OBJECTIVE

- This ongoing Phase 2 study aims to assess the reduction in pain in adult subjects with hallux valgus following treatment with AboBoNT-A vs. placebo.

METHODS

Study design
- Randomised, placebo-controlled, parallel-group, multicentre study conducted in two periods:
  - a double-blind period lasting for at least 12 weeks
  - an open-label period which will last up to 24 weeks (Figure 1)
- Eligible subjects (Table 1) will be randomised (1:1:1) to treatment with AboBoNT-A (2 dose groups), or placebo.
- Following completion of double-blind Cycles 1, subjects who meet retreatment criteria will be eligible for open-label treatment.
- Patients who do not meet retreatment criteria at 12 weeks post-injection will be re-evaluated at the next scheduled visit (every 28 days) to determine eligibility to commence open-label treatment.

Study treatment and assessments
- Subjects will receive four intramuscular injections (divided equally) in the study foot under electrical stimulation guidance on Day 1 of double-blind Cycle 1.
- Evaluations of efficacy will be based solely on the foot selected for treatment meeting the study entry criteria.
- For subjects with bilateral hallux valgus, the most affected foot will be selected for double-blind treatment.

RESULTS

- Study NCT03566008 is currently recruiting.
- A total of 156 subjects will be planned to be enrolled in the study.
- Subjects enrolled during the double-blind period will rollover into the open-label period.

CONCLUSIONS

- Treatment with AboBoNT-A is a new potential intervention for patients suffering from hallux valgus and who have very limited pharmacological treatment options for this painful condition.