Pharmaceuticals That Contribute to the Communities in Which We Live

A pharmaceutical company’s work does not end when the product is successfully launched. Drugs must be used properly in order to be fully effective. This means that there must be a process for providing appropriate information on drugs to medical institutions, for collecting feedback from the institutions once the drugs are in use, and for informing the various institutions of the Company’s evaluations and responses on key issues. Mochida Pharmaceutical sees this type of information-disseminating activity as a way to further contribute to society.
Producing Products with Beneficial Effects Tailored to Specific Fields

• Cardiovascular medicine

*Epadel* is the first drug in the world in which EPA-E (ethyl icosapentate: one of the poly-unsaturated fatty acids contained in fish oil) was successfully extracted and purified to a high degree. This drug has opened up a new field in the treatment for arteriosclerosis obliterans and hyperlipidemia. *Atelec®*, cilnidipine, a calcium channel blocker that is presently considered the first choice for the treatment of high blood pressure, lowers blood pressure all day long with just a single daily dose. *Atelec®* is a dual L/N type calcium channel blocker which, unlike regular L type channel blockers, has the unique property of also providing a renoprotective effect.

Mochida launched *Atedio®*, a combination of valsartan and cilnidipine, in May 2014, and is maintaining position through sales of both *Atelec®* and *Atedio®*.

• Obstetrics and Gynecology

Mochida Pharmaceutical has traditionally placed strong emphasis on the Ob/Gyn area, where it has built an impressive record with hormonal preparations and pregnancy test kits. *Estriel* is widely recognized for the treatment of post menopausal disorders, vaginitis, and geriatric osteoporosis. Some other examples are *Ortho® 777-21* and *Ortho® M-21*, a low-dose triphasic oral contraceptive and a low-dose monophasic oral contraceptive. The launch of *Dinagest*, a novel oral progestin, in January 2008 has expanded medication for patients suffering from endometriosis, in addition to *Suprecur®,* a GnRH analogue. The Company is presently conducting clinical trials on *Dinagest* to confirm its effectiveness for treating uterine adenomyosis as an additional indication.
• Dermatology

Florid®, an antimycotic drug, is a leading product in this treatment area. The drug is provided in the form of a cream for dermatomycosis. Arasena-A is the first antiviral drug for the topical treatment of herpes zoster and herpes simplex to be developed in Japan. Beselna was launched in December 2007 as the first therapeutic agent for condyloma acuminatum (external genital and perianal warts) in Japan, which gives patients a new treatment option other than surgical therapies. Beselna was approved for the additional indication of actinic keratosis in November 2011.

• Emergency Medicine

Miraclid has demonstrated excellent clinical efficacy as a drug for treatment of acute circulatory failure caused by shock, and acute pancreatitis. This drug represents the first commercial application of ulinastatin, which inhibits various enzyme activities. It reflects Mochida Pharmaceutical’s advanced technological capabilities in the development of new biologically active agents. Thrombin, a hemostatic agent, and Novo-Heparin, an anticoagulant agent, are also indispensable drugs to emergency medical care.

• Psychiatry

The antidepressant Lexapro® (escitalopram), which went on sale in August 2011, is a selective serotonin reuptake inhibitor (SSRI). The drug is approved in over 97 countries worldwide, and has been highly evaluated overseas as an antidepressant that provides the best possible balance between efficacy and acceptability. Lexapro® is expected to be well received in Japan as a new treatment option. An application has been filed for Lexapro® for the additional indication of social anxiety disorder. With the addition of Lexapro® to our tetracyclic antidepressant Tecipul and our autonomic dystomia drug Grandaxin, Mochida Pharmaceutical is committed to improving the QOL for psychiatric patients.
Tramcet®, an analgesic for chronic pain and tooth extraction pain which the Company started co-marketing with Janssen Pharmaceutical K.K. from October 2013, is the first analgesic in Japan combining tramadol hydrochloride and acetaminophen.

Lexapro® (escitalopram)
Lexapro® selectively inhibits the reuptake of serotonin and has an antidepressant effect. It provides the best possible balance between efficacy and acceptability as a first-line therapy in the treatment of depression.

Grandaxin (tofisopam)
Grandaxin relieves various symptoms caused by tension imbalances between the sympathetic and para-sympathetic nervous systems. It has proved effective in treating a variety of stress-induced ailments.

Mochida received approval for manufacturing and sales of Treprost®, for injection, a treatment for pulmonary arterial hypertension, which is an intractable disease, in March 2014 and began sales from September. We are advancing development of drugs for the treatment of intractable diseases to follow Treprost®, and will continue to embrace challenges in new medical fields.

Biosimilars
Filgrastim BS Syringe for Inj. MOCHIDA, a Granulocyte Colony Stimulating Factor (G-CSF) which is used to treat neutropenia in cancer chemotherapy, was launched in May 2013. This drug is a biosimilar co-developed with Fuji Pharma Co., Ltd., and the first G-CSF biosimilar approved for marketing in Japan.

The biosimilars market is expected to grow given the medical economics needs. Mochida has entered into a comprehensive collaboration agreement with Gedeon Richter Plc. and concluded a contract with LGLS for the development and sales in Japan of etanelcept and adalimumab biosimilars. Mochida will continue advancing the biosimilars business in the future.

Diagnostic Reagents
In the field of diagnostic reagents, Mochida Pharmaceutical pioneered immunological diagnostics in Japan, and developed Gonavis, the nation’s first pregnancy test kit. Since the launch of Gonavis, the Company has developed a number of products with its own technologies and through joint research and/or technology transfer with leading overseas companies. Our product lineup includes Gonastick W, a one-step, stick-type pregnancy test kit; and Cand-Tec, a candida antigen detection test.

The Prominence of EBM
Mochida Pharmaceutical considers evidence-based medicine (EBM) to be important. The Company participated in a large-scale clinical trial, the Japan EPA Lipid Intervention Study (JELIS), investigating whether Epadel can prevent cardiovascular events in hyperlipidemic patients. In November 2005, the test results were presented in a late-breaking clinical trials session at the American Heart Association’s (AHA’s) Scientific Sessions 2005; results showing Epadel significantly suppressed onset of major coronary events received much attention from experts in the field.

The high regard in which the efficacy of Epadel is held was confirmed in March 2007, when the study results were presented in the eminent British medical journal, The Lancet (2007, Vol. 369, pp. 1090–1098). Epadel is also recommended as a pharmaceutical treatment in the various guidelines of The Japanese Circulation Society as primary prevention for high-risk cardiovascular cases, secondary prevention for myocardial infarction, and to prevent recurrence of cerebral apoplexy.

A stream of useful information is being derived from JELIS. Utilizing these results, Mochida Pharmaceutical will provide beneficial and high-quality information to medical experts.