

# Hiroyuki Fukase

fukase@cpc-jp.com

---

## QUALIFICATIONS

- ♦ 24 years' experience in early phase clinical trials as a Principal Investigator.
- ♦ 5 years' experience in cardiac safety evaluation as a program chair or program member of DIA Cardiac Safety Workshop in Japan

## EXPERIENCE

### **Clinical Research Center, Clinical Research Hospital Tokyo, Tokyo**

**2017-present**

Medical facility with 50 beds dedicated to conducting clinical trials from Phase I to Phase III.

#### **Director**

### **CPC Clinic, Medipolis Medical Research Institute, Kagoshima**

**2017-2017**

Medical facility with 19 beds dedicated to conducting early phase clinical trials.

#### **Director**

- ♦ Conducted early phase clinical trials of new drugs as a Principal Investigator.

### **CPC Clinical Trial Hospital, Medipolis Medical Research Institute, Kagoshima**

**2011-2017**

Medical facility with 60 beds dedicated to conducting early phase clinical trials.

#### **Director**

- ♦ Conducted early phase clinical trials of new drugs as a Principal Investigator.

### **CPC Clinic, Kagoshima**

**1993-2011**

Medical facility with 19 beds dedicated to conducting early phase clinical trials.

#### **Director**

- ♦ Conducted early phase clinical trials of new drugs as a Principal Investigator.

### **Alcohol and Drug Abuse Research Center, McLean Hospital, Boston**

**1991-1993**

Research facility dedicated to substance dependence/abuse research.

#### **Postdoctoral Research Fellow**

- ♦ Conducted physical and psychological drug dependence/abuse liability studies with various psychoactive drugs using monkeys.

**Heart Institute Japan, Tokyo Women's Medical University, Tokyo  
1986-1987**

Medical facility dedicated to cardiovascular medicine.

**Resident**

- ♦ Trained as a resident of cardiovascular internal medicine.

**Toyoko Hospital, St. Marianna University School of Medicine, Kanagawa  
1985-1986**

General hospital with 500 beds.

**Resident**

- ♦ Trained as a resident of internal medicine.

**EDUCATION**

**Ph D of Medical Science, St. Marianna University School of Medicine, Kanagawa (1991)**

- ♦ Investigated hormonal regulation of adrenoceptors using ligand binding assay.

**MD, St. Marianna University School of Medicine, Kanagawa (1985)**

## **BIBLIOGRAPHY**

### **Anticoagulants/antiplatelets**

Tomoko Hasunuma, Hiroyuki Fukase, Atsuhiko Miyazaki, Yasuhiro Nishikawa

Evaluation of the Pharmacokinetics and Pharmacodynamics of Prasugrel in Japanese Elderly Subjects. *Clinical Drug Investigation*, **2017**; 37: 679–685.

Naomi Yamahira, Charles Frost, Hiroyuki Fukase, Zhigang Yu, Jessie Wang, Janice Pursley, Frank LaCreta, Masaki Hiraoka

Safety, tolerability, pharmacokinetics, and pharmacodynamics of multiple doses of apixaban in healthy Japanese male subjects.

*International Journal of Clinical Pharmacology and Therapeutics*, **2014**; 52(7): 564-573.

### **Opioids**

Ken Shimada, Hiroyuki Fukase, Mariko Shibuya, Yukio Kimura, Takefumi Saito, Keiichi Fujiwara, Hiroshi Yoshino, Masahiro Ando, Yasuo Saito, Hiroshi Shirota, Masato Fujii, Satoshi Oizumi, Takashi Yamaguchi, Shunichi Sugawara, Hiroomi Nakatsu, Shinya Murakami, Terumasa Noike, Kozo Yoshimori, Shiro Saito, Ahihiko Yamamoto, Jun Morita, Kunihiro Kobayashi

Adhesive ability to skin and skin irritation of FENTANYL Tape for 3 days “Meiji” in Japanese.

*Japanese Journal of Generic Medicines*, **2014**; 8(2): 76-80

Hiroyuki Fukase, Koichiro Fukuzaki, Takeshi Koja, Ryoichi Nagata, Scott E. Lukas

Effects of morphine, naloxone, buprenorphine, butorphanol, haloperidol and imipramine on morphine withdrawal signs in cynomolgus monkeys.

*Psychopharmacology*, **1994**; 116(4): 396-400

### **Local Anesthetics**

Hajime Suzuki, Hiroyuki Fukase, Jun Kato

Pharmacokinetic Study of Levobupivacaine Hydrochloride (MR8A2)-A Single Intravenous Administration in Healthy Adult and Elderly Male Subjects-

*Anesthesia and Resuscitation*, **2008**; 44(Supplement): 91-102

Hajime Suzuki, Hiroyuki Fukase, Jun Kato

A Phase I Study of Levobupivacaine Hydrochloride (MR8A2), a Long-Acting Local Anesthetic-Intradermal Papule Study and Ulnar Nerve Block Study-

*Anesthesia and Resuscitation*, **2008**; 44(Supplement): 81-90

## **Vaccines**

Hiroyuki Fukase, Hidetoshi Furuie, Yuji Yasuda, Ryoya Komatsu, Kenji Matsushita, Taketsugu Minami, Yutaka Suehiro, Hiroshi Yotsuyanagi, Haruko Kusadokoro, Hiroshi Sawata, Noriko Nakura, Maria Lattanzi

Assessment of the immunogenicity and safety of varying doses of an MF59®-adjuvanted cell culture-derived A/H1N1 pandemic influenza vaccine in Japanese paediatric, adult and elderly subjects.

*Vaccine*, **2012**; Volume 30, Issue 33(13): 5030-5037

## **Inhaled Corticosteroids**

Hiroyuki Fukase, Hiroaki Kubota

Phase 1 studies of budesonide/formoterol fixed combination: safety, tolerability, pharmacodynamic effects and pharmacokinetics of budesonide and formoterol after single and 7-day repeated-dose inhalation in healthy male volunteers

*Allergy & Immunology*, **2009**; 16(10): 1586-1602

Hiroyuki Fukase

Multiple Dose Study of Ciclesonide in Healthy Male Volunteers —Phase I Study—

*Jpn Pharmacol Ther*, **2006**; 34(11): 1201-1208

Hiroyuki Fukase

Single Dose Study of Ciclesonide in Healthy Male Volunteers —Phase I Study—

*Jpn Pharmacol Ther*, **2006**; 34(11): 1191-1199

## **SSRI**

永田 良一, 深瀬 広幸, 井之川 芳之, 成田 裕保

塩酸パロキセチンの第 I 相臨床試験 (第 5 報) —健康高齢者に塩酸パロキセチン 20 mg を単回経口投与した時の薬物動態及び安全性に関する検討—.

薬理と治療, 2000; 28(s1): s89-s110

## **Antiosteoporotics**

Hiroyuki Fukase, Fuminori Miyagi, Kimie Saito, Noriko Ito

Bioequivalence of Bonalon® Oral Jelly 35 mg versus Bonalon® Tablet 35 mg.

*Journal of New Remedies & Clinics*, **2012**; 61(9): 1833-1847

## **Cardiac Safety**

Hiroyuki Fukase

Role of Early Phase Clinical Trials on Proarrhythmic Risk Evaluation.

*J Clin Ther Med*, **2018**; in press

Hiroyuki Fukase, Maki Ito, Yuji Kumagai, Kaori Shinagawa, Kinue Nisioka, Koki Nakamura, Philip T. Sager

Summary and Future Perspectives of Kirishima Meeting, Report from Clinical Pharmacology Working Group; Roles and the Desirable Form of Early Phase Clinical Trials in Future Cardiac Safety Evaluation.

*Japanese J Electrocardiol*, **2014**; 34(3): 323-325

Hiroyuki Fukase

Session 1 Clinical Cardiac Safety Evaluation – ICH E14 and Thereafter  
Trends and Problems in Integrated Cardiac Safety Evaluation

*Japanese J Electrocardiol*, **2014**; 34(3): 276-281

Hiroyuki Fukase

5th DIA Cardiac Safety Workshop in Japan

*DIA Global Forum*, **2014**; 6(6): 18-19

Hiroyuki Fukase, Boaz Mendzelevski, Kentaro Ando, Zhe Jin, Yuji Kumagai, Koki Nakamura, Atsushi Sugiyama

The Current Trends and Future Perspectives on the Cardiac Safety Paradigm in Drug Development.

*Jpn J Clin Pharmacol Ther*, **2014**; 45(5): 197-199

Hiroyuki Fukase

Moxifloxacin Cardiac Safety Study in Japanese Subjects - Comparative Study between Japanese and Caucasian Subjects -

*Journal of Clinical Therapeutics & Medicines*, **2013**; 29(1): 33-43

Ryoichi Nagata, Hiroyuki Fukase, Shinichi Nagayama, Gong Qi, Nao Uchimura, Junko Matsuo, Go Kito

Evaluation Methods of Proarrhythmia in Safety Pharmacology  
Effects of Various Drugs on HERG Current and Action Potentials of Cardiomyocytes.

*Jpn J Clin Pharmacol Ther*, **2003**; 34(1): 109S-110S

### **Antilipemics**

Hiroyuki Fukase, Shigeto Kaneta

Clinical Pharmacology Study of Ezetimibe -Double-blind, Placebo-Controlled, Comparative Study in Adult Male Volunteers with Hyperlipidemia-

*Journal of Clinical Therapeutics & Medicines*, **2007**; 23(6): 451-467

Hiroyuki Fukase, Kensuke Ishikawa, Fumihito Tsuji, Fumito Tsuji, Takayuki Yoshioka  
The phase I multiple dose study of Ezetimibe.  
*Journal of Clinical Therapeutics & Medicines*, **2007**; 23(6): 407-415

Hiroyuki Fukase, Kensuke Ishikawa, Fumihito Tsuji, Fumito Tsuji, Takayuki Yoshioka  
The phase I rising single dose study of Ezetimibe.  
*Journal of Clinical Therapeutics & Medicines*, **2007**; 23(6): 397-406

### **Antidiabetics**

Kasahara-Ito N, Fukase H, Ogama Y, Saito T, Ohba Y, Shimada S, Takano Y, Ichihara T, Terao K, Nakamichi N, Kumagai Y, Ikeda S  
Pharmacokinetics and Pharmacodynamics of Tofogliflozin (a Selective SGLT2 Inhibitor) in Healthy Male Subjects.  
*Drug Res (Stuttg)*. **2017**;67(6):349-357. doi: 10.1055/s-0043-104779. Epub 2017 Apr 20.

N. Kasahara, H. Fukase, Y. Ohba, T. Saito<sup>1</sup>, K. Miyata, S. Iida, Y. Takano, S. Ikeda, M. Harigai, K. Terao  
A Pharmacokinetic/Pharmacodynamic Drug–Drug Interaction Study of Tofogliflozin (a New SGLT2 Inhibitor) and Selected Anti-Type 2 Diabetes Mellitus Drugs.  
*Drug Res (Stuttg)*. **2016** ;66(2):74-81. doi: 10.1055/s-0035-1549967. Epub 2015 Jul 9.

Shunji Haruta, Takashi Hanafusa, Hiroyuki Fukase, Hiroaki Miyajima, Toshikazu Oki  
An Effective Absorption Behavior of Insulin for Diabetic Treatment Following Intranasal Delivery Using Porous Spherical Calcium Carbonate in Monkeys and Healthy Human Volunteers.  
*Diabetes Technology & Therapeutics*, **2003**; 5(1): 1-9

### **Antibiotics**

Yutaka Saisho, Takayuki Katsube, Scott White, Hiroyuki Fukase, Jingoro Shimada  
Pharmacokinetics, Safety, and Tolerability of Cefiderocol, a Novel Siderophore Cephalosporin for Gram-Negative Bacteria, in Healthy Subjects  
*Antimicrobial Agents and Chemotherapy*, accepted manuscript posted online 8 January 2018, doi: 10.1128/AAC.02163-17

Jingoro Shimada, Yutaka Saisho, Takayuki Katsube, Scott White, Hiroyuki Fukase  
S-649266, a Novel Cephalosporin for Gram Negative Bacterial Infection: Pharmacokinetics (PK), Safety and Tolerability in Healthy Subjects  
Session: 169-Beta-Lactam-Siderophore Conjugates: Trojan Horse Antibiotics Sep 08, **2014**,

*54th Interscience Conference on Antimicrobial Agents and Chemotherapy, Washington, DC*

Hiroyuki Fukase, Yoshinori Saiki, Junko Yoshikawa, Toshio Kasama

A Phase I Clinical Trial of Vancomycin Ophthalmic Ointment in Healthy Volunteers-Single-Dose Study, Multiple-Dose Study-

*Journal of Clinical Therapeutics & Medicines*, **2011**; 27(3): 227-235

Kohya Shiba, Shinichi Minamitani, Tomoyuki Monma, Hiroyuki Fukase

Evaluation of regimens reducing injection site reaction by intravenous levofloxacin in healthy subjects.

*Japanese Journal of Chemotherapy*, **2011**; 59(S-1): 10-17

Kohya Shiba, Hiroyuki Fukase, Atsushi Sugiyama

Phase I study of intravenous levofloxacin in healthy adult male volunteers.

*Japanese Journal of Chemotherapy*, **2011**; 59(S-1): 1-9

Kohya Shiba, Hiroyuki Fukase, Atsushi Sugiyama

Phase I study of levofloxacin in healthy and elderly volunteers.

*Japanese Journal of Chemotherapy*, **2009**; 57(S-2): 1-11

深瀬 広幸, 倉田 靖, 伊藤 雅之, 相澤 一雅, 柴 孝也

健康成人男子におけるメイアクトMS錠100mgとメイアクト錠100の生物学的同等性の検討.  
診療と新薬, 2006; 43(6): 620-625

### **Antivirals**

Yutaka Saisho, Toru Ishibashi, Hidenori Fukuyama, Hiroyuki Fukase, Jingoro Shimada

Pharmacokinetics and safety of intravenous peramivir, neuraminidase inhibitor of influenza virus, in healthy Japanese subjects.

*Antiviral Therapy*, published on line 2 November **2016**.

Hiroyuki Fukase, Yuichiro Miyazono, Ryoichi Nagata

Phase I Clinical Study of SCH 18908 (Ribavirin), an Antiviral Agent. A Single Oral Administration Study in Healthy Adult Male Volunteers.

*Journal of Clinical Therapeutics & Medicines*, **2002**; 18(4): 521-538

### **Antiemetics**

Junichi Azuma, Hiroyuki Fukase

Pharmacokinetics of a single 150-mg intravenous infusion of fosaprepitant: Effects of concentration and infusion time in healthy Japanese men.

*Clinical Pharmacology in Drug Development*, **2013**; 2(4): 394-399.

Ryoichi Nagata, Hiroyuki Fukase

Pharmacokinetic Study of Ondansetron Injection in Single Bolus Administration and Drip Infusion.

*Journal of Clinical Therapeutics & Medicines*, **2001**; 17(8): 1151-1161

### **Contrast Mediums**

Hiroyuki Fukase, Kazuya Kawahara

Examination on Biological Equivalence of IOPAQUE and its Imaging Effects.

*The Japanese Journal of Clinical and Experimental Medicine*, **2002**; 79(1): 176-185

Ryoichi Nagata, Hiroyuki Fukase, Ichiro Tanaka, Tetsuhito Kubo, Ichiro Yanase

Bioequivalence and imaging effect of Oypalomin.

*The Japanese Journal of Clinical and Experimental Medicine*, **1997**; 74(2): 495-505

### **Antiallergics**

Hiroko Ino, Katsutoshi Hara, Gosuke Honma, Yohei Doi, Hiroyuki Fukase

Comparison of levocetirizine pharmacokinetics after single doses of levocetirizine oral solution and cetirizine dry syrup in healthy Japanese male subjects.

*Journal of Drug Assessment*, **2014**; 3(0): 38-42

### **Other Classes**

Yoshinari Yokoyama, Jasper Dingemans, Motonori Hatta, Hiroyuki Fukase

Tolerability, Safety, Pharmacokinetics, and Pharmacodynamics of Macitentan, a New Endothelin Receptor Antagonist, in Healthy Japanese Male Subjects.

*Japanese Journal of Clinical Pharmacology and Therapeutics*, **2016**; 47(4): 143-150

Hiroyuki Fukase

Bioequivalence Between NA872D and NA872solution.

*Journal of New Remedies & Clinics*, **2004**; 53(4): 388-415

### **Clinical Trials or Clinical Development**

Shihoko Sakurai, Naoki Matsumoto, Setsuo Hasegawa, Jun Kono, Shin Irie, Naoyuki Takemoto, Koichi Nakamura, Noriko Koshimura, Hiroyuki Fukase, Yoshitaka Tanaka, Kuninobu Yasuda; Norito Takemoto, Takanori Tanaka, Takeshi Chiyoda, Shinichi Kobayashi

Questionnaire Regarding the Attitude towards Clinical Trials for Healthy Volunteers of Phase I Study.

*Japanese Journal of Clinical Pharmacology and Therapeutics*, **2005**; 36(6): 315-322



R. Nagata, H. Fukase, J.-D. Rafizadeh-Kabe

East-West development: understanding the usability and acceptance of foreign data in Japan.

*International Journal of Clinical Pharmacology and Therapeutics*, **2000**; 38(2): 87-92