Press Release

STADA launches ustekinumab biosimilar in Europe

- Launch of Europe-made ustekinumab in Europe with approved national pricing and reimbursement promotes access, coming immediately upon expiry of exclusivity rights for molecule used in select indications within gastroenterology, dermatology and rheumatology[1]
- Creates competition at earliest opportunity, enabling straightforward switching to broaden patient access and control costs in a growing market, with accessible indications currently valued at approximately €2.4 billion
- STADA CEO Peter Goldschmidt: "This opportunity to improve patient access through wider usage of a life-changing biological treatment emphasizes STADA's purpose of Caring for People's Health as a Trusted Partner."

Bad Vilbel – 22 July 2024 – STADA has launched Europe's first approved ustekinumab biosimilar in multiple European countries. The launch comes immediately upon expiry of exclusivity rights linked to the European reference molecule patent, offering patients, physicians and payers expanded access at the earliest possible opportunity to a life-altering medicine used in select indications in gastroenterology, dermatology and rheumatology[1]. Launches in further European countries are scheduled over the coming months via a fully European supply chain.

STADA's ustekinumab is indicated for Crohn's disease, psoriasis and psoriatic arthritis; it is not currently approved for the ulcerative colitis indication, since the originator still has exclusivity for this indication. The accessible indications are currently valued at approximately €2.4 billion annually in Europe.

[1] STADA's biosimilar is indicated for Crohn's disease, psoriasis and psoriatic arthritis; it is not currently approved for the ulcerative colitis indication, since the originator still has exclusivity for this indication

“Launching ustekinumab at the earliest opportunity, including in Europe’s largest pharmaceutical markets, creates competition in an expanding market,” stated STADA CEO Peter Goldschmidt. “This opportunity to improve patient access through wider usage of a life-changing biological treatment emphasizes STADA’s purpose of Caring for People’s Health as a Trusted Partner.”

In January 2024, STADA obtained the first approval from the European Commission for an ustekinumab biosimilar, authorized as having equivalent efficacy, safety and immunogenicity to the reference product.[2]

“With comparable safety, efficacy and immunogenicity, biosimilars give clinicians an opportunity for a seamless and simple switch for their patients,” commented STADA’s Global Specialty Head, Bryan Kim. “Physicians and patients can have full confidence that STADA has more than 15 years of experience in enhancing patient access through high-quality biosimilars in Europe, having launched our first biosimilar in 2008.”

Ustekinumab is STADA’s seventh biosimilar supplied in Europe, complementing the company’s existing biosimilars portfolio in immunology through its high-concentration adalimumab. STADA also offers biosimilars in the bone health, nephrology, oncology and ophthalmology therapeutic sectors, alongside differentiated Specialty therapies in nephrology and neurology. Ustekinumab is expected to make a significant financial impact on STADA’s Specialty business, which is the group’s fastest-growing segment.

Both ustekinumab and the high-concentration adalimumab biosimilar were developed and are produced through a strategic alliance that STADA formed with Iceland’s Alvotech in 2019. The partners also recently announced a development, manufacturing and marketing alliance for a proposed denosumab biosimilar.[3]

[2] Union Register of medicinal products - Public health - European Commission (europa.eu)
[3] Alvotech & STADA add to strategic alliance through denosumab | STADA

Alvotech is primarily responsible for development and manufacturing of these STADA biosimilars at its facility in Reykjavik, Iceland, that benefits from nearly 100% domestically produced renewable energy, including geothermal and hydroelectric power, which is aligned with STADA's core commitment to sustainability.

About STADA Arzneimittel AG

STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of consumer healthcare products, generics and specialty pharma. Worldwide, STADA Arzneimittel AG sells its products in approximately 115 countries. In financial year 2023, STADA achieved group sales of EUR 3,735 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 802 million. As of 31 December 2023, STADA employed 11,667 people worldwide.

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