Allergy

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Correspondence: The First Biosimilar for Biologics in Allergy: CT-P39 (Omlyclo-Omalizumab-Igec) Is Available for Asthma, Chronic Spontaneous Urticaria, and Chronic Rhinosinusitis With Nasal Polyps

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To the Editor,

In the type 2-mediated inflammatory diseases Chronic RhinoSinusitis with Nasal Polyps (CRSwNP), chronic spontaneous urticaria (CSU), and asthma blocking IgE antibodies is a common therapeutic strategy. The positive effect on disease burden and reduction in the need for oral corticosteroid treatment in asthma and CRSwNP is unquestionable, but the high costs of biologics limit their use in many patients and health-care systems [1–4]. Cost-effectiveness has been evaluated for omalizumab in CSU [3], CRSwNP [2, 4] and asthma [5]. Replacement of biologics with biosimilars in other medical disciplines led to a significant cost reduction, making effective treatments available for a wider range of patients and reducing the financial burden on health-care systems [6]. Despite previous concerns, the first head-to-head comparison studies showed similar safety and efficacy to the originator drug, and guideline recommendations were adapted accordingly [7]. Omalizumab is now the first monoclonal antibody worldwide for which a biosimilar is available in chronic inflammatory type 2 diseases [8–11].

CT-P39 [Omlyclo (omalizumab-igec: marketing authorization number EU/1/24/1817)] is the biosimilar for the reference monoclonal anti-IgE antibody omalizumab and received an EU marketing authorization on 16 May 2024. It is approved for use in all indications for which the reference omalizumab is approved [9–11]: severe CRSwNP, severe persistent allergic asthma, and CSU.

A biosimilar in general is a biological drug that is highly similar, but not necessarily identical, to a biological drug already approved (the so-called reference product) with regard to structure, biological activity, efficacy, safety, and immunogenicity [12]. Biosimilars are not considered generics of biologics, as the natural variability of biological systems and the complexity of their manufacturing processes make an exact replication of the molecular microheterogeneity virtually impossible. The European Medicines Agency (EMA) has played a pioneering role in the regulation of biosimilars by establishing a robust approval framework to demonstrate their safety and efficacy, introducing the first guidelines in 2005 [12]. This process includes a centralized approval process with a single marketing authorization, valid across all EU member states plus Iceland, Norway, and Liechtenstein [12]. Directives 2001/83/EC and Regulation (EC) No 726/2004 established stringent requirements for quality, safety, and efficacy in biosimilar development [12], covering comparability studies (to demonstrate similarity to the reference product in terms of structure, function, and clinical performance), clinical trials (focused trials for pharmacokinetics, pharmacodynamics, and immunogenicity), and marketing authorization application (analytical data comparing biosimilar and reference product, clinical and non-clinical study results, risk management plan, and post-approval commitments). Ongoing pharmacovigilance and periodic safety updates (PSURs) are mandatory to monitor the product's long-term safety [12].

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CT-P39 has similar physicochemical and pharmacodynamic properties to those of the reference omalizumab, and the pharmacokinetic equivalence and comparability in clinical efficacy, safety and immunogenicity profiles of the agent have been demonstrated in healthy volunteers [10] and patients with CSU, respectively [8, 11]. Furthermore, switching from the reference omalizumab to CT-P39 had no impact on efficacy or safety [8, 11]. Taken together, the available evidence supports CT-P39 as a clinically appropriate alternative to reference omalizumab across its approved indications, including its use in patients initiating anti-IgE therapy and, where appropriate, in those switching from the reference product without loss of efficacy or safety. While ongoing real-world pharmacovigilance will continue to clarify its long-term safety and effectiveness, the introduction of a biosimilar anti-IgE antibody offers the potential to expand access to biologic therapy and promote cost-conscious prescribing. Notably, CT-P39 is priced approximately 30% lower than the reference product across most European healthcare systems. New cost-effectiveness analyses of biologics in CRSwNP including Omlyclo are recommended and might lead to consideration of a broader use of this substance for the treatment of CRSwNP, despite the inferior efficacy compared to another biologic in this indication [13]. In this sense, CT-P39 represents not only a regulatory milestone, but also a meaningful translational advance toward more sustainable care in allergy and airway diseases. Similar pharmacoeconomic considerations might be required for other biosimilars that become available.

Author Contributions

L.K., J.M., S.R., L.G., J.M.-S., M.L., S.B., F.B., R.G., M.S., J.H., C.A., V.H., S.T.-S., I.A., G.M.E., O.P., A.M., P.B., M.O., J.B., E.C., M.S., M.J.T.J.: conceptualization and final proofreading. S.A. and L.K.: supervision and writing, original draft preparation.

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Conflicts of Interest

L.K. has received research grants from Allergy Therapeutics/Bencard, Great Britain/Germany; ALK-Abelló, Denmark; Allergopharma, Germany; Aimmune, USA; ASIT Biotech, Belgium; AstraZeneca, Sweden; Bionorica, Germany; BioNTech, Germany; Biomay, Austria; Blueprint, USA; Boehringer Ingelheim, Germany; Celltrion, South Korea; Circassia, USA; Chiesi, Italy; Cytos, Switzerland; Curalogic, Denmark; HAL, Netherlands; Lofarma, Italy; Menarini, Italy; Viatris/Mylan, USA; Novartis, Switzerland; Leti, Spain; ROXALL, Germany; GlaxoSmithKline (GSK), Great Britain; Sanofi, France; Stallergenes, France; Thermofisher, USA and/or has served on the speaker's bureau or was consulting for the above-mentioned pharmaceutical companies. L.K. is the current President of the German Society of Allergology AeDA, Governance Committee Board Member, and ENT Section Board Member of the European Academy for Allergy and Clinical Immunology (EAACI), Vice-President of the German Academy for Allergy and Environmental Medicine, and Editor-in-Chief of AllergoJournal and AllergoJournal International. J.M. is or has been a member of national and international scientific advisory boards, performed consultations, and has received fees for lectures and grants for research projects or clinical trials from Almirall, AstraZeneca, Eli Lilly, Genentech-Roche, GSK, LETI Pharma, Menarini Group, Mitsubishi Tanabe Pharma, MSD, NOUCOR/Uriach Group, Novartis, OptiNose, Proctor & Gamble, Regeneron Pharmaceuticals, Sanofi Genzyme, UCB Pharma, Upstream Bio, and Viatris/MEDA Pharmaceuticals. S.R. has acted as a consultant, speaker, and/or advisory board member for, and has received research grants from Sanofi-Regeneron, AstraZeneca, GlaxoSmithKline, and Novartis. J.M.-S. has received fees for consulting, projects, advisory boards, and speaking engagements from AstraZeneca, GlaxoSmithKline, MSD, Novartis, and Sanofi. S.B. reports grants from BencardAllergie, BRAIN AG, Karl Storz GmbH, Altamira AG, and the German Federal Ministry of Education

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Data Availability Statement

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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