Press release

For media and investors only

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FDA approves *Benlysta* (belimumab) Autoinjector for children with active lupus nephritis

- With this approval, pediatric patients aged five years and older with active lupus nephritis will have a first-of-its-kind treatment option for at-home administration.

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved a 200 mg/mL autoinjector of *Benlysta* (belimumab), a B-lymphocyte stimulator (BlyS)-specific inhibiting monoclonal antibody, for subcutaneous injection in patients five years of age and older with active lupus nephritis (LN) who are receiving standard therapy. With this approval, GSK is expanding choices for belimumab treatment, offering pediatric lupus nephritis patients and caregivers a first-of-its-kind subcutaneous option that can be administered at home. The 200 mg/mL autoinjector was approved for pediatric patients with active systemic lupus erythematosus (SLE) in 2024.

Lupus nephritis is one of the most serious complications of lupus and occurs when the immune system mistakenly attacks the kidneys, leading to inflammation and possibly to organ damage. About 30-50% of children with lupus develop LN, typically within one to two years after their initial lupus diagnosis.[1,2]

Louise Vetter, President and Chief Executive Officer, Lupus Foundation of America said: “In children, lupus tends to be more aggressive and severe than it is in adults. The symptoms can be more intense, and the disease can have long-term effects on a child's growth and quality of life.[1,2] Having the *Benlysta* autoinjector provides a much-needed option that can help reduce the burden of frequent clinic visits for treatment and add greater flexibility for children and their families when considering continuity of care and routines of daily life."

Court Horncastle, Senior Vice President, and Head of US Specialty, GSK said: “For children and parents of children with lupus nephritis, this approval represents a choice in their care. Providing this at-home treatment option with the efficacy and safety of *Benlysta* is a testament to our ongoing commitment to the lupus community. GSK is driven by the belief that our therapeutic solutions should always prioritize improving patients' well-being and easing their treatment journey, including for younger patients.”

Caregivers of children who are currently using intravenous infusions of belimumab to manage their LN can work with their child’s healthcare provider to decide if at-home administration via autoinjector 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. The 200 mg/mL autoinjector of belimumab will be available for pediatric patients and their caregivers immediately.

About systemic lupus erythematosus (SLE) and lupus nephritis (LN)
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. LN is a complication of SLE and occurs when the immune system mistakenly attacks the kidneys and leads to inflammation and potential organ damage. This inflammation can harm the kidney’s ability to remove waste from the blood.[1]

LN can lead to end-stage kidney disease, which requires kidney dialysis or a transplant. Despite improvements in both diagnosis and treatment over the last few decades, LN remains an indicator of poor prognosis for people living

with lupus.[3,4] Manifestations of LN include proteinuria, elevations in serum creatinine and the presence of red and white blood cells in the urine.

About *Benlysta*
Benlysta (belimumab) is a B-lymphocyte stimulator (BLyS) specific inhibitor that binds to soluble BLyS. By binding BLyS, *Benlysta inhibits* the 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 ≥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 (e.g., 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 (≥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 (≥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 ≥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.

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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 in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024, and GSK's Q1 Results for 2025.

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[1] Lupus Foundation of America. Childhood Lupus. Available at https://www.lupus.org/our-work/childhood-lupus. Accessed June 2025.
[2] Francesco Peyronel, Giovanni M Rossi, Giulia Palazzini, Ludovica Odone, Carmela Errichiello, Giacomo Emmi, Augusto Vaglio, Early-onset lupus nephritis, Clinical Kidney Journal, Volume 17, Issue 8, August 2024, sfae212, https://doi.org/10.1093/ckj/sfae212.
[3] National Kidney Foundation: Lupus Nephritis. Available at https://www.kidney.org/kidney-topics/lupus-nephritis. Accessed June 2025.
[4] Hocaoğlu M,, et al. Incidence, Prevalence, and Mortality of Lupus Nephritis: A Population-Based Study Over Four Decades Using the Lupus Midwest Network. Arthritis Rheumatol. 2023;75(4):567-573. doi:10.1002/art.42375.