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## Successful treatment of refractory chronic spontaneous urticaria with stapokibart: a case report

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### Introduction

Chronic spontaneous urticaria (CSU) is a mast cell-mediated skin disorder presenting with wheals and/or angioedema. While standard therapies include antihistamines and omalizumab, some patients remain refractory. Stapokibart, a humanized anti-interleukin-4 receptor alpha (IL-4Rα) monoclonal antibody, offers a novel therapeutic approach by blocking IL-4 and IL-13 signaling.

### Materials and Methods

We present a case of a 44-year-old female with refractory CSU who had inadequate response to multiple prior treatments, including oral antihistamines, Chinese patent medicine, narrowband ultraviolet B (NB-UVB) phototherapy, and omalizumab. After 9 weeks of omalizumab (300 mg every 3 weeks) without sufficient control, treatment was switched to subcutaneous stapokibart. A loading dose of 600 mg was administered, followed by 300 mg every 2 weeks initially, with subsequent extension of dosing intervals based on clinical response. Concomitant loratadine and NB-UVB phototherapy were maintained. Disease activity was monitored using the Urticaria Control Test (UCT), Urticaria Activity Score over 7 days (UAS7), and Dermatology Life Quality Index (DLQI).

### Results

After presentation at our hospital, the patient showed poor disease control despite 9 weeks of treatment with omalizumab 300 mg every 3 weeks (Q3W), loratadine 10 mg once daily, and NB-UVB phototherapy Q3W (UCT score of 6, UAS7 of 30, and DLQI of 21), with new erythema and wheals appearing every 2-3 days. Subsequently, she switched from omalizumab to stapokibart (600 mg loading dose, 300 mg thereafter) in December 2024, with loratadine tablet and NB-UVB phototherapy maintained. Marked improvements in symptoms and quality of life were evident by week 2. After 16 weeks of subcutaneous stapokibart every 2 weeks, erythema and wheals were well controlled, with mild pruritus. At week 19, UCT score increased to 15, and UAS7 and DLQI reduced to 0 and 1, respectively (figure 1). Then, the dosing interval for stapokibart was increased to every 3 weeks for 3 doses, and later further to every 6 weeks for 2 doses. During extended-interval dosing, the patient experienced no new erythema, wheals, or pruritus, with UCT, UAS7, and DLQI scores of 16, 0, and 0, respectively (figure 1). Follow-up laboratory tests showed a positive ASST, with total IgE at 2.29 IU/mL and a basophil activation test result of 2.34%. No abnormalities were found in the complete blood count, D-dimer, erythrocyte sedimentation rate, immunological parameters, or C-reactive protein. Three months after discontinuation of stapokibart, no relapse occurred (figure 1). No adverse events were reported throughout the stapokibart treatment period.

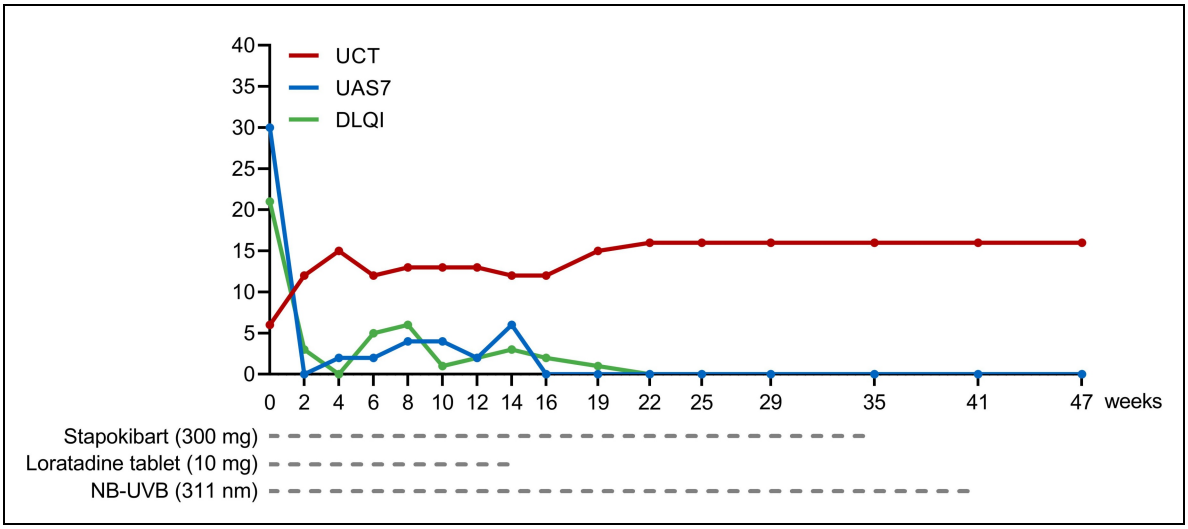


Figure 1 Timeline of stapokibart treatment and outcomes Stapokibart was administered at 300 mg (600 mg loading dose at week 0) every 2 weeks from weeks 0 to 16, every 3 weeks from weeks 19 to 25, and every 6 weeks from weeks 29 to 35. Loratadine tablet was used on an as-needed (SOS) basis from weeks 2 to 14. DLQI, Dermatology Life Quality Index; NB-UVB, narrowband ultraviolet B; UAS7, Seven days urticaria activity score; UCT, Urticaria control test.

## Conclusions

This case demonstrates that stapokibart is well tolerated and provides rapid and significant improvements in urticaria activity and health-related quality of life in patients with refractory CSU, supporting its potential role as an effective add-on therapy to standard-of-care therapies.