RESULTS

DOSE LEVELS EVALUATED

In Part 1, subjects were assigned to receive single SC doses of ALG-020572: 50 mg (Cohort 1), 150 mg (Cohort 2), 300 mg (Cohort 3) and 480 mg (Cohort 4) or matching placebo.

BASELINE CHARACTERISTICS

The baseline characteristics were similar across dose levels and are typical for a HV population.

SAFETY

ALG-020572 was well tolerated after single subcutaneous doses of up to 480 mg:

- No serious adverse events were reported.
- There was no apparent relationship between dose and any treatment emergent adverse events (TEAEs) reported.

PHARMACOKINETICS

- Plasma exposures increased in a more than dose proportional manner between 50 and 480 mg.
- Low to moderate PK variability (CV: ~30% for AUC, 30-64% for CL/F).
- Quick absorption (τmax—3 hrs), high volume of distribution (V/F > 150 L) and relatively high plasma CL (CL/F > 6 L/hr).
- Low urinary excretion (<6% total administered dose).

CONCLUSIONS

- ALG-020572 demonstrated an acceptable safety and PK profile in HVs receiving single SC doses from 50 mg to 480 mg.
- Exposures increased in a more than dose proportional manner with moderate variability and no differences across ethnicities.
- Multiple doses of ALG-020572 (Part 2) were evaluated subsequently in CHB subjects per SPC recommendations.

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REFERENCES