Fresenius Kabi receives listing on the Pharmaceutical Benefits Scheme (PBS) for adalimumab biosimilar IDACIO®

Sydney, 1st April 2021 - Fresenius Kabi receives listing on the Pharmaceutical Benefits Scheme (PBS) for adalimumab biosimilar IDACIO®

- IDACIO® (adalimumab), a Tumor Necrosis Factor α (TNFα) inhibitor, is Fresenius Kabi's first biosimilar approved by the Therapeutic Goods Administration (TGA) in all indications of the reference product* in the areas of rheumatology, gastroenterology and dermatology[4]
- IDACIO® (adalimumab) provides a new adalimumab choice in Australia for people suffering with Autoimmune Disease[4]

Fresenius Kabi, a global healthcare company that specialises in lifesaving medicines and technologies, announced today that the Australian Federal Government will make IDACIO®, an adalimumab biosimilar, available through the Pharmaceutical Benefits Scheme (PBS).

"It is an exciting moment and an important milestone for us as a company to launch our first biosimilar product in Australia. Biosimilars are an important contributing factor to the sustainability of the PBS and in line with our philosophy of 'caring for life' the launch of IDACIO® provides a new adalimumab choice for patients suffering with autoimmune disease" said Martin Monaghan, Country Manager, Australia and New Zealand.

The Australian approval of IDACIO® (adalimumab) was based on the totality-of-evidence detailed in the comprehensive data package submitted to the Therapeutic Goods Administration (TGA) including analytical, preclinical and clinical data in healthy volunteers and patients[1,2,3]

IDACIO® (adalimumab) is the first approved molecule of the Fresenius Kabi biosimilars portfolio with a focus on autoimmune and oncology medicines. The TGA approval and subsequent reimbursement on the PBS of IDACIO® (adalimumab) is an important milestone for Fresenius Kabi as a company and for patients who now have a new adalimumab choice in Australia.

Idacio® (adalimumab) is PBS listed with schedule equivalence ('a' flag) for the same indications as Humira® (reference product), except for:

- Paediatric patients weighing less than 40 kg

Note:

Prescribing of the biosimilar brand IDACIO® is encouraged for treatment naïve patients.

Encouraging biosimilar prescribing for treatment naïve patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

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About IDACIO®

IDACIO® (adalimumab) was developed by Fresenius Kabi and belongs to the therapeutic class of Tumor Necrosis Factor α (TNFα) inhibitors.

The Therapeutic Goods Administration approved IDACIO® for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis in adults and children, hidradenitis suppurativa in adults and adolescents (from 12 years of age), Crohn's disease in adults and children (≥ 6 years), ulcerative colitis and uveitis [4].

CONTRAINDICATIONS: Severe infections including sepsis, active tuberculosis, opportunistic infections; concurrent anakinra administration; moderate to severe heart failure (NYHA class III/IV); known hypersensitivity to Idacio® or its excipients. PRECAUTIONS: Infections (bacterial, mycobacterial, invasive fungal e.g. histoplasmosis, viral or other opportunistic); hepatitis B, TB (reactivation, new onset, or latent); demyelinating disorders* (central or peripheral; neurologic evaluation require prior to initiation and ongoing for patients with intermediate uveitis); haematologic events; live vaccines; immunosuppression; new or worsening CHF; renal, hepatic impairment; malignancy; hypersensitivity reactions; autoimmune processes (auto antibodies, lupus-like syndrome), use in psoriasis with phototherapy, concurrent biologic DMARDs or other TNF antagonists; elderly; pregnancy, lactation, surgery. *Refer to Neurologic Events in PI. ADVERSE EFFECTS (very common and common): Respiratory tract infections; systemic infections; intestinal infections; skin and soft tissue infections; ear infections; oral infections; reproductive tract infections; urinary tract infections; fungal infections; joint infections; benign neoplasm; skin cancer excluding melanoma; lymphoma; solid organ neoplasm; melanoma; leukopenia; anaemia; thrombocytopenia; leucocytosis; hypokalaemia; uric acid increased; blood sodium abnormal; hypocalcaemia; hyperglycaemia; hypophosphotemia; dehydration; mood alterations; anxiety; insomnia; headache; paraesthesias; migraine; nerve root compression; visual impairment; conjunctivitis; blepharitis; eye swelling; vertigo; tachycardia; hypertension; flushing; haematoma; cough; asthma; dyspnoea; abdominal pain; nausea; vomiting; GI haemorrhage; dyspepsia; gastroesophageal reflux disease; sicca syndrome; liver enzymes elevated; rash; musculoskeletal

pain; muscle spasms; haematuria; renal impairment; injection site reaction; chest pain; oedema; coagulation and bleeding disorders; autoantibody test positive; blood lactate dehydrogenase increased; impaired healing[4].

To obtain a copy of the full Product Information please phone Fresenius Kabi Australia Medical Affairs on 1300 361 004 (AU) or visit www.tga.gov.au

PBS Information: Authority required. Refer to PBS schedule for full authority information. IDACIO® is not listed for the treatment of enthesitis-related arthritis, paediatric psoriasis or uveitis and paediatric patients weighing less than 40kgs[5]

*Reference product Humira®

1. Magnenat L, et al. MAbs 2017;9:127–39.
2. Hyland E, et al. Comparison of the pharmacokinetics, safety and immunogenicity of MSB11022, a biosimilars of adalimumab, with Humira® in healthy subjects. *Br J Clin Pharmacol*. 2016;82(4):983–932.
3. Hercogová J et al. AURIEL-PsO: a randomised, double-blind phase III equivalence trial to demonstrate the clinical similarity of the proposed biosimilar MSB11022 to reference adalimumab in patients with moderate-to-severe chronic plaque-type psoriasis. *Br J Derm*. 2019;182(2):316–26.
4. IDACIO® Approved Product Information. Available at www.ebs.tga.gov.au
5. Pharmaceutical Benefits Scheme. Available at www.pbs.gov.au

About Fresenius Kabi

Fresenius Kabi is a global healthcare company that specialises in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. The company's products and services are used to help care for critically and chronically ill patients. Fresenius Kabi's product portfolio comprises a comprehensive range of I.V. generic drugs, infusion therapies and clinical nutrition products as well as the devices for administering these products. In the field of biosimilars, Fresenius Kabi focuses on autoimmune diseases and oncology. In 2019, the first biosimilar product by Fresenius Kabi was launched in Europe. Within transfusion medicine and cell therapies, Fresenius Kabi offers products for collection of blood components and extracorporeal therapies.

With its corporate philosophy of "caring for life", the company is committed to putting essential medicines and technologies in the hands of people who help patients and finding the best answers to the challenges they face.

Fresenius Kabi employs around 40,500 people worldwide. In 2020, the company reported sales of around €7.0 billion. Fresenius Kabi AG is a wholly owned subsidiary of the Fresenius SE & Co. KGaA healthcare group.

For more information, please visit www.fresenius-kabi.com.au