



# Otsuka Pharmaceutical Co., Ltd.

Otsuka Pharmaceutical Co., Ltd. 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.

In pharmaceuticals, Otsuka is a leading firm in the challenging area of mental health and also has research programs on several under-addressed diseases including tuberculosis, a significant global public health issue. These commitments illustrate more powerfully than words how Otsuka is a "big venture" company at heart, applying a youthful spirit of creativity in everything it does.

Otsuka is a wholly owned subsidiary of Otsuka Holdings Co., Ltd., the holding company for the Otsuka Group. The chairman Akihiko Otsuka is the third generation of Otsuka family members to lead the business, whose origins date from 1921. The Otsuka Group employs approximately 42,000 people globally and its products are available in more than 80 countries worldwide. Consolidated sales were approximately €10 billion (USD 13 billion) for fiscal year 2012 (4/1/2012-3/31/2013). Otsuka Pharmaceutical invites you to visit its global website at <https://www.otsuka.co.jp/en/>.

## 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**

Most antipsychotics to date have been based on suppression of dopamine. Otsuka took a new idea and, through trial and error, created *ABILIFY*, a partial agonist that instead controls the amount of dopamine produced. 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 research efforts to fulfill unmet medical needs.

- **Special features of Otsuka's R&D**

The success of *Mikelan*, *Meptin*, *Pletal*, *Mucosta* and *ABILIFY* have all been based on carbostyryl. Rather than taking a standardized approach, Otsuka's research philosophy 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

5,652

### President

Dr. Taro Iwamoto, Ph.D

### Pharmaceutical Products

*Abilify*® (aripiprazole), *Pletal*® (cilostazol), *Mucosta*® (rebamipide), *Meptin*® (procatamol hydrochloride), *Samsca*® (tolvaptan), *Busulfex*® (busulfan) 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.<sup>1</sup> 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 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.<sup>2</sup>

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. Enrollment recently began for a clinical program exploring the use of delamanid in pediatric MDR-TB and will evaluate the bioequivalence of a dispersible formulation for use with younger children and infants.

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 case management activities in connection with the company's global TB program.<sup>3</sup>

## 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 endeavors 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 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 – Global Tuberculosis Report 2013. [http://apps.who.int/iris/bitstream/10665/91355/1/9789241564656\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/91355/1/9789241564656_eng.pdf) (Accessed 28 October 2013)
2. Treatment Action Group (TAG) and Stop TB Partnership. 2013 Report on Tuberculosis Research Funding Trends, 2005-2012
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), 8.6 million people became sick. Nearly 1.3 million people died from TB, including 320,000 deaths among HIV-positive people, 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.