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## FDA approves *Benlysta* (belimumab) Autoinjector for children with systemic lupus erythematosus

- At-home treatment is the first and only in its class for pediatric patients aged five years and older with systemic lupus erythematosus.

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GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved a 200 mg subcutaneous route of administration of *Benlysta* (belimumab), a B-lymphocyte stimulator (BLyS)-specific inhibiting monoclonal antibody, for patients five years of age and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy. This option provides pediatric patients the possibility to receive the treatment at home.

Previously, children aged five years and older could only receive belimumab through an intravenous (IV) formulation, administered by healthcare professionals to patients as a weight-based dose of 10 mg/kg, via a one-hour infusion in a hospital or clinic setting every four weeks (following an initial loading phase given on days 0, 14 and 28). Now, a child's healthcare provider will determine if at-home administration is appropriate. If so, the healthcare provider will administer treatment or the healthcare provider will provide instructions to the patients' caregiver that will allow them to administer the medicine at home via an autoinjector once per week for children who weigh 40 kg or more, or once every two weeks for children who weigh 15 kg to <40 kg.

Lupus is a chronic, multi-organ (systemic) inflammatory disease caused when the immune system attacks its own tissues. There are between 5,000 and 10,000 children with SLE in the US. Children with lupus are more likely than adults to experience problems with vital organs – notably the kidney – and these organs accrue more damage in children.<sup>1,2</sup>

**Mary T. Crimmings, Interim CEO and Senior Vice President for Marketing and Communications, Lupus Foundation of America said:** "Lupus tends to be more aggressive and affect children more severely than adults, with those diagnosed in childhood having higher rates of organ damage.<sup>3</sup> Going to the doctor's office once every four weeks can be a logistical hurdle for some children and their caregivers, so having the option to administer *Benlysta* in the comfort of their home provides much-needed flexibility."

**Court Horncastle, Senior Vice President, and Head of US Specialty, GSK said:** "Patients are our top priority, and we are always working to innovate solutions that can improve lives and address unmet needs. This approval for an at-home treatment is the first and only of its kind for children with lupus and is a testament to our continued commitment to the lupus community."

The 200 mg autoinjector of belimumab will be available immediately for caregivers of pediatric patients five years of age and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy.

### About lupus

Systemic lupus erythematosus (SLE), the most common form of lupus, is a chronic, incurable, autoimmune disease associated with a range of symptoms that can fluctuate over time including painful or swollen joints, extreme fatigue, unexplained fever, skin rashes and organ damage.



### About Benlysta

*Benlysta* (belimumab), a B-lymphocyte stimulator (BLyS) specific inhibitor, is a fully human monoclonal antibody that binds to soluble BLyS, which is found to be increased in patients with systemic autoimmune diseases like systemic lupus erythematosus (SLE) and lupus nephritis (LN). ABy bding BLyS, *Benlysta* inhibits the prolonged survival of B cells, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells. *Benlysta* does not bind B cells directly. The US FDA first approved *Benlysta* for the treatment of active SLE; it is the first and only approved biologic for both SLE and LN in more than 50 years, including for the pediatric population.

Please see the [US Prescribing Information for BENLYSTA](#)

### INDICATION

BENLYSTA is indicated for patients aged  $\geq 5$  with active systemic lupus erythematosus (SLE) or active lupus nephritis who are receiving standard therapy. BENLYSTA is not recommended in patients with severe active central nervous system lupus.

### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATION

Previous anaphylaxis with BENLYSTA.

#### WARNINGS AND PRECAUTIONS

**Serious Infections:** Serious and sometimes fatal infections have been reported and occurred more frequently with BENLYSTA. Use caution in patients with severe or chronic infections, and consider interrupting therapy in patients with a new infection.

**Progressive Multifocal Leukoencephalopathy (PML):** Cases of JC virus-associated PML resulting in neurological deficits, including fatal cases, have been reported. If PML is suspected, immunosuppressant therapy, including BENLYSTA, must be suspended until PML is excluded. If confirmed, stop immunosuppressant therapy, including BENLYSTA.

**Hypersensitivity Reactions (Including Anaphylaxis):** Acute hypersensitivity reactions, including anaphylaxis and death, and infusion-related reactions have been reported. Generally, reactions occurred within hours of the infusion but may occur later, including in patients who have previously tolerated BENLYSTA. Non-acute hypersensitivity reactions (eg, rash, nausea, fatigue, myalgia, headache, and facial edema) typically occurred up to a week after infusion. Monitor patients during and after treatment and be prepared to manage anaphylaxis and infusion-related reactions. Be aware of the risk of hypersensitivity reactions, which may present as infusion-related reactions. Discontinue immediately in the event of a serious reaction. With intravenous administration, if an infusion reaction develops, slow or interrupt the infusion.

**Depression and Suicidality:** Depression and suicidality were reported in patients receiving BENLYSTA. Before adding BENLYSTA, assess patients' risk of depression and suicide and monitor them during treatment. Instruct patients/caregivers to contact their HCP if they experience new/worsening depression, suicidal thoughts/behavior, or other mood changes.

**Malignancy:** There is an increased risk of malignancies with the use of immunosuppressants. The impact of BENLYSTA on the development of malignancies is unknown.

**Immunization:** Live vaccines should not be given for 30 days before or concurrently with BENLYSTA as clinical safety has not been established.



**Use With Biologic Therapies:** Available data do not support the safety and efficacy of concomitant use of BENLYSTA with rituximab in patients with SLE. An increased incidence of serious infections and post-injection systemic reactions in patients receiving BENLYSTA concomitantly with rituximab compared to patients receiving BENLYSTA alone has been observed. The safety and efficacy of BENLYSTA concomitantly with other biologic therapies, including B-cell-targeted therapies, have not been established. Caution should be exercised if BENLYSTA is administered in combination with other biologic therapies.

#### ADVERSE REACTIONS

The most common serious adverse reactions in adult SLE clinical trials were serious infections; some were fatal. The most common adverse reactions ( $\geq 5\%$ ) were nausea, diarrhea, pyrexia, nasopharyngitis, bronchitis, insomnia, pain in extremity, depression, migraine, pharyngitis, and injection site reactions (subcutaneous injection).

Adverse reactions reported in clinical trials with SLE pediatric patients ( $\geq 5$  years) and adult patients with lupus nephritis were consistent with those observed in adult SLE trials.

#### USE IN SPECIFIC POPULATIONS

**Pregnancy:** There are insufficient data in pregnant women to establish whether there is drug-associated risk for major birth defects or miscarriage. After a risk/benefit assessment, if prevention is warranted, women of childbearing potential should use contraception during treatment and for  $\geq 4$  months after the final treatment.

**Pregnancy Registry:** HCPs are encouraged to refer patients and pregnant women are encouraged to enroll themselves by calling 1-877-311-8972 or visiting <https://mothertobaby.org/ongoing-study/benlysta-belimumab/>.

#### About GSK

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at [gsk.com](https://www.gsk.com).

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#### Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2023, and GSK's Q1 Results for 2024.

<sup>1</sup> Cincinnati Childrens. Systemic Lupus Erythematosus in Children. Available at <https://www.cincinnatichildrens.org/health/s/systemic-lupus-erythematosus>. Accessed April 2024.

<sup>2</sup> Brunner HI et al. Difference in disease features between childhood-onset and adult-onset systemic lupus erythematosus. *Arthritis Rheum* 2008;58(2):556–62.

<sup>3</sup> Lupus Foundation of America. Lupus and children. Available at <https://www.lupus.org/resources/lupus-and-children>. Accessed April 2024.