



# Developing Innovative New Medicines for Tomorrow



Mochida Pharmaceutical's principal aim is to contribute to the health of the community by bringing innovative new drugs to market. The motivating force behind all Company endeavors begins with the initial quest for useful pharmaceuticals and continues through the often-lengthy R&D phase right up to the actual market launch of the product. Mochida Pharmaceutical applies to all R&D projects its unique resources, comprised of a broad spectrum of technical and developmental expertise cultivated over the years and an approach based on insight and originality. Work starts with an initial stage of probative studies and research. For successful products, the process culminates with clinical development and marketing.

As of May 13, 2011

Code	Name	Indications	Formulation	Stage	Remarks
MTD-39	imiquimod	Actinic keratosis	Topical	Submitted	Licensed-in from iNova Pharmaceuticals (Australia)
MD-0901	mesalazine	Ulcerative colitis	Oral	Phase III	Licensed-in from Shire Pharmaceuticals Group (UK)
AJH801	cilnidipine/valsartan combination	Hypertension	Oral	Phase III	Co-development with Ajinomoto Pharmaceuticals
MD-0701	treprostinil	Pulmonary arterial hypertension	Injection	Phase II/III	Originator: United Therapeutics (USA)
FSK0808	G-CSF	Neutropenia	Injection	Phase II/III	Biosimilar (Follow-on biologics) Co-development with Fuji Pharma
MND-21	ethyl icosapentate	Non-alcoholic steatohepatitis	Oral	Phase II	
MR-20V	ulinastatin	Threatened Premature Delivery	Vaginal suppository	Phase II	Suspended
MJR-35	dienogest	Uterine adenomyosis	Oral	Early Phase II	Licensed-in from Jenapharm (Bayer Pharma AG)
JR-031	Human Mesenchymal Stem Cells	GVHD	Injection	Phase I/II	Cellular-based Drug Co-development with JCR

## Rapid Development of New Medicines Used Worldwide

With its extensive technical resources and expertise, Mochida Pharmaceutical has established itself as a leader in developing pharmaceuticals utilizing natural bioactive substances, with successes in the development of *Thrombin*, *Uronase*, *Miraclid*, *IFN Mochida*, *Epadel*, and other products. To enable more rapid development of medicines for use throughout the world, we are currently focusing on research efforts in the fields of diabetes, obesity, and chronic pain, utilizing the latest in computer and high-throughput screening techniques.

Overeating and sedentary lifestyles in developed countries have resulted in an accelerating increase in the number of people suffering from metabolic syndrome and diabetes. Given that these symptoms can ultimately lead to atherosclerotic disease, providing prevention and treatment methods for obesity and diabetes is an important mission for a healthcare company.

Mochida is creating candidate substances for diabetes medicine, and introducing them worldwide.

Worldwide, 75–80 million people suffer from chronic pain; many of them reported that pain had deleterious effects on their mental health, employment status, sleep, and personal relationships. The impact of pain on patient QOL and the unmet needs in pain management were fully recognized by physicians and healthcare companies. With an aging population and the simultaneous rise in the conditions that lead to chronic pain, along with the need for better efficacy and safety profiles, new therapeutics need to be developed.

Mochida Pharmaceutical is also conducting Phase I clinical trials on an oral transient receptor potential vanilloid sub type 1 (TRPV1) receptor antagonist invented by Mochida Pharmaceutical as a potential treatment for pain.

## Extensive Links with Outside Research Organizations

We are introducing and utilizing new technologies to provide effective medicines for patients as quickly as we can. Mochida Pharmaceutical has achieved many tangible results, not only in its in-house research but also through joint research frameworks with external research organizations. These include joint research with the Osaka Bioscience Institute on apoptosis (programmed physiological cell death needed to remove unnecessary cells within the body). The research effort bore fruit in patents on a Fas/Fas Ligand system, and Mochida Pharmaceutical is now licensing the patents to a number of pharmaceutical companies. Such joint research with and connection to other research organizations is seen as critical in increasing the pace at which medicines are created.

As a member of the Pharmaceutical Consortium for Protein Structure Analysis, Mochida Pharmaceutical has since 2002 utilized “SPring-8,” a large-scale synchrotron radiation facility that operates at the world’s highest level of performance, to analyze the three-dimensional structure of target molecules and data on the bonding of therapeutic agents and their target. In addition, we are working to lay the foundation for boosting the probability of successful drug discovery, primarily by improving the environment for the usage of advanced research facilities in cooperation with academia through the Consortium.

## Epadel: The Outcome of Foresighted, Innovative Research

A drug that epitomizes the unique and innovative strengths of Mochida Pharmaceutical’s R&D capabilities is *Epadel*, a drug for hyperlipidemia and arteriosclerosis obliterans. *Epadel* is the world’s first high-purity ethyl icosapentate (EPA-E). Working in cooperation with Nippon Suisan, Mochida Pharmaceutical made a historical breakthrough by turning purified EPA-E into a pharmaceutical. A global epidemiological study on the relationship between diet and disease has found that people who consume EPA as part of their diet are much less likely to suffer from such diseases as high blood pressure and arteriosclerosis-induced myocardial infarction than those who do not consume EPA.

