INTRODUCTION

Hallux valgus (bunion) is a progressive foot deformity, affecting up to 35% of adults and characterised by pain, morphological changes in foot appearance, and functional disability.1 While hallux valgus is typically managed initially by orthotic applications such as splints, inserts or braces used to correct foot biomechanics, the efficacy of these interventions is widely considered to be largely ineffective with substantial evidence suggesting that these devices are no more effective than no treatment at all.2 Surgery is common, but is associated with a prolonged recovery, postsurgical pain and a significant chance of recurrence.3 Evidence suggests that the underlying cause of hallux valgus is related to a progressive imbalance among specific foot muscles, resulting in lateral deviation of the hallux and osseous changes with subsequent development of a pressure-sensitive prominence on the medial side of the first metatarsal which limits mobility.4,5 Based on this aetiology, localised injections of abobotulinumtoxinA (AboBoNT-A), have the potential to correct the underlying muscle imbalance, thereby reducing foot pain and improving functional mobility.2,6

PRIMARY OBJECTIVE

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

METHODS

Table 1: Subjects

<table>
<thead>
<tr>
<th>Key inclusion criteria</th>
<th>Key exclusion criteria</th>
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<tr>
<td>Male or female, aged 18 to 75 years</td>
<td>Hallux valgus angle of ≥15° or &lt;30° in the study foot</td>
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<tr>
<td>Correct diagnosis of hallux valgus as determined by the investigator based on evidence of lateral deviation of either great toe or right or left foot</td>
<td>Hallux valgus angle between ≥15° and &lt;30° in the study foot or great toe</td>
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<tr>
<td>Presence of flat or square metatarsal head, metatarsus primus elevatus and/or severe cavus/plains in the study foot</td>
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<tr>
<td>Any other podiatric or orthopaedic condition which may interfere with the accurate evaluation of pain and/or function</td>
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</tr>
<tr>
<td>History of ankle or foot surgery in the study foot</td>
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</tr>
<tr>
<td>Use of orthotic devices or devices on the study foot</td>
<td>Score of 0 on the Numeric Pain Rating Scale (NPRS) (where 0 = no pain and 10 = worst possible pain) in the study foot</td>
</tr>
<tr>
<td>Use of orthotic devices or devices on the study foot</td>
<td>Score of ≥3 on the modified foot function index (mFFI) Pain subscale in the study foot</td>
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<tr>
<td>History of diabetes, peripheral neuropathy, inflammatory arthritis including gout or osteoarthritis conditions or disease causing aperistalsis, e.g., Marfan’s syndrome, Ehlers-Danlos syndrome</td>
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</tr>
<tr>
<td>Investigator judgement that the subject’s deformity is reducible following clinical evaluation including compression of the intermetatarsal angle or rotation of the proximal phalanx</td>
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Study design

This is a randomised, placebo-controlled, parallel-group, multicentre study conducted in two periods: a double-blind period lasting for at least 12 weeks, followed by an open-label period which will last up to 24 weeks (Figure 1).

 eligible subjects will be randomised 1:1:1 to treatment with AboBoNT-A (2 dose groups), or placebo.

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.

Safety is assessed through adverse event reporting, and clinical evaluations including physical examination of the study foot.

RESULTS

Study INT03569098 is currently recruiting. A total of 165 subjects are 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 who have very limited pharmacological treatment options for this painful condition.

References


Author Contributions

Substantial contributions to conception design: DGA, LD, BB, RS; PP: Drafting of the publication, or revising it critically for important intellectual content: DGA, LD, BB, RS, PP. Final approval of the publication: DGA, LD, BB, RS, PP.

Disclosures

Dr Armstrong, Dr Baravarian, and Dr Picaut are investigators for the current study and report consultancy (advisory board) for Ipsen and report consultancy (advisory board) for Ipsen.

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