

**BASE PROSPECTUS SUPPLEMENT N°1**  
**dated 24 October 2023**



**UCB SA**

*(incorporated with limited liability in Belgium) as Issuer*  
*Allée de la Recherche 60, B-1070 Brussels, Belgium*  
*BE 0403.053.608 (RLE Brussels)*

**EUR 5,000,000,000**  
**Euro Medium Term Note Programme**

This base prospectus supplement N°1 (the “**Supplement N°1**”) constitutes a supplement for the purposes of Article 23(1) of Regulation (EU) 2017/1129 (as amended, the “**Prospectus Regulation**”). The Supplement N°1 is supplemental to, forms part of, and must be read in conjunction with the base prospectus dated 17 October 2023 (the “**Base Prospectus**”), prepared in connection with the EUR 5,000,000,000 Euro Medium Term Note Programme (the “**Programme**”) established by UCB SA, a limited liability company (*naamloze vennootschap/société anonyme*) incorporated under the laws of Belgium, having its registered office at Allée de la Recherche 60, B-1070 Brussels, Belgium and registered with the Crossroads Bank for Enterprises (*Kruispuntbank van Ondernemingen/Banque-Carrefour des Entreprises*) under number 0403.053.608 (RLE Brussels) (the “**Issuer**”), for the purpose of giving information with regard to the issue of Notes under the Programme.

Terms defined in the Base Prospectus shall, unless the context requires otherwise, have the same meaning when used in this Supplement N°1.

This Supplement N°1 has been approved on 24 October 2023 by the Belgian Financial Services and Markets Authority (*Autoriteit voor Financiële Diensten en Markten/Autorité des Services et Marchés Financiers*) (the “**FSMA**”) in its capacity as competent authority under the Prospectus Regulation. The approval by the FSMA should not be considered as an endorsement of the Issuer or of the quality of the Notes that are the subject of the Base Prospectus, as supplemented by this Supplement N°1. Investors should make their own assessment as to the suitability of investing in any Notes. The Issuer has requested this Supplement N°1 to be notified by the FSMA to the *Commission de Surveillance du Secteur Financier* in its capacity as competent authority under the Prospectus Regulation for the offer to the public and/or the admission to trading on a regulated market of any Notes in the Grand Duchy of Luxembourg.

The Issuer accepts responsibility for the information contained in this Supplement N°1. To the best of the knowledge of the Issuer, the information contained in this Supplement N°1 is in accordance with the facts and does not omit anything likely to affect its import.

## 1 Background

This Supplement N°1 is prepared and published following the approval by the U.S. Food and Drug Administration of (i) ZILBRYSQ® (zilucoplan) for the treatment of adults with generalised myasthenia gravis and (ii) BIMZELX® (bimekizumab) for the treatment of adults with moderate to severe plaque psoriasis, on 17 October 2023 and 18 October 2023, respectively.

## 2 New information

In order to ensure that the information contained in the Base Prospectus is up-to-date, as required by the Prospectus Regulation, the Base Prospectus is deemed to be amended as set out below.

### 2.1 Risk Factors

The part “Risk Factors” on pages 9 to and including 38 of the Base Prospectus will be deemed to be amended as set out below:

- the fifth paragraph (on page 19 of the Base Prospectus) of the risk factor entitled “*There are specific risks associated with developing, testing, manufacturing and commercialising medicines*” shall be deemed deleted and replaced by the following paragraph:

*“The development, testing, manufacturing, and commercialisation of medicines are subject to extensive regulation by various regulatory bodies. The regulatory framework for these products is highly complex and stringent. Failure to satisfy such regulatory requirements may deprive the UCB Group of the potential to receive or maintain marketing authorisation of the relevant medicines. For example, in May 2022 the U.S. Food and Drug Administration (the “FDA”) issued a Complete Response Letter (“CRL”) for the bimekizumab Biologics License Application (“BLA”) for the treatment of adults with moderate to severe plaque psoriasis. This CRL indicated that the FDA could not approve the BLA in its current form and that certain pre-approval inspection observations had to be resolved before the approval of the application could take place. The observations were addressed and the subsequent resubmission (including the UCB Group’s response to the observations in the CRL as well as, as a standard practice in case of resubmission, additional safety data obtained since the date of the initial submission) was accepted by the FDA in December 2022. In September 2023, UCB announced that it has received the Establishment Inspection Report (“EIR”) from the FDA following the pre-license inspection conducted in April 2023 at the Braine-l’Alleud (Belgium) manufacturing facility. The FDA concluded that this inspection is successfully closed. In October 2023, the FDA approved bimekizumab under the brand name Bimzelx® for the treatment of adults with moderate to severe plaque psoriasis. In combination with previous setbacks, this means a total delay of approximately two years compared to the originally expected FDA approval timeline.”*

- the eight paragraph (on page 19 of the Base Prospectus) of the risk factor entitled “*There are specific risks associated with developing, testing, manufacturing and commercialising medicines*” shall be deemed deleted and replaced by the following paragraph:

*“The ingredients necessary to produce biologic medical products are derived from bacterial or mammalian cells and cannot be produced synthetically. Given the limited availability of the materials and often high demand for biologics, the manufacturing of biologics is very expensive. Access to and supply of cell lines and related biological materials is limited and may be restricted following government regulations. Insufficient access to such materials can make it difficult or impossible to conduct research or maintain the required manufacturing capacity and may increase the manufacturing and development costs. The UCB Group’s biologic products currently on the market are Cimzia®, Evenity® (in partnership with Amgen in U.S. and Japan), Bimzelx® (with Bimzelx® expected to be available in the U.S. approximately one month following the FDA approval in October 2023) and Rystiggo® (following its approval in the U.S. in June 2023 and in*

Japan in September 2023). Biologic products in the pipeline include rozanolixizumab (currently under review in the EU), dapirolizumab pegol (Phase 3), and bepranemab (Phase 2).”

- the second paragraph (on pages 23 and 24 of the Base Prospectus) of the risk factor entitled “Products, including products in development or new indications for existing products, cannot be marketed unless the UCB Group obtains and maintains regulatory approval” shall be deemed deleted and replaced by the following paragraph:

“Even if the UCB Group develops new products, or new indications for existing products, it will not be able to market any of those products, unless and until it has obtained the required regulatory approvals in each jurisdiction where it proposes to market the product for each new indication. For example, in June 2019, the Committee for Medicinal Products for Human Use (“CHMP”) of the European Medicines Agency adopted a negative opinion for romosozumab. On 18 October 2019, following a re-examination procedure, the CHMP of the European Medicines Agency adopted a positive opinion recommending marketing authorisation for Evenity® (romosozumab) for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture and with no history of myocardial infarction or stroke. The CHMP’s recommendation was eventually reviewed by the European Commission, which granted marketing authorisation for Evenity® (romosozumab) on December 12, 2019. This followed the earlier approval in April 2019 by the FDA of Evenity® (romosozumab) for the treatment of osteoporosis in postmenopausal women at high risk for fracture after the UCB Group and Amgen received a positive vote from the FDA Bone, Reproductive and Urologic Drugs Advisory Committee (“BRUDAC”). The BRUDAC evaluated the FRAME and ARCH clinical studies in its review of the clinical benefit-risk profile of romosozumab, including the cardiovascular safety finding seen in the ARCH study, for the potential to reduce the risk of fractures and increase bone mineral density in postmenopausal women with osteoporosis. As a further example, in May 2022, the FDA issued a CRL for the bimekizumab BLA for the treatment of adults with moderate to severe plaque psoriasis. This CRL indicated that the FDA could not approve the BLA in its current form and that certain pre-approval inspection observations had to be resolved before the approval of the application could take place. The observations were addressed and the subsequent resubmission (including the UCB Group’s response to the observations in the CRL as well as, as a standard practice in case of resubmission, additional safety data obtained since the date of the initial submission) was accepted by the FDA in December 2022. In September 2023, UCB announced that it has received the EIR from the FDA following the pre-license inspection conducted in April 2023 at the Braine-l’Alleud (Belgium) manufacturing facility. The FDA concluded that this inspection is successfully closed. In October 2023, the FDA approved bimekizumab under the brand name Bimzelx® for the treatment of adults with moderate to severe plaque psoriasis. In combination with previous setbacks, this means a total delay of approximately two years compared to the originally expected FDA approval time. For further information, please refer to section 9 “Research and Development” in “Description of UCB”.”

## 2.2 Description of UCB

The part “Description of UCB” on pages 88 to and including 123 of the Base Prospectus will be deemed to be amended as set out below.

- the sixth paragraph (on page 88 of the Base Prospectus) of section 1 “Overview of UCB and its business” shall be deemed deleted and replaced by the following paragraph:

“The UCB Group is seeking to supplement its current marketed products by a research and development pipeline focusing on underserved patient populations, including patients living with myasthenia gravis, hidradenitis suppurativa, Parkinson’s disease and Alzheimer’s disease. As a result, Rystiggo® (rozanolixizumab) and Zilbrysq® (zilucoplan) have been approved for the treatment of generalised myasthenia gravis (“gMG”) in adult patients in the U.S. (respectively in June 2023 and in October 2023) and in Japan (in September 2023). The UCB Group’s two different

*medicines for gMG, each with a distinct mechanism of action, offer a unique portfolio of treatments that embody its commitment to addressing the gMG community's unmet needs. In the EU, in September 2023, the CHMP has issued a positive opinion recommending granting marketing authorisation for zilucoplan as an add-on to standard therapy for the treatment of adult patients with gMG."*

- the second paragraph (on pages 96 and 97 of the Base Prospectus) of the sub-section "(b) The development of the pipeline, including optimising the life cycle of products" in section 6 "Key Strengths and Strategies of the UCB Group"<sup>5</sup> shall be deemed deleted and replaced by the following paragraph:

*"Building on its research and development capacities, new treatment options of the UCB Group were approved over the last years. In 2019, Evenity® (romosozumab) was approved for post fracture osteoporosis (partnered with Amgen) and Nayzilam® (midazolam nasal spray, acquired from Proximagen in 2018) was approved for acute repetitive epileptic seizures. Since 2021, and following the approval by the FDA in October 2023, Bimzelx® (bimekizumab) has been approved by 11 regulatory authorities and is now approved in 40 countries worldwide for the treatment of psoriasis. Additionally, in 2023, Bimzelx® has been approved in the EU and the UK for the treatment of psoriatic arthritis and axial spondyloarthritis. Each product is further described in section 7 "Core Therapeutic Areas". Rystiggo® (rozanolixizumab) and zilucoplan (Zilbrysq®) have been approved for the treatment of gMG in adult patients in the U.S. (respectively in June 2023 and October 2023) and in Japan (in September 2023). In the EU, in September 2023, the CHMP has issued a positive opinion recommending granting marketing authorisation for zilucoplan as an add-on to standard therapy for the treatment of adult patients with gMG. With several new molecular entities, (rozanolixizumab for myelin oligodendrocyte glycoprotein (MOG) antibody disease, dapirolizumab pegol for systemic lupus erythematosus (partnered with Biogen), Staccato® alprazolam for stereotypical prolonged seizures, fenfluramine for cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder, and MT1621 for thymidine kinase 2 deficiency (TK2d) disorder) in the last development phase before regulatory review, or under preparation of submission for regulatory review, the UCB Group is well positioned for continued growth. All these molecules have the potential to be highly differentiated, are long-term patent or data exclusivity protected and could qualify for a good reimbursement position – subject to final product profile and reimbursement. See section 9 "Research and Development" for further details on the current main clinical development projects of the UCB Group. With several different programs and indications, the UCB Group also has a promising preclinical and early clinical development pipeline."*

- the second paragraph (on page 102 of the Base Prospectus) of the sub-section "Bimzelx® (bimekizumab)" in section 7 "Core Therapeutic Areas"<sup>6</sup> shall be deemed deleted and replaced by the following paragraphs:

*"In August 2021, bimekizumab received marketing authorisation in countries of the European Union (EU)/European Economic Area (EEA) and Great Britain for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. In January 2022, bimekizumab received marketing authorisation in Japan for the treatment of plaque psoriasis, generalised pustular psoriasis and psoriatic erythroderma in patients who are not sufficiently responding to existing treatments. In June 2023 and September 2023, bimekizumab received marketing authorisation for the treatment of adults with active psoriatic arthritis (PsA) and adults with active axial spondyloarthritis (axSpA) including non-radiographic axSpA (nr-axSpA) and ankylosing spondylitis (AS), also known as radiographic axSpA, in the EU and the UK, respectively.*

*In May 2022, UCB announced that the FDA has issued a CRL regarding the BLA for bimekizumab for the treatment of adults with moderate to severe plaque psoriasis, stating that the FDA cannot approve the application in its current form. The CRL stated that certain pre-approval inspection observations must be resolved before approval of the application. The observations were addressed,*

and the subsequent resubmission was accepted by FDA in December 2022. In September 2023, UCB announced having received the EIR from the FDA following the pre-license inspection conducted in April 2023 at the Braine-l'Alleud (Belgium) manufacturing facility. The FDA has concluded that this inspection is successfully closed. In October 2023, the FDA approved bimekizumab under the brand name Bimzelx® for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. After this approval, the UCB Group aims to submit supplemental BLA's for PsA, nr-axSpA and hidradenitis suppurativa for review by the FDA.

Further regulatory reviews, including for the use of bimekizumab in hidradenitis suppurativa, are ongoing worldwide.”

- the fourth paragraph (on page 102 of the Base Prospectus) of the sub-section “Bimzelx® (bimekizumab)” in section 7 “Core Therapeutic Areas<sup>6</sup>” shall be deemed deleted;
- the fourth paragraph (on page 106 of the Base Prospectus) of the sub-section “Neurology” in section 9 “Research and Development” shall be deemed deleted and replaced by the following paragraph:

“In 2020, the UCB Group completed the acquisition of Ra Pharmaceuticals, Inc. making it a wholly owned subsidiary of UCB. This acquisition added zilucoplan, a peptide inhibitor of complement component 5 (C5) for the potential treatment of myasthenia gravis (in patients who are anti-acetylcholine receptor (AChR) antibody-positive), a long-term neuromuscular disease, to the UCB Group pipeline. Regulatory applications for zilucoplan as a treatment for generalised myasthenia gravis are underway worldwide. In September 2023, the Japanese MHLW has granted approval for Zilbrysq® (zilucoplan) for the treatment of gMG in adult patients and the CHMP has issued a positive opinion recommending granting marketing authorisation for zilucoplan in the EU as an add-on to standard therapy for the treatment of gMG in adult patients. In October 2023, the FDA approved Zilbrysq® (zilucoplan) for the treatment of gMG in adult patients.”

- the table (on page 110 of the Base Prospectus) under the sub-section “(a) Patents and regulatory exclusivity” in section 12 “Intellectual Property” shall be deemed deleted and replaced as follows:

Marketed Products	Europe	U.S.	Japan
<b>Bimzelx®</b> (bimekizumab)	August 2036 <sup>(1)</sup>	January 2032 <sup>(7)</sup>	January 2037 <sup>(1)</sup>
<b>Briviact®</b> (brivaracetam)	August 2026 <sup>(1)(4)</sup>	February 2026 <sup>(1)(5)</sup>	Not yet authorised
<b>Cimzia®</b> (certolizumab pegol)	October 2024 <sup>(1)</sup>	February 2024 <sup>(1)</sup>	June 2026 <sup>(1)</sup>
<b>Evenity®</b> (romosozumab)	April 2031 <sup>(1)</sup>	April 2033 <sup>(1)</sup>	April 2031 <sup>(1)</sup>
<b>Fintepla®</b> (fenfluramine)	December 2032 <sup>(6)</sup>	December 2027 <sup>(5)(6)</sup>	September 2032 <sup>(6)</sup>
<b>Nayzilam®</b> (midazolam nasal spray)	Not authorised/commercialised	January 2028 <sup>(5)</sup>	Not authorised/commercialised
<b>Neupro®</b> (rotigotine)	December 2030 <sup>(2)</sup>	Expired	March 2024 <sup>(1)</sup>
<b>Rystiggo®</b> (rozanolixizumab)	May 2033 <sup>(8)</sup> Not yet authorised	January 2035 <sup>(8)</sup>	May 2033 <sup>(8)</sup>
<b>Vimpat®</b> (lacosamide)	Expired	Expired	July 2024 <sup>(3)</sup>
<b>Zilbrysq®</b> (zilucoplan)	June 2035 <sup>(9)</sup> Not yet authorised	June 2035 <sup>(9)</sup>	June 2035 <sup>(9)</sup>

- the seventh point of the numbered list (on page 111 of the Base Prospectus) of the sub-section “(a) Patents and regulatory exclusivity” in section 12 “Intellectual Property” shall be deemed deleted and replaced by the following wording:

*“7. Following US market approval, Bimzelx® has become eligible for patent term extension until 2037, although such extension has not been granted yet.”*

- the ninth point of the numbered list (on page 111 of the Base Prospectus) of the sub-section “(a) Patents and regulatory exclusivity” in section 12 “Intellectual Property” shall be deemed deleted and replaced by the following wording:

*“9. Following U.S. market approval, Zilbrysq® has become eligible for patent term extension until 2037 in the U.S. In Japan Zilbrysq® is eligible for patent term extension for the approved indication. Such extensions have not been granted yet and duration in Japan depends on several factors. Following EU market approval, patent protection may be extended for Zilbrysq® until 2038 in the EU.”*

- the fifth paragraph (on page 113 of the Base Prospectus) of the sub-section “Marketing Approval for New Products” in the sub-section “(a) Product approval” in section 13 “Governmental Regulation” shall be deemed deleted and replaced by the following paragraph:

*“In the United States, the FDA is expected to take action on an application for a standard drug within 12 months of submission of the registration dossier. At the end of the review cycle, FDA may approve the application or issue a so called “complete response letter”, which sets out reasons why the application has not been approved and identifies information needed to correct deficiencies. For priority drugs, the expected review time is eight months. Average total review times in the U.S. are 18-21 months. For example, on 13 May 2022, the FDA issued a complete response letter regarding the BLA for bimekizumab for the treatment of adults with moderate to severe plaque psoriasis, stating that the FDA cannot approve the application in its current form. The complete response letter states that certain preapproval inspection observations must be resolved before approval of the application. The observations were addressed and the subsequent resubmission (including the UCB Group’s response to the observations in the CRL as well as, as a standard practice in case of resubmission, additional safety data obtained since the date of the initial submission) was accepted by the FDA in December 2022. In September 2023, UCB announced having received the EIR from the FDA following the pre-license inspection conducted in April 2023 at the Braine-l’Alleud (Belgium) manufacturing facility. The FDA concluded that this inspection is successfully closed. In October 2023, the FDA approved bimekizumab under the brand name Bimzelx® for the treatment of adults with moderate to severe plaque psoriasis.”*

### **3 General**

Save as disclosed in this Supplement N°1, there has been no other significant new factor, material mistake or material inaccuracy relating to the information included in the Base Prospectus since the date of the Base Prospectus.

A copy of this Supplement N°1 is available on the website of the Issuer (<https://www.ucb.com/investors/UCB-financials>).

To the extent that there is an inconsistency between (a) any statement in this Supplement N°1 and (b) any statement in, or incorporated by reference into, the Base Prospectus, the statements in this Supplement N°1 will prevail.