Introducing

Cretrol ®

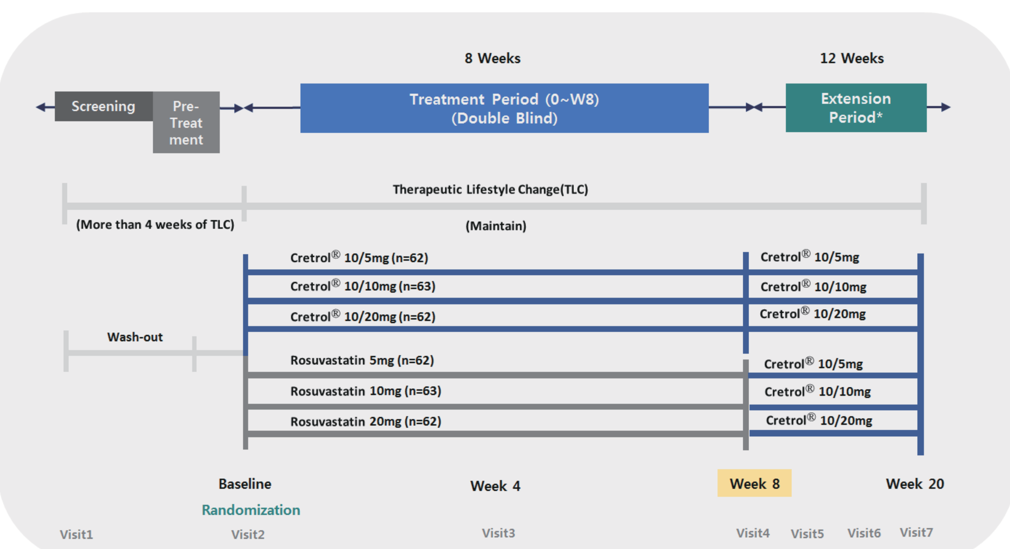
A Powerful LDL–C Lowering Therapy with Proven Clinical Efficacy

Key Features:

- **Dual Mechanism:**
  Cretrol® combines the cholesterol absorption inhibitor **ezetimibe** and the potent statin **rosuvastatin** to provide enhanced LDL–C reduction.
- **Dosage Forms:**
  Available in 10/5mg, 10/10mg, and 10/20mg formulations
- **Proven Efficacy:**
  Demonstrates superior LDL–C and total cholesterol (TC) reduction across all dose ranges compared to rosuvastatin monotherapy.
- **Flexible Dosing:**
  Three different dosage combinations available, allowing personalized treatment for patients with primary hypercholesterolemia.

Phase III Clinical Trial Overview

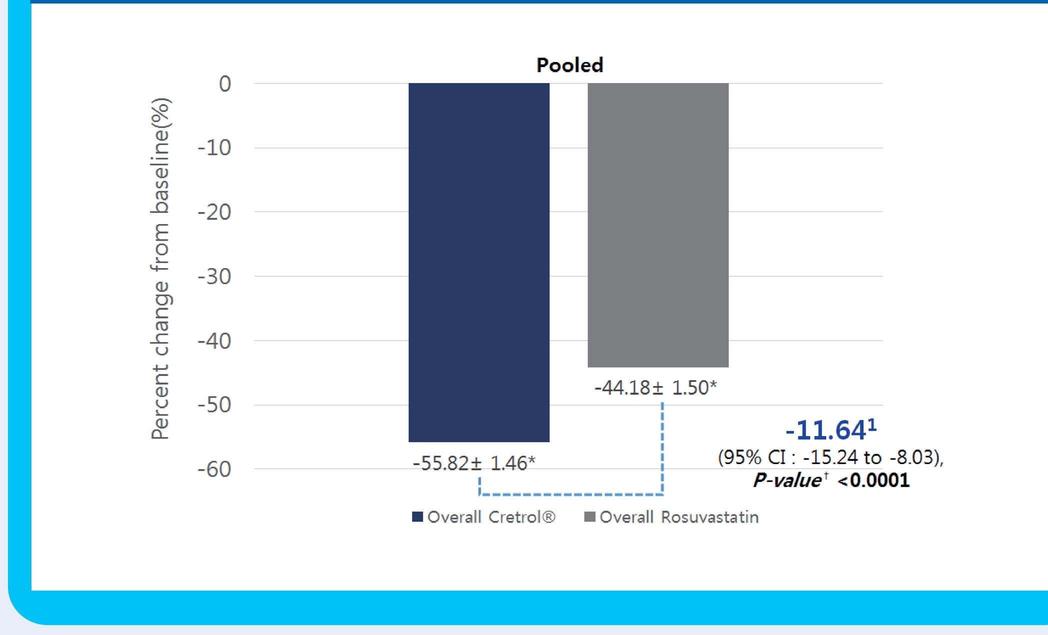
- **Objective:**
  To evaluate the LDL–C lowering efficacy and safety of combination therapy with ezetimibe and rosuvastatin compared to rosuvastatin monotherapy in patients with primary hypercholesterolemia.
- **Study Design:**
  Type: Multicenter, randomized, double–blind, parallel group factorial design.
  Participants: 374 patients with primary hypercholesterolemia from 23 Korean hospitals were randomly assigned



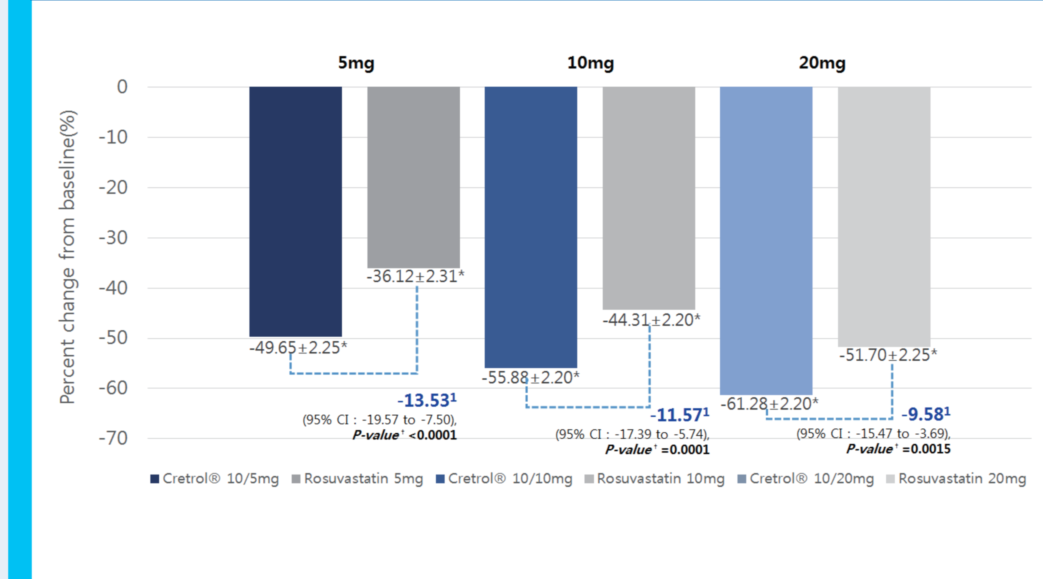
*The subjects who participated in the extension study were given the same dose of a Cretrol® as the Rosuvastatin dose administered during the 8–week treatment period. Rosuvastatin dose kept blinded.
References. Data on file. Clinical Phase III trial in Korea. HL140 (2016)

- **Primary Endpoint**
  At all doses (5mg, 10mg, and 20mg), Cretrol® provided significantly greater reductions in LDL–C compared to rosuvastatin monotherapy at 8 weeks, with an overall reduction of –55.82% vs. –44.18% (LS Mean Difference: –11.64%, p<0.0001), and for individual doses (p<0.0001, p=0.0001, p=0.0015).

Percent change from baseline in LDL–C(mg/dL) at Week–8 (FAS)



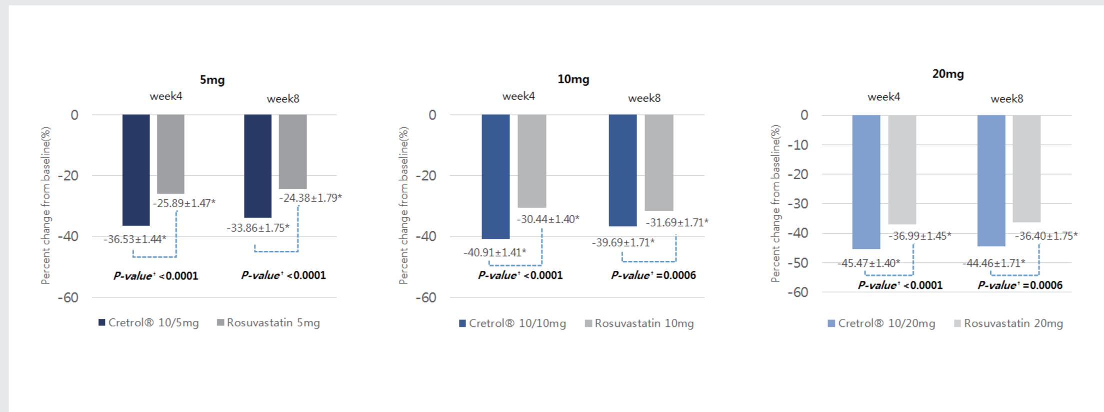
Percent change from baseline in LDL–C(mg/dL) at Week–8 (FAS)



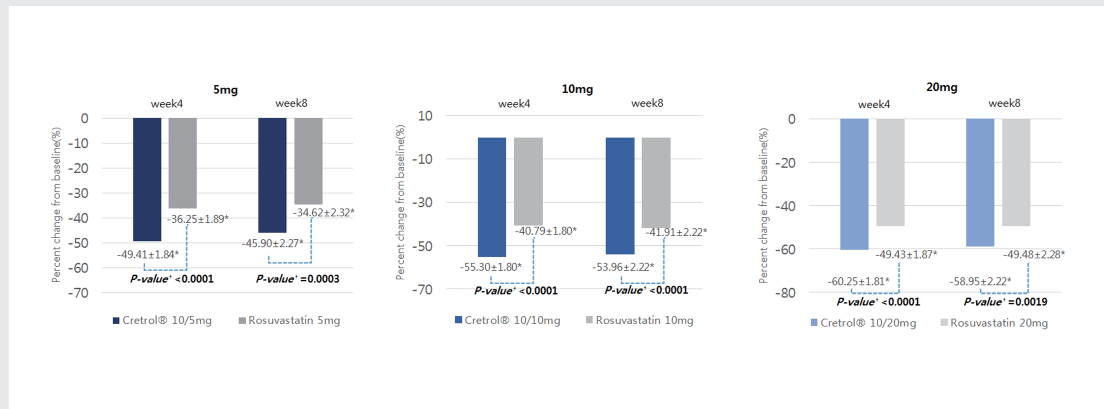
Percent change(%) = (week 8 - baseline) / baseline * 100
*LS Mean ± SE
1Difference between LS Mean
† Difference between groups (ANCOVA using baseline value and NCEP ATP III risk category as covariants)
LDL–C, Low density lipoprotein cholesterol; FAS, Full analysis set
References. Data on file. Clinical Phase III trial in Korea. HL140 (2016)

- **Secondary Endpoint**
  Across dose ranges, Cretrol® significantly reduced total cholesterol, non–HDL–C, and Apo B more than rosuvastatin monotherapy at both 4–week and 8–week treatments.

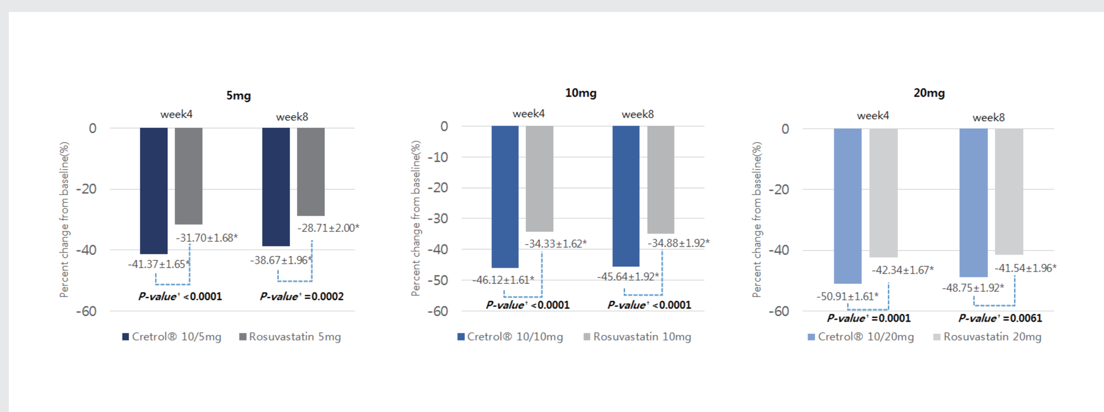
Percent change from baseline in TC at Week–4 and Week–8 (FAS)



Percent change from baseline in non HDL–C at Week–4 and Week–8 (FAS)



Percent change from baseline in Apo B at Week–4 and Week–8 (FAS)



Percent change(%) = (week 8 - baseline) / baseline * 100; LS Mean ± SE,
† Difference between groups (ANCOVA using baseline value and NCEP ATP III risk category as covariants);
TC: total cholesterol, HDL–C: high–density lipoprotein–cholesterol, Apo B: apolipoprotein B; FAS: Full analysis set.
References. Data on file. Clinical Phase III trial in Korea. HL140 (2016)

Safety Profile

- **Favorable Safety:**
  Cretrol® showed no significant differences in adverse event incidence compared to rosuvastatin during the treatment period.