creation of *Samsca*, which was released in Europe and the U.S. in 2009. Both are examples of researcher efforts to fulfill unmet medical needs.
- **Special features of Otsuka's R&D**
Many of Otsuka's successes have been based on carbostyryl. *Mikelan* was the starting point and led to major success with *Meptin*, *Pletal*, *Mucosta* and *ABILIFY*. The company's research methods are not at all standardized. Otsuka's approach to research is to encourage in every way possible the creativity and perseverance of researchers.

QUICK FACTS

Head Office

2-9 Kanda-Tsukasamachi,
Chiyoda-ku Tokyo 101-8535, Japan

Number of Employees

5,701

President

Dr. Taro Iwamoto, Ph.D

Pharmaceutical Products

Abilify® (aripiprazole), *Pletal*® (cilostazol), *Mucosta*® (rebamipide), *Meptin*® (procaterol hydrochloride), *Samsca*® (tolvaptan), *Busulfex*® (bulsulfan) and others

Nutraceutical Products

SOYJOY, *Nature Made*, *Pocari Sweat*, *CalorieMate*, *Oronamin-C*, *Soysh*, *SoyCarat* and others

Website

<http://www.otsuka.co.jp/en>

UNIQUE R&D PROGRAM

Another research aspect that may be "uniquely Otsuka" is that the company obtains insights into drug development from actual medical needs. Research staff meet directly with doctors around the world to get a first-hand feel for whether their research is actually useful in medical care.

COMMITMENT TO TUBERCULOSIS

In line with its corporate philosophy, Otsuka's drug research and development efforts are focused on providing innovative products that improve health worldwide. There are many kinds of health issues facing us today, but TB remains an insurmountable disease that affects millions of people around the world.¹ The company's philosophy is to address true unmet medical needs and Otsuka saw TB as a unique area of contribution, as no other companies were attempting to tackle this major issue.

Otsuka has had a TB drug discovery program for over 30 years and has been a recognized leader in TB research through its commitment to the discovery and development of new TB compounds as well as the building of a clinical infrastructure within developing countries affected by the disease. Today, Otsuka is recognized as the top private funder of TB drug development in the world.²

The Otsuka MDR-TB clinical development program represents a major step forward for the TB community, where there is an urgent need for short, simple, easily tolerated regimens that are effective in patients who are resistant to current TB regimens. Continuing its commitment, Otsuka recently initiated an international Phase III clinical study, which has begun in Estonia, Latvia, Lithuania, Moldova, Peru, Philippines and South Africa.

Furthering its TB commitment, in May 2011 Otsuka established Otsuka SA in Geneva, Switzerland, to serve as the central operations unit for developing and implementing public health policies and corporate social responsibility programs in connection with the company's global TB program.³

SOCIAL RESPONSIBILITY

Otsuka's social responsibility initiatives focus on the priorities of health, the environment and local communities. The company disseminates useful health-related information by holding lectures and seminars to increase interest and understanding among citizens around disease prevention and recovery. Otsuka also strives to promote healthy lifestyles, regularly holding events in cooperation with local communities.

Otsuka strives to conduct all business activities with respect for the natural environment and local communities. The company works hard to develop helpful new technologies; is engaged in continuous improvement (kaizen) activities; and is committed to helping build low-carbon, recycling-oriented societies. This spirit also can be found in its product development. Otsuka developed an eco-friendly bottle that is 30 percent lighter than previous styles, and applied this technology to its best-selling sports drink, Pocari Sweat.

Otsuka has a long history of assisting local communities in crisis. Efforts include the establishment of the Otsuka Welfare Clinic, which provides free medical support to refugees in Peshawar, Pakistan. In response to natural disasters, such as the 2011 earthquake and tsunami in Japan, Otsuka promptly supplied needed health and nutrition products to people in affected areas.

REFERENCES

1. WHO – Tuberculosis. <http://www.who.int/mediacentre/factsheets/fs104/en/index.html> (Accessed 22 February 2013)
2. Treatment Action Group (TAG) and Stop TB Partnership. 2010 Report on Tuberculosis Research Funding Trends, 2005-2009
3. Otsuka SA Press Release. Otsuka Pharmaceutical Establishes Subsidiary, Otsuka SA, to Facilitate Public Advocacy for the Company's Global Tuberculosis Program. May 18, 2011

UNMET NEEDS OF TB PATIENTS

According to the World Health Organization (WHO), 8.7 million people became sick, and nearly 1.4 million people died from TB or TB-related causes, the majority of which are in developing countries. The situation is further intensified by the high rate of TB and HIV co-infection, and the growing emergence and transmission of drug resistant strains. Today it is estimated that nearly four percent of new TB cases are MDR-TB.

With the rise of drug resistance, short, simple and easily tolerated regimens that are suitable for those sensitive or resistant to current anti-TB agents are urgently needed.