EDA Assessment Report for Biological Medicinal Product

(Scientific Discussion)

Idacio

Date: November 2024

Unit: Technical Assessment Unit

Assessment report

Idacio PFS

Administrative information:

Trade name of the medicinal product:	Idacio Prefilled Syringe 40 mg
INN (or common name) of the active substance(s):	ADALIMUMAB 40 mg;
Manufacturer of the finished product	Merck Serono S.p.A., Via delle Magnolie, 15 (loc. frazione Zona Industriale), 70026, Modugno (BA) - ITALY.
Marketing Authorization holder	Fresenius Kabi Deutschland GmbH, Else-Kroner StraBe 1, 61352 Bad Homburg v.d.Hohe - GERMANY
Applied Indication(s):	Rheumatoid arthritis, Juvenile idiopathic arthritis, Axial spondyloarthritis, Psoriatic arthritis, Psoriasis, Paediatric plaque psoriasis, Hidradenitis suppurativa (HS), Crohn's disease, Paediatric Crohn's disease, Ulcerative colitis, Uveitis and Paediatric Uveitis.
Pharmaceutical form(s) and strength(s):	- Solution for injection -Strength: 40 mg
Route of administration	Subcutaneous
Approved pack	2 prefilled syringes 0.8 ml each + 2 alcohol pads. 6 prefilled syringes 0.8 ml each + 6 alcohol pads.

List of abbreviations:

pfs	Prefilles syringe
HS	Hidradenitis suppurativa
sTNF	Soluble Tumor Necrosis Factor
RMP/RP	Humira EU/ Humira-US
FP	finished product
ADCC	Antibody-dependent cell-mediated cytotoxicity
FcRn	Neonatal Fc receptor
MoAs	Mechanism/mode of actions
tmTNF	Transmembrane Tumor Necrosis Factor
FcγRs	Fc gamma receptor
CDC	Complement-dependent cytotoxicity

Dossier initial submission and evaluation process:

- The product was submitted for registration via Normal Track
- The dossier was initially received by the registration administration units on 20.8.2023 after providing all the required documents according to Preliminary checklist.

1. **General introduction about the product including brief description of the AI, its mode of action and indications**:

-The active substance of idacio has been developed in Merck Serono S.A. – Corsier-sur-Vevey (MS-Vevey) Chemin du Fenil, Zone Industrielle B CH-1804 Corsier-sur-Vevey - SWITZERLAND

-The finished product (FP) is a clear solution.

- Idacio is a 'biosimilar medicine'. The reference medicine for Idacio is Humira

- all excipients are also components of the approved Merck formulation. The composition of the Adalimumab drug product is chosen to optimize the chemical and physical stability as well as the clinical properties of the drug product.

- The product is available in 0.8 ml syringe is made of a pre-fillable 1 ml type I glass syringe closed with a bromobutyl plunger stopper combined with a 29 Gauge, 12 mm thin wall steel needle protected by a rigid needle shield.The pre-filled syringes, as primary containers, can be further assembled in the following ways in the manufacturing facility:

- A needle safety device based on the Safe'n'Sound® passive anti-needle stick device.
- A pre-filled pen device based on the PhysiojectTM RNS platform device defined in Ph. Eur., USP and JP

-Idacio is used to treat Rheumatoid arthritis, Juvenile idiopathic arthritis, Axial spondyloarthritis, Psoriatic arthritis, Psoriasis, Paediatric plaque psoriasis, Hidradenitis suppurativa (HS), Crohn's disease, Paediatric Crohn's disease, Ulcerative colitis, Uveitis and Paediatric Uveitis

Quality aspects:

- **Manufacturer(s):**

-The active substance is performed at Merck Serono S.A. – Corsier-sur-Vevey (MS-Vevey) Chemin du Fenil, Zone Industrielle B CH-1804 Corsier-sur-Vevey - SWITZERLAND
-The drug product is performed at Merck Serono S.p.A., Via delle Magnolie, 15 (loc. frazione Zona Industriale), 70026, Modugno (BA) - ITALY.
-Batch release site is performed at Fresenius Kabi Austria GmbH, Hafnerstraβe 36, 8055 Graz – AUSTRIA.

- **Stability**

Drug substance:

Approved Shelf Life: 36 months
Approved storage Conditions: Store at -80°C ± 10°C

Drug product:

Approved Shelf Life: 24 months
Approved Storage Conditions:

- Store in a refrigerator (2°C – 8°C).
- Do not freeze
- Keep the PFS in the outer carton in order to protect from light.

2. Non-clinical aspect and clinical aspect

-The results obtained show that MSB11022 and RMP/RP are similar in activities related to binding and neutralization of sTNF, and binding to FcRn, the known MoA of adalimumab that is relevant across all indications approved for RMP/RP. MSB11022 and RMP/RP are also similar in activities related to binding to tmTNF, binding to FcγRs and C1q, and also have comparable ADCC and CDC activities. In addition, the comparison with MSB11022 supports the bridging of in vivo data obtained with US RP and EU RMP.
-In conclusion the overall benefit/risk of idacio pfs is favorable in the treatment of Rheumatoid arthritis , Juvenile idiopathic arthritis, Axial spondyloarthritis, Psoriatic arthritis,

Psoriasis, Paediatric plaque psoriasis, Hidradenitis suppurativa (HS), Crohn's disease, Paediatric Crohn's disease, Ulcerative colitis, Uveitis and Paediatric Uveitis

- **General Conclusion and Recommendations if any:**
  Based on the review of CTD modules and other supplementary documents, the product is approved.

For more information, please visit EMA published assessment report link:
https://www.ema.europa.eu/en/medicines/human/EPAR/idacio