**INTRODUCTION:**
Icosabutate, an orally active structurally enhanced fatty acid (SEFA), has demonstrated reduction in triglycerides (TG) and cholesterol in several rodent models of dyslipidemia and diabetes. In clinical single and multiple dose studies icosabutate was well tolerated and significantly lowered LDL-C, non-HDL-C and TG in subjects with mixed dyslipidemia.

**AIM:**
This phase 1b study explored the lipid lowering effects of icosabutate in subjects with hypercholesterolemia.

**METHODS:**
Randomized double blind, placebo controlled study of icosabutate 600mg OD. Subjects with hypercholesterolemia treated with a statin had temporarily withdrawn from statin, 28 days treatment with icosabutate and at days 1, 7, 14, 21, 28, and 29. The exploratory analyses considered changes from baseline to day 28.

**RESULTS:**
24 white, male subjects with an average age of 55 (33-65) and BMI of 27.9 kg/m² (24.7-32.2) were randomized to icosabutate, 600 mg OD, and at days 1, 7, 14, 21, 28, and 29. The exploratory analyses considered changes from baseline to day 28.

**COMMENT TO VALUES:**
There is a slight variance in values presented in the abstract and those presented in this poster: – The values in the abstract are reported as median percentage change from baseline average in visit 2-6 to 24 hours after last dose (day 28) – The values in this poster are reported in line with the clinical study report as LS mean change from baseline (day-1) to day 28.

**SAFETY:**
The number of subjects reporting adverse events (AEs) were balanced between the treatment arms (Table 2).

There were no other findings of clinical importance in the clinical laboratory evaluations, vital signs, 12-lead ECGs, telemetry, physical examinations, or body weight observed during the study.

**CONCLUSION:**
In this exploratory phase ib study in hypercholesterolemic subjects temporarily withdrawn from statin, 28 days treatment with icosabutate showed promising results.

ICOSABUTATE:
- Reduced Total-C, LDL-C, non-HDL-C, TG, and apo B compared to placebo
- Reduced plasma apo C3 substantially from baseline
- Increased plasma PCSK-9 levels compared to placebo
- Appeared safe and well tolerated

The results extend and confirm pre-clinical data on icosabutate and suggest a unique pharmacological profile with large, robust reductions in both LDL-C and TGs. These explorative data indicate that icosabutate may be an important novel lipid-lowering agent in several patient populations. The results await confirmation in designated efficacy studies.

**AUTHOR’S DISCLOSURE:**
This study was in whole sponsored by Pronova BioPharma Norge AS – part of BASF. Authors not employed by Pronova BioPharma/BASF have no conflict of interest.