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Satisfaction with Sebetralstat Treatment of HAE Attacks in the KONFIDENT-S Open-Label Study

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Rationale

- Global hereditary angioedema (HAE) guidelines recommend considering the early use of on-demand treatment upon recognition of an HAE attack to reduce morbidity and prevent mortality[1–3]
- Until recently, available on-demand treatments were only administered parenterally (via intravenous infusion or subcutaneous injection), which has been previously shown to delay treatment[4]
- Sebetralstat, an oral, on-demand plasma kallikrein inhibitor, was recently approved for the treatment of HAE attacks in patients aged ≥12 years in the US, Europe and the UK,[5-7] and received orphan drug designation in Japan[8]
- Here, we present interim findings from the KONFIDENT-S open-label extension trial on time to beginning of symptom relief and treatment satisfaction with oral sebetralstat from patients with HAE who experienced the use of conventional on-demand treatment

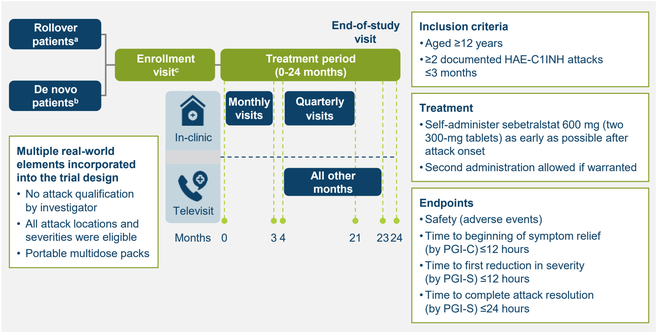
Methods

- KONFIDENT-S is an ongoing, 2-year, multicenter, open-label extension trial (NCT05505916; EudraCT: 2021-001176-42) (**Figure 1**)
  - Eligible patients aged ≥12 years with HAE due to C1-inhibitor deficiency (HAE-C1INH) and ≥2 documented attacks within 3 months before enrollment or had completed the phase 3 KONFIDENT trial (NCT05259917)
  - Patients using long-term prophylactic (LTP) were eligible to participate, provided they had been on a stable dose regimen of a protocol-allowed LTP for ≥3 months before enrollment
- All attacks that included satisfaction data as of September 14, 2024, were included in this assessment

KONFIDENT-S endpoints evaluated

- Time to beginning of symptom relief defined as at least "a little better" at 2 consecutive time points within 12 hours of the first dose, measured by the Patient Global Impression of Change (PGI-C)
- Treatment satisfaction was assessed 24 hours after the first dose of sebetralstat for each attack on a 7-point Likert scale (**Figure 2**)

Figure 1. KONFIDENT-S OLE trial design



NCT05505916; EudraCT: 2021-001176-42.
[a]Completed the phase 3 KONFIDENT trial. [b]All other patients, including those who participated in the phase 2 trial. [c]For de novo patients, the enrollment visit is a screening visit.
HAE-C1INH, hereditary angioedema due to C1 inhibitor deficiency; OLE, open-label extension; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity.

Figure 2. Treatment satisfaction rating (7-point Likert scale)

Overall, how satisfied were you with sebetralstat therapy for this HAE attack?

−3	−2	−1	0	1	2	3
Dissatisfied			Neutral	Satisfied		

Results

Table 1. Baseline characteristics (N=107)

	Previously used on-demand treatment				
	Icatibant (n=47)	pdC1INH (n=18)	rC1INH (n=2)	Multiple treatments[a] (n=40)	Overall (N=107)
Age, median (IQR), years	35 (21.0–47.0)	19 (15.0–36.0)	34 (25.0–44.0)	41 (31.5–52.5)	35 (21.0–49.0)
Sex, female, n (%)	29 (61.7)	13 (72.2)	2 (100)	30 (75.0)	74 (69.2)
Race, n (%)					
White	35 (74.5)	12 (66.7)	2 (100)	30 (75.0)	79 (73.8)
Asian	6 (12.8)	1 (5.6)	0	8 (20.0)	15 (14.0)
Country, Japan, n (%)	4 (8.5)	0	0	7 (17.5)	11 (10.3)
BMI, median (IQR), kg/m²	25.6 (22.0–30.0)	23.6 (19.8–30.0)	25.4 (19.5–31.2)	25.1 (23.0–30.5)	25.4 (22.3–30.1)
Type of HAE-C1INH					
Type 1	42 (89.4)	17 (94.4)	2 (100)	37 (92.5)	98 (91.3)
Type 2	5 (10.6)	1 (5.6)	0	3 (7.5)	
Treatment, n (%)					
On-demand only	33 (70.2)	12 (66.7)	1 (50.0)	33 (82.5)	79 (73.8)
LTP	14 (29.8)	6 (33.3)	1 (50.0)	7 (17.5)	28 (26.2)

Data cutoff: September 14, 2024.
[a]Patients reported using >1 conventional on-demand treatment at screening.
BMI, body mass index; HAE-C1INH, hereditary angioedema due to C1 inhibitor deficiency; IQR, interquartile range; LTP, long-term prophylaxis; pdC1INH, plasma-derived C1-inhibitor; rC1INH, recombinant C1-inhibitor.

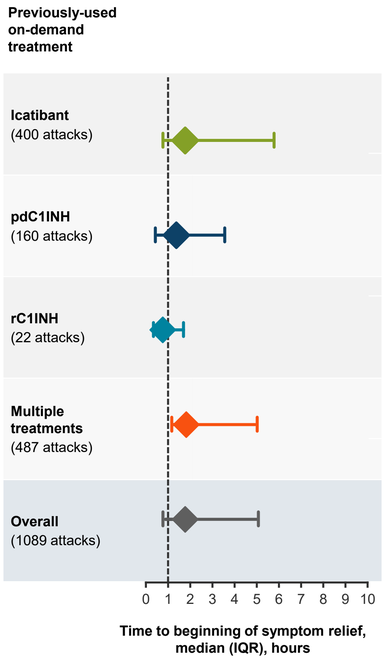
Table 2. Baseline characteristics of sebetralstat-treated attacks (N=1089)

	Previously used on-demand treatment				
Attacks	Icatibant (n=409)	pdC1INH (n=167)	rC1INH (n=22)	Multiple treatments (n=491)[a]	Overall (N=1089)
Baseline severity (PGI-S), n (%)					
Mild[b]	147 (35.9)	54 (32.3)	3 (13.6)	224 (45.6)	428 (39.3)
Moderate	165 (40.3)	71 (43.1)	12 (54.5)	234 (47.7)	482 (44.3)
Severe/very severe	97 (23.7)	41 (24.6)	7 (31.8)	33 (6.7)	178 (16.3)
Primary pooled attack location, n (%)					
Mucosal[c]	154 (37.7)	98 (58.7)	13 (59.1)	166 (33.8)	431 (39.6)
Involving the larynx	8 (2.0)	7 (4.2)	0	3 (0.6)	18 (1.7)
Subcutaneous only[c]	254 (62.1)	69 (43.1)	9 (40.9)	325 (66.2)	657 (60.3)
Missing	1 (0.2)	0	0	0	1 (0.1)
Time from attack onset to treatment, median (IQR), minutes	6.0 (1.0–63.0)	6.0 (1.0–39.0)	37.5 (18.0–61.0)	21.0 (1.0–100.0)	12 (1–65)
Attacks treated with a second dose within 12 hours, n (%)	74 (18.1)	45 (26.9)	6 (27.3)	115 (23.4)	406 (37.3)
Attacks treated with conventional treatment within 12 hours, n (%)	14 (3.4)	7 (4.2)	0	31 (6.3)	52 (4.8)

Data cutoff: September 14, 2024.
[a]Icatibant + pdC1INH, n=282; icatibant + pdC1INH + rC1INH, n=124; icatibant + rC1INH, n=51; and pdC1INH + rC1INH, n=34.
[b]Baseline severity was classified as "None" for 4 attacks in the icatibant, 3 in the pdC1INH, and 3 in the multiple treatments.
[c]Mucosal: attacks with primary location of "Abdomen" and/or "Larynx/throat"; subcutaneous: other attacks not involving the mucosal locations. IQR, interquartile range; pdC1INH, plasma-derived C1-inhibitor; PGI-S, Patient Global Impression of Severity; rC1INH, recombinant C1-inhibitor.

- Across all subgroups (**Table 1**), most attacks were mild (38.5%) or moderate (44.3%; **Table 2**)
- A second dose of sebetralstat was administered within 12 hours of their first dose for a total of 240 attacks (22.0%) across all subgroups
- In total, conventional on-demand treatments were administered for 52 attacks (4.8%) within 12 hours after use of sebetralstat

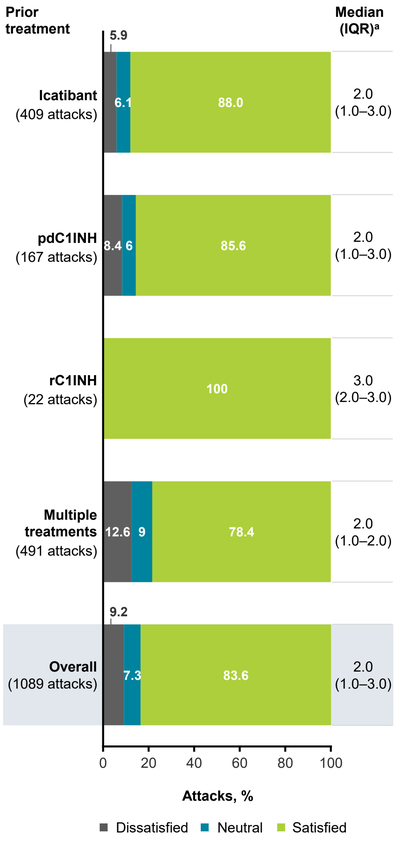
Figure 3. Time to beginning of symptom relief[a] with sebetralstat by previously used on-demand treatments



Data cutoff: September 14, 2024.
Diamonds are the medians met within time window. Error bars are IQR.
[a]Defined as a PGI-C rating of at least "A little better" for 2 consecutive time points, with missing data entries between consecutive time points within 12 hours of the first dose of sebetralstat.
IQR, interquartile range; pdC1INH, plasma-derived C1-inhibitor, rC1INH, recombinant C1-inhibitor.

- Time to beginning of symptom relief was similar regardless of which on-demand treatment was previously used (**Figure 3**)
  - Median time to beginning of symptom relief ranged from 0.76 to 1.82 hours across subgroups

Figure 4. Satisfaction with sebetralstat for each attack by previously used on-demand treatments (N=1089)



[a]Based on the 7-point Likert satisfaction scale, from −3 to 3 (where 1=somewhat satisfied, 2=very satisfied and 3=extremely satisfied).
IQR, interquartile range; pdC1INH, plasma-derived C1-inhibitor, rC1INH, recombinant C1-inhibitor.

- Median satisfaction rating for sebetralstat for all attacks was 2.0 (1.0–3.0) (**Figure 4**)
- No dissatisfaction (ie, neutral or satisfied) was reported for 90.8% of attacks (7.3% neutral; 83.6% satisfied)

Conclusions

- **In this interim analysis of the KONFIDENT-S trial, oral sebetralstat enabled early treatment and resulted in early symptom relief**
- **Patients who had experienced the use of any conventional on-demand treatment reported being very satisfied with sebetralstat on-demand therapy**

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Acknowledgments

Medical writing and editorial support for the development of this poster, under the direction of the authors, was provided by Penny Baron, MS, and Celia Nelson, ELS, of Ashfield MedComms, an Inizio company, and was funded by KalVista Pharmaceuticals.

Disclosures

DH has served as a speaker for and advisor to BioCryst, CSL Behring, KalVista Pharmaceuticals, Takeda, and Torii; as a consultant for the Diagnostic Consortium to Advance the Ecosystem for Hereditary Angioedema (DISCOVERY); and as a cooperating physician for HAEJ. **MEO** has received grants, royalties or licenses, consulting fees, honoraria, payment for expert testimony, meeting/travel support, and/or served on advisory boards and/or data safety monitoring for ADMA, ARS, AstraZeneca, BioCryst, Blueprint, Cogent, Cycle Pharma, Grifols, Pharvaris, GSK, KalVista Pharmaceuticals, Novartis, Pharming, Regeneron, Sanofi, and Takeda. **MEM** has received grants, consulting fees, honoraria, clinical trial support, medical writing support, article processing charges, meeting/travel support, and/or served on advisory boards and/or data safety monitoring for Astria, BioCryst, BioMarin Pharmaceutical Inc, CSL Behring, Intellia Therapeutics, Ionis Pharmaceuticals, KalVista Pharmaceuticals, Pharming, Pharvaris, and Takeda. **IMS** has received grants, royalties or licenses, consulting fees, honoraria, clinical trial support, medical writing support, article processing charges, meeting/travel support, course sponsorship, and/or served on advisory boards and/or data safety monitoring for BioCryst, CSL Behring, KalVista Pharmaceuticals, Octapharma, Pharming, Pharvaris, and Takeda. **SS** has received consulting fees and/or honoraria from AstraZeneca, BioCryst, CSL Behring, KalVista Pharmaceuticals, Novartis, and Pharvaris. **DFS** has received grants, consulting fees, and/or honoraria from BioCryst, BioMarin, CSL Behring, KalVista Pharmaceuticals, Pharming, Pharvaris, and Takeda. **JH, PB, PKA** are salaried employees of KalVista Pharmaceuticals. **RT** has received grants, consulting fees, honoraria, and/or served on advisory boards and/or data safety monitoring for AstraZeneca, Astria, BioCryst, CSL Behring, GSK, Ionis Pharmaceuticals, KalVista Pharmaceuticals, Pharming, Pharvaris, Regeneron, Sanofi, and Takeda.

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Presented at the 125th Annual Meeting of the Japanese Dermatological Association. June 11–14, 2026, Kyoto, Japan.

遺伝性血管性浮腫における経口セベトラルスタットによる急性発作時治療の有効性と患者満足度

P9-10

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背景

- 国内外の遺伝性血管性浮腫（HAE）ガイドラインにおいて、HAE発作が認められた場合、急性発作時治療薬の早期投与を検討し、疾病負荷を低下させ死亡を防ぐことが推奨されている[1–4]
- 従来の急性発作時治療薬は、非経口薬（静注又は皮下注射）のみであった
- 最近、米国、欧州及び英国において、経口の急性発作時治療用血漿カリクレイン阻害薬であるセベトラルスタットが、12歳以上の患者におけるHAE発作の治療薬として承認された。[5–7] 日本においては同様に2026年3月に発売された[8]
- 本発表では、従来の急性発作時治療薬を使用した経験のあるHAE患者において非盲検継続試験（KONFIDENT-S）の中間解析から得られた、経口セベトラルスタットによる症状緩和開始までの時間及び治療への患者満足度を示す

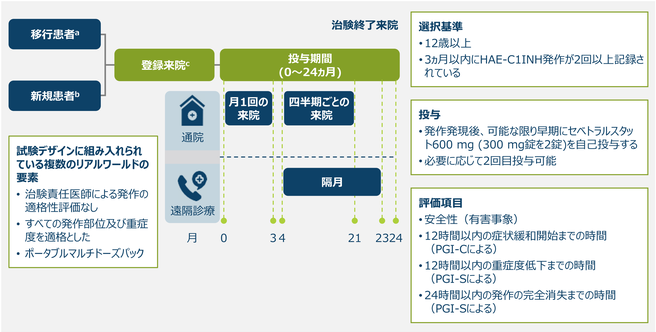
方法

- KONFIDENT-S試験は、2年間に及ぶ多施設共同非盲検継続投与試験（NCT05505916; EudraCT: 2021-001176-42）である（**図1**）
  - C1インヒビター欠損によるHAE（HAE-C1INH）を有する12歳以上の患者で、登録前3カ月以内に2回以上の発作が記録されているか、第Ⅲ相KONFIDENT試験（NCT05259917）を完了している患者を適格とした
  - 長期予防薬（LTP）を使用している患者は、登録前3カ月以上にわたって治験実施計画書で認められたLTPの用法・用量が安定している限り、参加に適格とした
- 2024年9月14日時点の満足度データを含むすべての発作を本評価に含めた

KONFIDENT-Sの評価項目

- 症状緩和開始までの時間は、初回投与から12時間以内の連続する2つの時点で、患者による全般印象度変化（PGI-C）の測定結果が「やや改善した」以上の場合と定義した
- 7段階評価のリッカート尺度を用いて、各発作に対するセベトラルスタット初回投与の24時間後に治療満足度を評価した（**図2**）

図1. KONFIDENT-S OLE試験デザイン



NCT05505916; EudraCT: 2021-001176-42.
[a]第Ⅱ相KONFIDENT試験を完了済み。[b]第Ⅱ相試験に参加した患者を含む。その他すべての患者。[c]新規患者の場合、登録来院はスクリーニング来院である。
HAE-C1INH：C1インヒビター欠損による遺伝性血管性浮腫；OLE：非盲検継続投与；PGI-C：患者による全般印象度変化；PGI-S：重症度に関する患者の全般印象度。

図2. 治療満足度評価（7段階リッカート尺度）

全体として、このHAE発作に対するセベトラルスタットによる治療満足度はどうか？

−3	−2	−1	0	1	2	3
非常に不満	とても不満	やや不満	どちらでもない	やや満足	とても満足	非常に満足

結果

表1. ベースライン特性（N=107）

	過去に使用した従来の急性発作時治療薬				
	イカチバント（n=47）	pdC1INH（n=18）	rC1INH*（n=2）	複数の投与薬[a]（n=40）	全体（N=107）
年齢、中央値（IQR）、歳	35 (21.0–47.0)	19 (15.0–36.0)	34 (25.0–44.0)	41 (31.5–52.5)	35 (21.0–49.0)
性別、女性、n (%)	29 (61.7)	13 (72.2)	2 (100)	30 (75.0)	74 (69.2)
人種, n (%)					
白人	35 (74.5)	12 (66.7)	2 (100)	30 (75.0)	79 (73.8)
アジア人	6 (12.8)	1 (5.6)	0	8 (20.0)	15 (14.0)
国, 日本, n (%)	4 (8.5)	0	0	7 (17.5)	11 (10.3)
BMI, 中央値（IQR）, kg/m²	25.6 (22.0–30.0)	23.6 (19.8–30.0)	25.4 (19.5–31.2)	25.1 (23.0–30.5)	25.4 (22.3–30.1)
HAE-C1INHの型					
1型	42 (89.4)	17 (94.4)	2 (100)	37 (92.5)	98 (91.3)
2型	5 (10.6)	1 (5.6)	0	3 (7.5)	
投与薬, n (%)					
On-demand only	33 (70.2)	12 (66.7)	1 (50.0)	33 (82.5)	79 (73.8)
LTP	14 (29.8)	6 (33.3)	1 (50.0)	7 (17.5)	28 (26.2)

データカットオフ：2024年9月14日。
*本邦未承認薬。
[a]スクリーニング時に従来の急性発作治療薬を2種類以上使用したと報告した患者。
BMI：body mass index; HAE-C1INH：C1インヒビター欠損による遺伝性血管性浮腫; IQR：四分位範囲; LTP：長期予防薬; pdC1INH：血漿由来C1阻害薬; rC1INH：組換えヒトC1阻害薬。

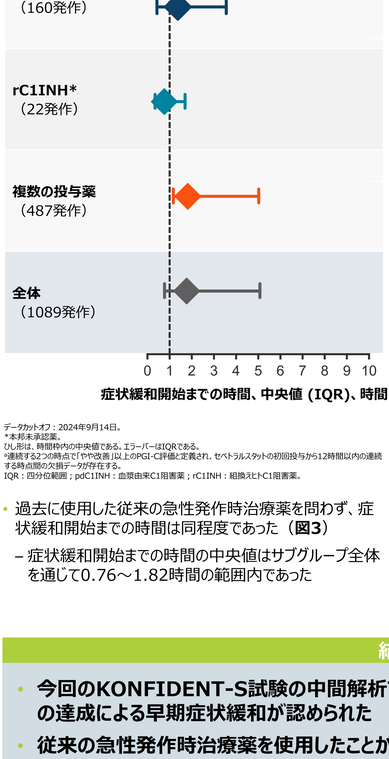
表2. セベトラルスタットを投与した発作のベースライン特性（N=1089）

	過去に使用した従来の急性発作時治療薬				
発作	イカチバント（n=409）	pdC1INH（n=167）	rC1INH*（n=22）	複数の投与薬[a]（n=491）	全体（N=1089）
ベースライン時の重症度（PGI-S), n (%)					
軽症[b]	147 (35.9)	54 (32.3)	3 (13.6)	224 (45.6)	428 (39.3)
中等症	165 (40.3)	71 (43.1)	12 (54.5)	234 (47.7)	482 (44.3)
重症／極めて重症	97 (23.7)	41 (24.6)	7 (31.8)	33 (6.7)	178 (16.3)
主要統合発作部位, n (%)					
粘膜[c]	154 (37.7)	98 (58.7)	13 (59.1)	166 (33.8)	431 (39.6)
喉頭	8 (2.0)	7 (4.2)	0	3 (0.6)	18 (1.7)
皮下のみ[c]	254 (62.1)	69 (43.1)	9 (40.9)	325 (66.2)	657 (60.3)
欠測	1 (0.2)	0	0	0	1 (0.1)
発作発現から投与までの時間, 中央値（IQR）, 分	6.0 (1.0–63.0)	6.0 (1.0–39.0)	37.5 (18.0–61.0)	21.0 (1.0–100.0)	12 (1–65)
12時間以内に従来薬の投与を行った発作, n (%)	14 (3.4)	7 (4.2)	0	31 (6.3)	52 (4.8)

データカットオフ：2024年9月14日。
*本邦未承認薬。
[a]イカチバント + pdC1INH, 282例; イカチバント + pdC1INH + rC1INH, 124例; イカチバント + rC1INH, 51例; and pdC1INH + rC1INH, 34例. rC1INHは本邦未承認薬。
[b]ベースライン時の重症度は、イカチバント群の4例の発作、pdC1INH群の3例の発作及び2種類の投与薬群の3例の発作が「なし」に分類された。
[c]粘膜：主な部位が「腹部」及び／又は「喉頭／咽喉」である発作；皮下：粘膜部位に関連しないその他の発作。
IQR：四分位範囲；pdC1INH：血漿由来C1阻害薬；PGI-S：重症度に関する患者の全般印象度；rC1INH：組換えヒトC1阻害薬。

- すべてのサブグループにおいて（**表1**）、発作のほとんどは軽症（38.5%）又は中等症（44.3%）であった（**表2**）
- 合計52の発作（4.8%）に対して、セベトラルスタット使用後12時間以内に従来の急性発作治療薬が投与された

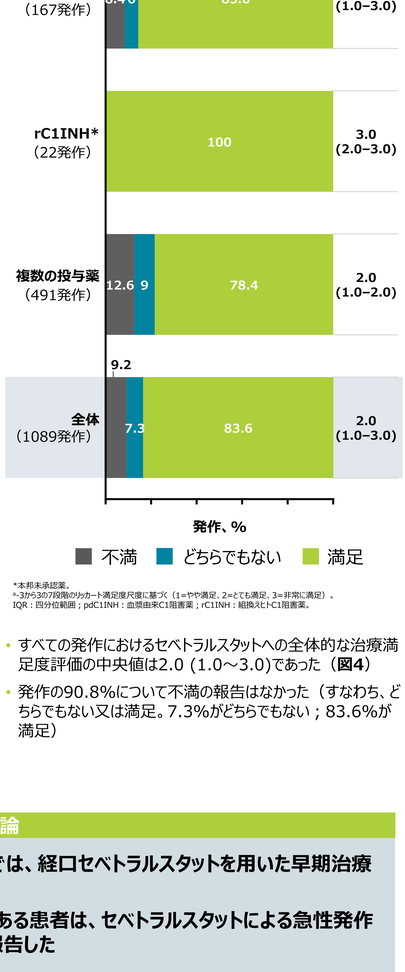
図3. セベトラルスタットによる症状緩和開始までの時間[a]（過去に使用した従来の急性発作時治療薬別）



データカットオフ：2024年9月14日。
*本邦未承認薬。
ひし形は、時間枠内の中央値である。エラーバーはIQRである。
[a]連続する2つの時点で「やや改善」以上のPGI-C評価と定義され、セベトラルスタットの初回投与から12時間以内の連続する時点間の欠損データが存在する。
IQR：四分位範囲；pdC1INH：血漿由来C1阻害薬；rC1INH：組換えヒトC1阻害薬。

- 過去に使用した従来の急性発作時治療薬を問わず、症状緩和開始までの時間は同程度であった（**図3**）
  - 症状緩和開始までの時間の中央値はサブグループ全体を通じて0.76～1.82時間の範囲内であった

図4. セベトラルスタットへの全体的な治療満足度（過去に使用した急性発作時治療薬別、N=1089）



*本邦未承認薬。
[a]-3から3の7段階のリッカート満足度尺度に基づく（1＝やや満足、2＝とても満足、3＝非常に満足）。
IQR：四分位範囲；pdC1INH：血漿由来C1阻害薬；rC1INH：組換えヒトC1阻害薬。

- すべての発作におけるセベトラルスタットへの全体的な治療満足度評価の中央値は2.0（1.0～3.0）であった（**図4**）
- 発作の90.8%について不満の報告はなかった（すなわち、どちらでもない又は満足。7.3%がどちらでもない；83.6%が満足）

結論

- **今回のKONFIDENT-S試験の中間解析では、経口セベトラルスタットを用いた早期治療の達成による早期症状緩和が認められた**
- **従来の急性発作時治療薬を使用したことがある患者は、セベトラルスタットによる急性発作時治療にとても満足している（中央値）と報告した**

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謝辞

著者らの脇示の下、Inizio傘下のAshfield MedCommsのPenny Barons, MS及びCelia Nelson, ELSによる本ポスターの作成におけるメディカルライティング及び編集上の支援を受け、KalVista Pharmaceuticalsの資金援助を受けた。

利益相反

DH has served as a speaker for and advisor to BioCryst, CSL Behring, KalVista Pharmaceuticals, Takeda, and Torii; as a consultant for the Diagnostic Consortium to Advance the Ecosystem for Hereditary Angioedema (DISCOVERY); and as a cooperating physician for HAE). **MEO** has received grants, royalties or licenses, consulting fees, honoraria, payment for expert testimony, meeting/travel support, and/or served on advisory boards and/or data safety monitoring for ADMA, ARS, AstraZeneca, BioCryst, Blueprint, Cogent, Cycle Pharma, Grifols, Pharvaris, GSK, KalVista Pharmaceuticals, Novartis, Pharming, Regeneron, Sanofi, and Takeda. **MEM** has received grants, consulting fees, honoraria, clinical trial support, medical writing support, article processing charges, meeting/travel support, and/or served on advisory boards and/or data safety monitoring for Astria, BioCryst, BioMarin Pharmaceutical Inc, CSL Behring, Intellia Therapeutics, Ionis Pharmaceuticals, KalVista Pharmaceuticals, Pharming, Pharvaris, and Takeda. **IMS** has received grants, royalties or licenses, consulting fees, honoraria, clinical trial support, medical writing support, article processing charges, meeting/travel support, course sponsorship, and/or served on advisory boards and/or data safety monitoring for BioCryst, CSL Behring, KalVista Pharmaceuticals, Octapharma, Pharming, Pharvaris, and Takeda. **SS** has received consulting fees and/or honoraria from AstraZeneca, BioCryst, CSL Behring, KalVista Pharmaceuticals, Novartis, and Pharvaris. **DFS** has received grants, consulting fees, and/or honoraria from BioCryst, BioMarin, CSL Behring, KalVista Pharmaceuticals, Pharming, Pharvaris, and Takeda. **JH, PB, PKA** are salaried employees of KalVista Pharmaceuticals. **RT** has received grants, consulting fees, honoraria, and/or served on advisory boards and/or data safety monitoring for AstraZeneca, Astria, BioCryst, CSL Behring, GSK, Ionis Pharmaceuticals, KalVista Pharmaceuticals, Pharming, Pharvaris, Regeneron, Sanofi, and Takeda.

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