



Press Release, December 14, 2009

**Announcement of CMIC and ROCHE Sign License Agreement  
on L-FABP diagnostic for predicting the progression of renal diseases**

CMIC Co., Ltd. (Head Office: Tokyo; CEO: Kazuo Nakamura; hereafter “CMIC”), and F.HOFFMANN-LA ROCHE LTD. (Head Office: Basel, Switzerland; hereafter “ROCHE”), have signed a License Agreement whereby a worldwide patent right of non-exclusive use on L-FABP (Liver type Fatty Acid-Binding Protein) diagnostic will be granted to ROCHE.

ROCHE will pay a one-time up-front fee, milestones and royalties to CMIC who acquires the worldwide Non-exclusive License of L-FABP diagnostic development under this agreement.

CMIC has been working on Intellectual Property Development (IPD) as one of CMIC’s newly established revenue streams, as well as CMIC’s conventional business model of accumulating intellectual properties through in-house and joint development of such drugs as diagnostics and orphan drugs. L-FABP diagnostics has marked our first in-house developed compound in IPD model. The compound which could predicts the progression of renal diseases at an early stage has been attracting international attention as a biomarker when the number of patients with chronic renal disease is estimated to increase.

**(Difficulty to diagnose the kidney disease)**

The prevalence of chronic kidney disease (CKD) is increasing all over the world. American Heart Association statement published in 2003 recommended that patients who had been diagnosed hypertension, diabetes and the cardiovascular disease (CVD) should take the screening test for kidney failure because the risk to develop CVD for such "high risk group" by decreasing the kidney function is 10 to 30 times higher than the healthy people. On the other hand, however, there is no diagnostic method to measure the risk to detect the progress of kidney failure from

early stages, and it is sought to develop an innovative biomarker.

### **(Characteristic of L-FABP)**

It is known that the kidney consists of glomerus, basic filtration unit, and kidney tubules, reabsorption role of filtrated urine. Although urinary albumin and serum creatinine are used as the markers for the kidney disease at this moment, many evidences showed that those two markers are not sufficient to detect the early symptom of the disease. As the result of the aggressive research to detect the tubulointerstitial damage, which has been found to be correlated more with the progress of the kidney disease, it was identified that Liver-type Fatty Acid Binding Protein (L-FABP), a carrier protein of 14.4 kDa expressed in the human proximal tubule, has been excreted into urine from the early stage of progress of tubulointerstitial damage. Urinary L-FABP does not show the outcome of the tubulointerstitial damage, but reflect the hypoxic condition caused by decreased peritubular capillary blood flow and/or oxidative stress against the kidney tubule, which cause for the tubulointerstitial damage. Therefore, L-FABP is expected to be a useful and highly accurate biomarker for the early detection of kidney disease.

### **(Current progress)**

CMIC identified the characteristics of L-FABP at the early development stage and started the product development. By measuring the urinary L-FABP, CMIC submitted the product application to PDMA as the diagnostic test for the purpose of early diabetic nephropathy in 2006. Afterwards, we found that L-FABP is also useful as the early diagnostic marker for acute kidney injury(AKI). As the only biomarker developed in Japan, L-FABP has been selected as one of the promising biomarker candidates at the conference sponsored by NIH and at several international medical conferences, and paid attention to by several world famous nephrologists.

### **(Current diagnostics market trends and future prospects)**

The diagnostics market targeting patients with early-stage renal diseases is estimated to be 30 billion yen worldwide. With this vast potential market, we expect to see stable long-term profits from L-FABP diagnostic development, our first achievement in the IPD business.

Considering the fact that we have settled on licensing contract with ROCHE among a number of domestic and overseas candidate companies including major diagnostic manufacturers, further revenue expand from L-FABP diagnostic development can

be expected. Impact on the financial results of FY2010 will be minimal, and therefore we have no plan to revise the FY 2010 financial forecasts at present.

We believe that this achievement of signing License Agreement on L-FABP diagnostic development with a global leading pharmaceutical and diagnostic company, ROCHE, will serve as a foundation for CMIC's further development and expansion in our IPD business.

### **About Roche**

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2008, Roche had over 80,000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: <http://www.roche.com>.

### Roche Media Release

[http://www.roche.com/media/media\\_releases/med\\_dia\\_2010-01-12.htm](http://www.roche.com/media/media_releases/med_dia_2010-01-12.htm)

### **About CMIC Co., Ltd.**

As Japan's first contract research organization (CRO), CMIC provides services that contribute to the efficient, expeditious implementation of clinical trials. Utilizing its abundant experience, CMIC comprehensively supports pharmaceutical companies in carrying out their core processes of drug development, manufacturing and marketing. Contributing to the maximization of pharmaceutical company value, CMIC offers a broad lineup of services. For further details, please visit the CMIC website at <http://www.cmic.co.jp/e/>