Clinical Study Report Synopsis

Drug Substance	Rosuvastatin calcium
Study Code	NIS-CCN-CRE-2008/1
Edition Number	1.0
Date	11 Feb, 2010

A cross-sectional study to survey the awareness of Chinese National Adult Lipid Treatment Guideline (2007) and the rate of patients (on treatment) achieving the hyperlipidemia treatment goal with Crestor® 5mg to 10mg for 8 weeks

Study dates: First subject enrolled: 24 Oct, 2008
Last subject last visit: 25 Jul, 2009

Phase of development: Post-market non-interventional study

This study was performed in compliance with Good Clinical Practice, including the archiving of essential documents.

Study centre(s)

There were 34 study centres involved in this study in China.

Publications

None at the time of writing this report.

Objectives and criteria for evaluation

Table S1 Primary and secondary objectives and outcome variables

Objectives	Outcome variables
Primary	**Primary**
To survey the awareness rate of Chinese National Adult Lipid Treatment Guideline (2007) by cardiologists (rationale of choosing lipid-lowering drug and target LDL-C level setting, treatment duration, control rate, frequency and parameters of reviewing lipids level).	The awareness rate of Chinese National Adult Lipid Treatment Guideline (2007) by cardiologists. The control rate of patients reaching target LDL-C level using either ***Chinese National Adult Lipid Treatment Guideline (2007)*** or US NCEP ATP III Guideline or European Joint Guideline evaluated by self-evaluation of doctors.
To survey the percentage of patients who have received any kind of regimens but not Crestor® reaching target LDL-C level according to Chinese National Adult Lipid Treatment Guideline (2007);	The control rate of patients who have received any kind of regimens but not Crestor® reaching target LDL-C level according to ***Chinese National Adult Lipid Treatment Guideline (2007).***
To evaluate the percentage of hyperlipidemia patients who achieved target LDL-C level according to the Chinese National Adult Lipid Treatment Guideline (2007) following 8-week treatment by Crestor® 5mg or 10mg.	The percentage of hyperlipidemia patients who achieved target LDL-C level according to the ***Chinese National Adult Lipid Treatment Guideline (2007).***
Secondary	**Secondary**
To evaluate the percent change from baselines in LDL-C, TC, TG, HDL-C following 8-week treatment by Crestor® 5mg or 10mg.	The percent change from baselines in LDL-C, TC, TG, and HDL-C.
To evaluate the percentage of hyperlipidemia patients in different risk categories who achieved target LDL-C level according to the Chinese National Adult Lipid Treatment Guideline (2007) following 8-week treatment by Crestor® 5mg or 10mg.	The percentage of hyperlipidemia patients in different risk categories who achieved target LDL-C level according to the Chinese National Adult Lipid Treatment Guideline (2007).

Study design

An open-label, non-interventional and multi-centre study to be conducted in 30 sites as planned.

This study consists of two parts.

The first part aimed to investigate the awareness rate of ***Chinese National Adult Lipid Treatment Guideline (2007),*** prescription behaviour and self-evaluation of control rate through answering the Investigator Questionnaire by each cardiologist. Meanwhile, patients being diagnosed as dyslipidemia but not receiving Crestor® were investigated for lipid control status in a cross-sectional way.

The second part observed the efficacy of Crestor® in hypercholesterolemia or mixed dyslipidemia patients who have received treatment of Crestor® 5mg or 10mg before enrollement. The total treatment duration was 8 weeks.

Target subject population and sample size

Patients aged 18 years old or above who has been diagnosed as hypercholesterolemia and decided by physician to use Crestor® 5mg or 10mg or other regimens (TLC or other lipid-lowering agents).

Investigational product: dosage, mode of administration

Crestor® 5mg or 10mg, tablet, oral, once daily.

Duration of treatment

8 weeks

Statistical methods

Descriptive statistical method was used in this study. Continuous data was described by their number, mean, median, standard deviation, minimum and maximum. Categorical data was described by the number and percentage of subjects in each category. Figures were plotted if appropriate and needed.

Subject population

This study was conducted in 34 centres.

In the first part, 257 cardiologists and 1258 dyslipidemia patients were enrolled into the study, and all the subjects were included into the FAS.

In the second part, 1222 dyslipidemia patients were enrolled into the study. Among these subjects, 11 patients were not included into FAS due to protocol violation.

Summary of efficacy results

- Primary variables：

  - The awareness rate of Chinese National Adult Lipid Treatment Guideline (2007) by cardiologists was evaluated by the following variables:

    - 75.5% of the cardiologists set individualized cholesterol target for hypercholesterolemia patients.

- 78.21% of the cardiologists take Chinese National Adult Lipid Treatment Guideline (2007) as practice standard most often when treating hypercholesterolemia.

- 99.22% of the cardiologists take LDL-C as the target when setting cholesterol target for hypercholesterolemia patients, other than TC or HDL-C.

- 66.15% of the cardiologists take LDL-C as the treating target when treating hypercholesterolemia, other than TC, TG, or HDL-C.

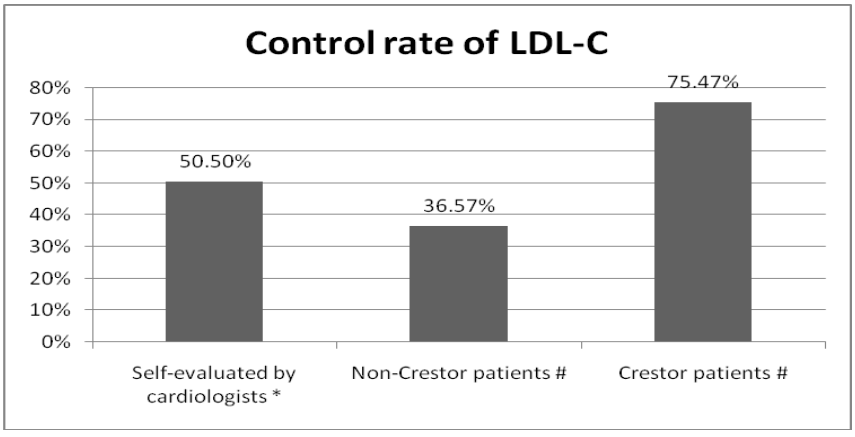
- The percentage of patients reaching target LDL-C level using either Chinese National Adult Lipid Treatment Guideline (2007) or US NCEP ATP III Guideline or European Joint Guideline evaluated by self-evaluation of doctors is 50.5%.

- The percentage of patients who have received any kind of regimens but not Crestor® reaching target LDL-C level according to Chinese National Adult Lipid Treatment Guideline (2007) is 36.57%.

- The percentage of patients of patients who received treatment of Crestor® reaching target LDL-C level according to Chinese National Adult Lipid Treatment Guideline (2007) is 75.47%.

The percentage of patients reaching target LDL-C is summarized in Figure S1 below.

Figure S1 Control rate of LDL-C



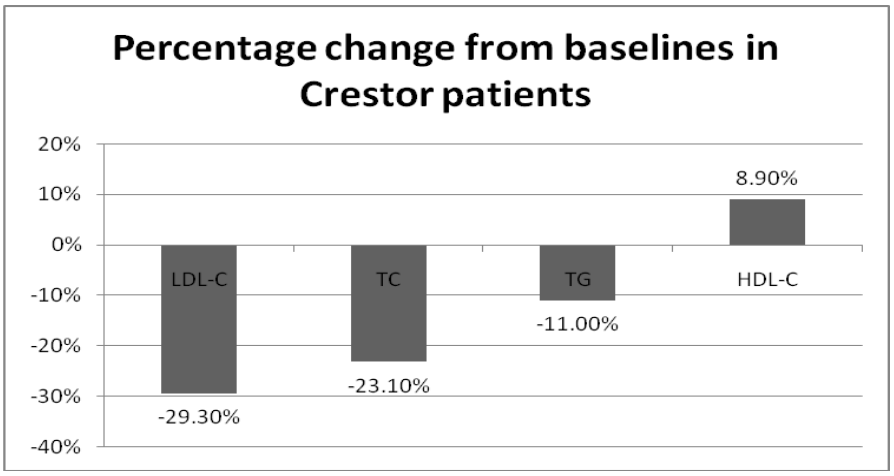
*: The self-evaluated control rate is according to either Chinese National Adult Lipid Treatment Guideline (2007) or US NCEP ATP III Guideline or European Joint Guideline.

#: The control rate of LDL-C is according to Chinese National Adult Lipid Treatment Guideline (2007).

- Secondary variables：

○ The percentage change from baselines in LDL-C, TC, TG, HDL-C of patients who received treatment of Crestor® is respectively: -29.3%, -23.1%, -11.0%, and 8.9% ($p<0.0001$). The results are summarized in Figure S2 below.

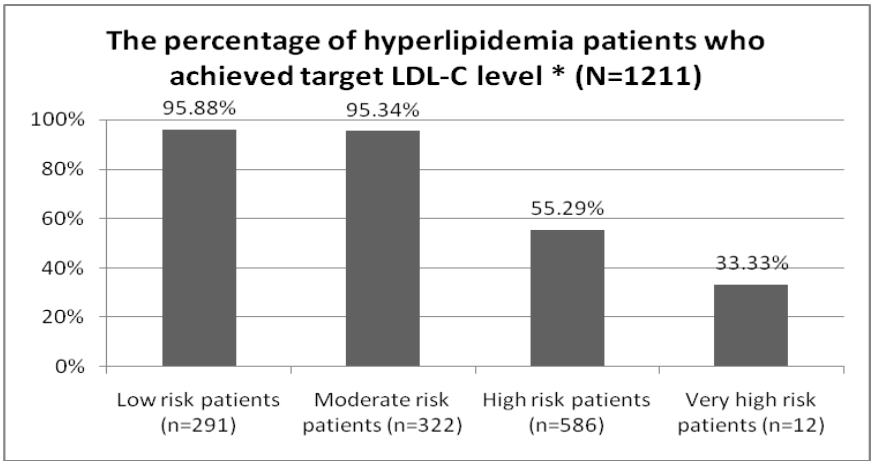
Figure S2 Percentage change from baselines in LDL-C, TC, TG, HDL-C of patients who received treatment of Crestor®



*: Compared with baselines, $p<0.0001$.

○ The percentage of dyslipidemia patients in different risk categories who achieved target LDL-C level according to the Chinese National Adult Lipid Treatment Guideline (2007) is respectively: low risk 95.88%, middle risk 95.34%, high risk 55.29%, very high risk 33.33%. The results are summarized in Figure S3 below.

Figure S3 The percentage of hyperlipidemia patients on Crestor® treatment in different risk categories who achieved target LDL-C level



*: LDL-C target and risk factors stratification is based on China Adult Lipid Treatment Guideline (2007)

Summary of pharmacokinetic results

Not applicable.

Summary of pharmacodynamic results

Not applicable.

Summary of pharmacokinetic/pharmacodynamic relationships

Not applicable.

Summary of pharmacogenetic results

Not applicable.

Summary of safety results

Not applicable.