# RECORDATI S.p.A.

# HEADQUARTER

Via Matteo Civitali, 1 20148 Milan, Italy Ph. +39 02 48 787.1 www.recordati.com

# CORPORATE BROCHURE

RECORDATI

# AT THE FOREFRONT OF LIFE-ENHANCING AND LIFE-CHANGING MEDICINES FOR ALMOST 100 YEARS

With its beginnings in a family-run pharmacy in Correggio, Italy in the 1920s, Recordati is now a global pharmaceutical group, listed on the Italian Stock Exchange, with over 4,450 employees.

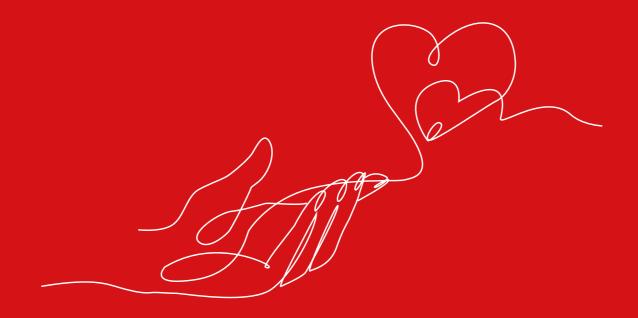
We are a group of like-minded, passionate individuals who go to extraordinary lengths for our partners, customers, investors, and the people across the globe we serve.

We develop and commercialise medicines to serve people living with common diseases, as well as those living with some of the rarest.

At Recordati, our mantra is simple. We've always believed that health, and the opportunity to live life to the fullest, is a right, not a privilege. Whether that is for common diseases or the rarest – we want to give people the opportunity to be the best version of themselves.

This drive will never stop. Together, we will always be reimagining tomorrow – with new ideas, new technologies and new innovations to fight diseases.

# Recordati. Unlocking the full potential of life.



# THE MILESTONES OF A LONG **SUCCESS STORY**



- a treatment for the homozygous familial hypercholesterolemia
- and Acromegaly and to Isturisa® (osilodrostat) for the treatment

- pharmaceutical product approved by the European Commission

- Acquisition of EUSA Pharma (UK) Ltd, a global specialist pharmaceutical company focused on Rare Diseases and niche oncology
- of Eligard® (leuprorelin acetate), for the treatment of hormone-dependent prostate cancer in Europe, Türkiye, Russia and other
- New indication for Carbaglu® 200 mg tablets
- simethicone) in Spain, for gastrointestinal

- Duodart® (dutasteride/tamsulosin) for the treatment of Benign Prostatic Hyperplasia (BPH)
- Carbaglu® receives marketing authorisation



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# CONTINUING OUR GROWTH JOURNEY

SPECIALTY & PRIMARY CARE 2023 REVENUES

**1,313.6** Million Euros

(65.7%)

RARE DISEASES 2023 REVENUES

**714.7** Million Euros

(34.3%)

01. RECORDATI: TODAY AND THE FUTURE

WE ARE CONTINUALLY GROWING, WITH A FOCUS ON DEVELOPING NEW SPECIALTIES, NEW TREATMENTS AND INVESTING IN MEDICAL INNOVATIONS THAT BRING A BRIGHTER FUTURE TO PATIENTS ACROSS THE WORLD.

We are uniquely structured to bring treatment options across Specialty & Primary Care, Consumer Healthcare (CHC), and Rare Diseases.

- We have fully-integrated operations across Research & Development, chemical and finished product manufacturing through to commercialisation and licensing.
- We promote well-being.
- We have a diversified portfolio operating in around 150 countries worldwide.
- We are a partner of choice due to our unique structure.
- We maintain the highest quality and safety standards of our products throughout all their life cycle.
- We manufacture pharmaceutical ingredients to support our supply-chain, whilst also providing to customers worldwide.



We are based in Milan, Italy and have been listed on the Italian Stock Exchange since 1984.

We produce and promote a wide range of innovative products in around 150 countries.

We market a number of specialties generated by our original research.

Our portfolio includes both products for Specialty & Primary Care and treatments for Rare Diseases.



RECORDATI: TODAY AND THE FUTURE



# SPECIALTY & PRIMARY CARE



We have a strong and proven heritage of supporting people living with a wide range of common illnesses that affect large populations day-to-day.

We create value for patients, payers, and physicians across Specialty & Primary Care with both prescription and self-medication treatments, with a focus on cardiovascular, urological and gastrointestinal areas.

We provide treatments globally, with direct presence in Europe and North Africa and have proven experience in supporting access to medicines throughout their lifecycle.

# RARE DISEASES



Of the 7,000 known Rare Diseases, less than 10% have an available treatment option. Since 2007, through our dedicated business unit Recordati Rare Diseases, we've focused on helping the few who suffer from little known conditions.

Our mission is to reduce the impact of rare and devastating diseases by providing urgently needed medicines in key therapeutic areas including:

- Metabolic. •
- Endocrinology. •
- Oncology.

# PHARMACEUTICAL CHEMICALS

We produce various active and intermediate ingredients which, in addition to meeting our own needs, we also sell to third-party pharmaceutical companies.



# **RECORDATI'S JOURNEY INTO THE FUTURE**

THE PROVEN ABILITY FOR **CREATING PROFITABLE** PARTNERSHIPS WITH IMPORTANT PLAYERS IN THE PHARMACEUTICAL SECTOR WILL CONTINUE TO SUPPORT **US IN OUR QUEST TO IDENTIFY NEW OPPORTUNITIES AND FINALIZE NEW LICENCE AGREEMENTS** FOR THE DEVELOPMENT **OF HIGH-VALUE MEDICINAL PRODUCTS**.

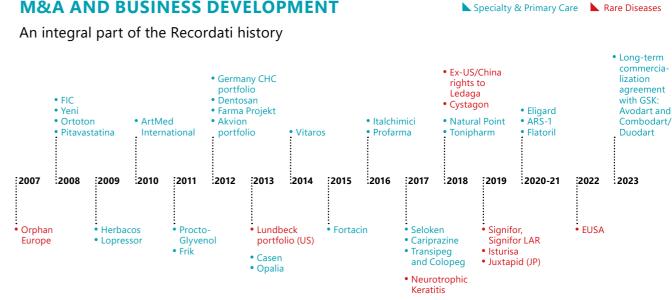
# A WIDE AND DIFFUSED PRESENCE

With operations in all European countries, in Russia and in the C.I.S. countries, in Ukraine, Türkiye and North Africa, in the United States, Canada, Latin America, Japan, Australia, China and South Korea, we continue to strengthen our geographical presence.

We are also increasing our activities in Europe with a new long-term commercialisation agreement with GSK in 2023 for Avodart® (dutasteride) and Combodart®/Duodart® (dutasteride/tamsulosin), whilst continuing to make our products for the treatment of Rare Diseases available worldwide, including in the United States (largest market), Canada, Latin America, Japan, China and the Asia-Pacific regions.



# **M&A AND BUSINESS DEVELOPMENT**



# A STRONGER PRODUCT PORTFOLIO

The launch of innovative new products, the enhancement of our product portfolio with specialties from our own research and development or from targeted licence agreements or specific acquisitions, will boost our growth.

# A CONSTANT INVESTMENT IN **RESEARCH AND INNOVATION**

We are committed to the innovation and marketing of high value-added products. We continuously develop new medicines and believe Research & Development is a fundamental basis for our growth. Dedication and scientific rigor are always behind our

specialties and self-medication products, which are also produced with the highest levels of quality and safety.

# A STRATEGIC PARTNER

We are an ideal partner for the development and marketing of new products in our markets thanks to:

- Our extensive geographical coverage.
- An efficient in-company network of medical representatives and orphan drug specialists.
- Our significant competence in handling regulatory processes.
- Our profound know-how in the handling of highly specialized products.



# 2023, A YEAR OF OUTSTANDING PERFORMANCE



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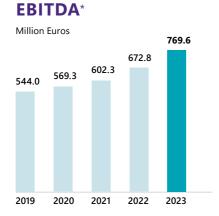


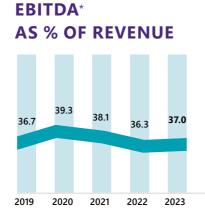




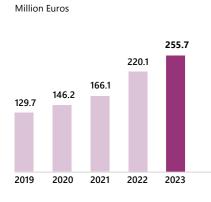
# 02. **RECORDATI'S KEY FIGURES**







# **RESEARCH** & DEVELOPMENT

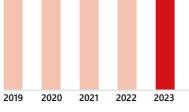


**NET INCOME** 

355.0

Million Euros

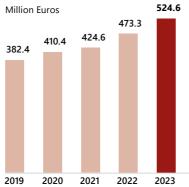
368.9



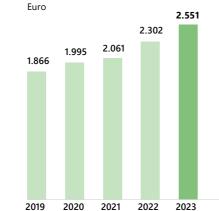
386.0

312.3

# **ADJUSTED**



# **ADJUSTED NET INCOME PER SHARE**



# PHARMACEUTICAL SALES BY THERAPEUTIC AREA

# SPECIALTY & PRIMARY CARE 65.7%

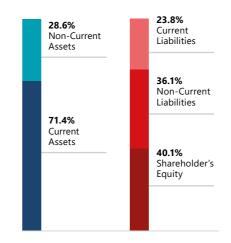


# **GEOGRAPHICAL COMPOSITION OF PHARMACEUTICAL SALES**



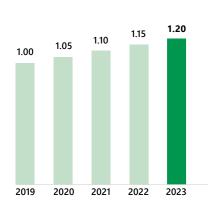
# **BALANCE SHEET**

31st December 2023



# DIVIDEND **PER SHARE**

Euro



# **NET INCOME PER SHARE**

2019

2020

2021

2022

2023





2023 was a year of outstanding performance. A number of new initiatives were pursued for

the our future development.

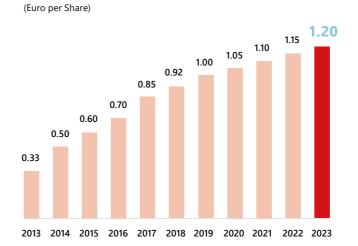
# RARE DISEASES 34.3%

- \* Net income before income taxes, financial income and expenses, depreciation, amortization and write-downs of property, plant and equipment, intangible assets and goodwill, non-recurring items and non-cash charges arising from the allocation of the purchase price of EUSA Pharma to the gross margin of acquired inventory according to IFRS 3.
- \*\* Net income excluding the amortization and write-down of intangible assets (except software) and goodwill, non-recurring items, non-cash charges arising from the allocation of the purchase price of EUSA Pharma to the gross margin of acquired inventory pursuant to IFRS 3, and monetary net gains/losses from hyperinflation (IAS 29), net of tax effects.



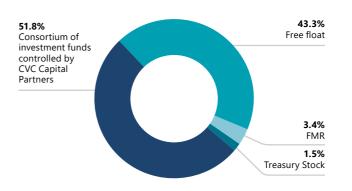
# 03. THE RECORDATI SHARE

DIVIDEND



# **PRINCIPAL SHAREHOLDERS**

31st December 2023





# THE RECORDATI SHARE 31st December 202

Listing	Borsa Italiana, Blue Chip segment, healthcare
ISIN Code	t 0003828271
Licker	Bloomberg REC IM, Reuters RECI.MI
Index	FTSE MIB, FTSE Italia All-Share Health Care Index, FTSE Italia All-Share Pharmaceuticals & Biotechnology Index, FTSE4Good Index Series, STOXX Europe 600, Euro STOXX Health Care, MSCI Indexes
Share Capital	n. 209,125,156 common shares
Nominal value	€ 0.125 per share
EPS (diluted)	€ 1.861
Dividend per share	€ 1.20

THE RECORDATI SHARE

# HEADQUARTERS IN MILAN, ACTIVITIES WORLDWIDE







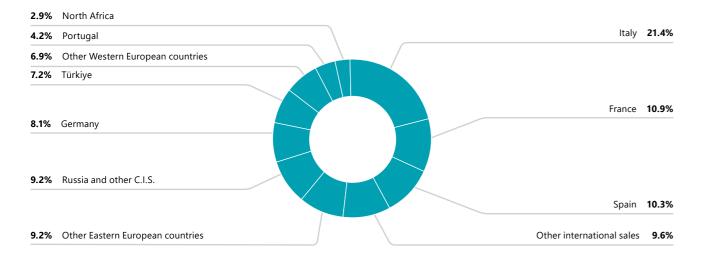
# 04. RECORDATI IN THE WORLD

We are present in around 150 countries with our Specialty & Primary Care products and our treatments for Rare Diseases.

# **SPECIALTY & PRIMARY CARE**

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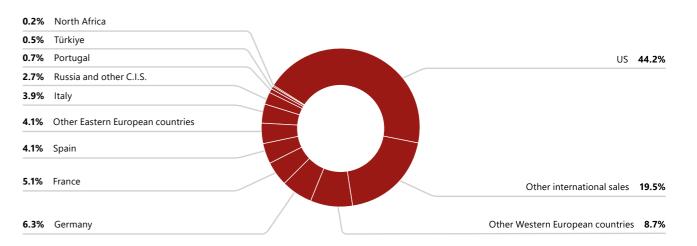
# **GEOGRAPHICAL COMPOSITION OF PHARMACEUTICAL SALES IN 2023**



# **RARE DISEASES**



# **GEOGRAPHICAL COMPOSITION OF PHARMACEUTICAL SALES IN 2023**





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RECORDATI IN THE WORLD

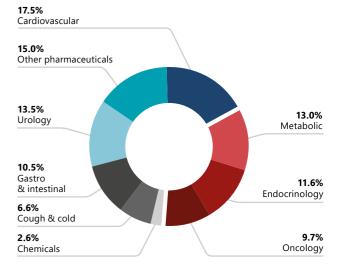
# A TOTAL GOMMITMENT

# 05. SUCCESSFUL ACTIVITIES AND PRODUCTS

Always committed to giving people the opportunity to unlock the full potential of life, we offer a number of innovative and high value-adding pharmaceutical products that constitute a large and qualified product portfolio.

# **BREAKDOWN OF REVENUE 2023**





SUCCESSFUL ACTIVITIES AND PRODUCTS



# SPECIALTY & PRIMARY CARE

WE MAKE MANY MEDICINES AVAILABLE IN VARIOUS THERAPEUTIC AREAS ACROSS EUROPE AND NORTH AFRICA.



# **PRESCRIPTION MEDICINES**

- We have a significant presence in this field and offer established treatments in the areas of cardiovascular, urological and gastrointestinal diseases.
- We market products developed from our own research and by specific licence agreements.

# **CONSUMER HEALTHCARE**

We offer several well-established brands, across a large range of therapeutic areas, such as digestive health, women's health & intimate care, and food supplements.



# MAIN PRESCRIPTION MEDICINES

### CARDIOVASCULAR

ZANIDIP®/CORIFEO®/LERCADIP® (lercanidipine) Antihypertensive

ZANIPRESS®/ZANEXTRA®/LERCAPREL®/ LERCARIL® (lercanidipine + enalapril) Antihypertensive

# SELOKEN®/SELOKEN®ZOK/BETALOK®ZOK

(metoprolol succinate) Angina pectoris, disturbances of cardiac rhythm, hypertension

LOGIMAX® (metoprolol succinate + felodipine) Antihypertensive

LOPRESOR® (metoprolol) Antihypertensive

LIVAZO®/ALIPZA® (pitavastatin) Hypercholesterolaemia

UROLOGY AND URO-ONCOLOGY

ELIGARD® (leuprorelin acetate) Hormone dependent advanced prostate cancer

AVODART® (dutasteride)\* Benign Prostatic Hyperplasia (BPH)

COMBODART®/DUODART® (dutasteride/tamsulosin)\* Benign Prostatic Hyperplasia (BPH)

UROREC®/SILODYX® (silodosin) Benign Prostatic Hyperplasia (BPH)

Trademarks are owned by or licensed to the GSK group of companies. Transition to Recordati of commercialization of Avodart® and Combodart®/Duodart® has been enacted in the following markets: Austria, Belgium, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Poland, Portugal, Spain, Sweden, Switzerland, UK.

# MAIN PRESCRIPTION MEDICINES

# GASTROENTEROLOGY

CITRAFLEET<sup>®</sup> (citric acid) and PHOSPHOSODA<sup>®</sup> (sodium dihydrogen phosphate dihydrate) Bowel evacuants

CASENLAX® (macrogol) and FLEET ENEMA® (monobasic sodium phosphate) Constipation and bowel cleansing

# **COUGH & COLD**

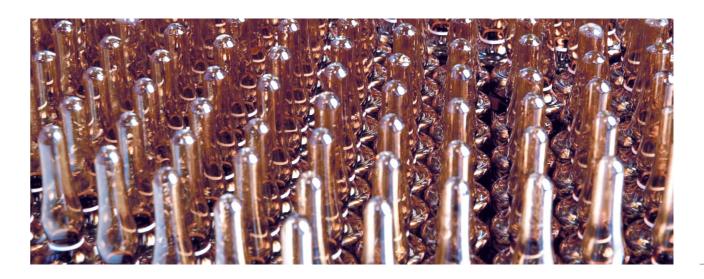
POLYDEXA® (neomycin sulfate) Treatment of ear infections

ISOFRA® (framycetin sulfate) Treatment of nose and throat infections

# OTHER

REAGILA® (cariprazine) Antipsychotic

TERGYNAN<sup>®</sup> (metronidazole) Gynecological infections





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MAIN CONSUMER HEALTHCARE BRANDS

PROCTO-GLYVENOL® (tribenoside+ lidocaine) Treatment of haemorrhoids

MAGNESIO SUPREMO® (magnesium carbonate) Food supplement

LOMEXIN®/FALVIN®/GYNOXIN® (fenticonazole) Antifungal

REUFLOR<sup>®</sup>, REUTERI<sup>®</sup>, CASENBIOTIC<sup>®</sup>, BIORALSUERO<sup>®</sup> (lactobacillus reuteri protectis) Probiotics

GINKOR<sup>®</sup> (ginkgo biloba) Venotonics

HEXASPRAY® (biclotymol) Antibacterial for sore throat

ALOVEX®/ALOCLAIR® (hyaluronic acid) Oral care - mouth sores

EUMILL® (natural moisturizers/hyaluronic acid) Eye care

# LOCAL BRANDS

Our portfolio also consists of a number of local brands, promoted by our subsidiaries who have established a strong presence in their respective markets.

# ITALY

In Italy, we are committed to the development and commercialisation of medicines as well as CHC brands.

Regarding prescription medicines, in addition to our consolidated presence in the cardiometabolic area, we offer a unique and complete portfolio for the treatment of urological diseases (BPH, prostate cancer, sexual dysfunction), treatments for respiratory and allergic diseases with a specific focus on paediatric patients, as well as treatments in the gastrointestinal and analgesia areas. We also have a broad offering of self-medications with a focus on food supplements, oral hygiene, eye care, and gastrointestinal remedies.

Historic brands include Alovex<sup>®</sup>, Proctolyn<sup>®</sup>, Eumill<sup>®</sup> - which includes the successful commercialisation of the recently launched Eumill<sup>®</sup> Allergy - Dentosan<sup>®</sup>, Imidazyl<sup>®</sup>.

Among food supplements, Magnesio Supremo® represents a successful example of our company's commitment to innovation, offering a wide range of new products to meet consumers' needs. In addition, Reuflor®, a leading probiotic in the paediatric area, is leveraging its expertise to expand into the adult population through new line extensions, aiming to become the microbiota reference across all age groups.

# FRANCE

Recordati is a prominent name in the French market, known for its diverse range of prescription medicines targeting key therapeutic areas such as cardiology, urology, and addiction. Additionally, our self-medication line includes well-established brands with a long-standing and solid performance in markets such as cough & cold, with Hexaspray® for sore throat and Exomuc®



for cough; Venotonics, with Ginkor<sup>®</sup> for heavy legs and hemorrhoids; and oral care, with the Alodont<sup>®</sup> range.

# SPAIN

Recordati in Spain has an extensive and substantial portfolio of medicines, in the area of gastroenterology, - where our brands for bowel cleansing and oral rehydration are undisputed market leaders - paediatrics, gynecology, urology and psychiatry.

In 2023, we also successfully launched a prescription medicine for the treatment of opioid-induced constipation in adult patients, as well as Muvagyn Vaginal Probiotic®, the first vaginal probiotic approved as a drug in the Spanish market.



# GERMANY

Recordati is well-established in Germany with a strong and growing presence in key therapeutic areas such as urology, orthopedics, and CNS. We offer a wide range of therapeutic solutions to healthcare professionals and their patients, and we are one of the most well-known German pharmaceutical companies in the field of orthopedics.

In addition to our prescription brands, our portfolio contains well-known self-medication brands that offer solutions for cough & cold treatment, wound and skin care, and sleeping disorders.

# RUSSIA, OTHER C.I.S. COUNTRIES AND UKRAINE

Our operations in Russia, Ukraine, the other C.I.S. markets and Central Asia successfully market medicines for otorhinolaryngological and vaginal infections, holding a leading position in their markets. The portfolio also includes popular self-medication brands, such as the well-known supplements Alfavit® and Qudesan®, OTC drugs like the oral antibacterials Hexaspray® and Hexalyse®, and the intestinal absorbent White Carbo®.

# TÜRKIYE

Recordati markets a diversified portfolio, well appreciated by practitioners, in the fields of urology, uro-oncology, cardiology, surgery, gynecology and physical medicine and rehabilitation.

# NORTH AFRICA

In North Africa and in Tunisia, we are one of the largest local pharmaceutical companies marketing branded generics, with leading products in cardiology, dermatology, gastrointestinal and respiratory therapeutic areas.

# OTHER COUNTRIES

We have strengthened our presence in Switzerland with headquarters in Zug, and operations also in Austria, Portugal, UK, Ireland, Greece, Sweden, Denmark, Norway, Finland, Iceland, Benelux, Czech Republic and Slovakia, Romania, Bulgaria, Poland and in the Baltic States.

# **RARE DISEASES**

# WE OPERATE IN THE RARE DISEASES SEGMENT WORLDWIDE THROUGH RECORDATI RARE DISEASES.



We research, develop, produce and market drugs for the treatment of a number of Rare Diseases. These are marketed directly in Europe, the Middle East, United States, Canada, Russia, Australia, Japan, China, South Korea and in some Latin American countries, and through selected partners in a number of other countries, covering more than 100 countries worldwide.

Highly-trained specialists and scientific support teams collaborate constantly with researchers, medical practitioners and health care professionals, with patient groups and families and with regulators to treat and improve the quality of life of people suffering from these diseases worldwide.

Thanks to a unique distribution system and to specialists dedicated to the promotion and distribution of these products, we are able to reach patients in their home countries.



# METABOLIC

Metabolic diseases can be caused by several genetic defects, causing abnormal accumulation of metabolites and/or defects in others. These inborn errors of metabolism affect neonates, children and adults. Since it was founded, Recordati Rare Diseases has been focussing on rare metabolic conditions, many of which can be difficult to diagnose and can be life-threatening.

# ENDOCRINOLOGY

Your endocrine system is comprised of a network of glands in your body that produces and secretes hormones. Hormones are chemical messengers that carry information and instructions from one part of the body to another, that control or regulate many bodily functions, including growth and development, metabolism, reproduction, and mood, among others.

Many diseases may impact how the varied endocrine glands work in the body, resulting in disordered hormone production and secretion, which may underlie burdensome and, in some cases, life-threatening syndromes and conditions if left untreated. Some of these diseases are rare and only affect a few people globally. These conditions are often difficult to diagnose due to lack of awareness of varied signs and symptoms, which can result in delayed diagnosis and/or undertreatment. Recordati Rare Diseases is focused on targeting endocrine conditions associated with high unmet need and burden, and is committed to providing better treatment options and solutions for patients, with a particular focus on improving the lives of those suffering from pituitary and adrenal gland dysfunctions or related conditions, which can impact growth and metabolism imbalances.



#ThisCushing is a global initiative developed by Recordati Rare Diseases in collaboration with an award-winning photographer and internationally-recognised experts in the field of pituitary endocrinological diseases.

thisiscushing.com

# ONCOLOGY

The human body is made up of trillions of cells. When these cells become old or damaged, they die, and need to be replaced with new ones.

Normally, human cells grow and multiply through cell division to create these new cells as they are needed. This cell division and cell growth is self-regulated and self-

SUCCESSFUL ACTIVITIES AND PRODUCTS



Cancerous tumours can start anywhere and spread to other parts of the body; these are called malignant tumours. Tumours can also be benign, meaning they grow but they don't spread through the body and tend not to create problems. Recordati Rare Diseases focuses on some of the rarest cancers, in both adult and paediatric indications, where very few treatment options exist.

# MAIN DRUGS FOR THE TREATMENT OF RARE DISEASES

# METABOLIC AND DERMATO-ONCOLOGY

# CARBAGLU® (carglumic acid)

Treatment of hyperammonemia due to N-AcetylGlutamate Synthase deficiency (NAGS deficiency) and some organic acidaemias (isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia)

# NORMOSANG®/PANHEMATIN®

(human hemin) Treatment of acute attacks of hepatic porphyria

CYSTADROPS® (cysteamine hydrochloride) Treatment of the ocular manifestations of Cystinosis

CYSTAGON® (cysteamine bitartrate) Treatment of nephropathic Cystinosis

CYSTADANE® (betaine anhydrous) Treatment of homocystinuria

LEDAGA® (chlormethine hydrochloride) Treatment of Mycosis Fungoides (MF), T-Cell Cutaneous Lymphoma (CTCL)

JUXTAPID® (lomitapide) Treatment of Homozygous Familial Hypercholesterolemia (HoFH)

# COSMEGEN® (dactinomycin for injection)

Treatment of rare cancers: Wilms tumour, infantile rhabdomyosarcoma, Ewing sarcoma and metastatic nonseminomatous testicular cancer

PEDEA®/NEOPROFEN® (ibuprofene IV) Treatment of Patent Ductus Arteriosus (PDA)

### ENDOCRINOLOGY

# ISTURISA® (osilodrostat)

Treatment of Cushing's disease (United States) and Cushing's syndrome (European Union, Switzerland)

SIGNIFOR<sup>®</sup> and SIGNIFOR<sup>®</sup> LAR (pasireotide) Treatment of Cushing's disease and Acromegaly

# ONCOLOGY

# QARZIBA® (dinutuximab beta, anti-GD2 monoclonal antibody)

Treatment of high-risk neuroblastoma patients aged 12 months and above, who achieved at least a partial response at the chemotherapeutical induction, followed by myeloablative therapy and stem cell transplantation

# **SYLVANT**®

(siltuximab, anti-IL-6 monoclonal antibody) Treatment of idiopathic Multicentric Castleman's Disease (iMCD) in adults

FOTIVDA® (tivozanib, oral highly selective small molecule Tyrosine Kinase Inhibitor (TKI) of Vascular Endothelial Growth Factor (VEGF) receptors 1, 2 and 3) Treatment of first-line of advanced renal cell carcinoma

# CAPHOSOL<sup>®</sup> (supersaturated calcium phosphate rinse)

Medical device on prescription for the treatment of oral mucositis due to chemo and radio therapy

# **INTERNATIONAL AWARDS**

We have an established track record in the field of orphan drug development. The establishment of scientific networks and engaging with patient organisations together with our efforts to reduce the impact of disease on the lives of patients are the reasons that have contributed to winning of prestigious international awards and that push us to continue in this direction every day.

Our Rare Diseases teams have received recognition for their work to raise awareness of Cushing's syndrome, with the #THISCUSHING campaign winning accolades at the International Content Marketing Awards.



These awards demonstrate the continued success of the campaign, which previously won the award for 'Patient-Centricity' at the Pharmaceutical Market Excellence Awards (PMEA) 2023, with the PharmaTimes naming Stefano de Socio from the campaign team as 2023 "Marketer of the Year".



The campaign was presented with the Silver Award for Best Specialist Campaign, and the Bronze Award for the Best Use of Imagery.



The results obtained in improving the diagnosis and management of Rare Diseases

were recognised by EURORDIS (European Organization for Rare Diseases) with an award that was presented to us during the celebration of the 2014 Rare Disease Day.

漱 NORD

Our commitment to making our products available to patients suffering from Rare Diseases was recognised by the National Organization for Rare Disorders (NORD) in the United States with its "Corporate Award". This important award was granted in 2011 in recognition of the introduction into the United States of Carbaglu®, the first specific treatment approved by the FDA (Food and Drug Administration) for NAGS deficiency, a very rare inherited metabolic disease.



# RECORDATI RARE DISEASES FONDATION D'ENTREPRISE

We are committed to supporting families affected by these diseases through the distribution of specific scientific knowledge within the medical community. The Foundation organises training on Rare Diseases to improve diagnosis and spread currently available knowledge on therapeutic options. The organisation promotes scientific sharing of experience and knowledge between centre of expertise and specialists across the globe.

Every year, the Foundation proposes tailored face-to-face courses that aim to provide physicians, worldwide, with clinically useful and the most up-to-date information concerning current knowledge and recommendations for care. The Foundation has delivered over 70 courses to over 3,000 health care professionals since its creation.

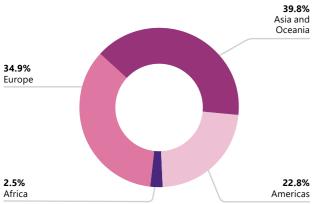
# PHARMACEUTICAL CHEMICALS

# WE USE A BROAD RANGE OF TECHNOLOGIES TO PRODUCE COMPETITIVELY, MAINTAINING THE HIGHEST QUALITY STANDARDS.

Our pharmaceutical chemicals business focuses on:

- Satisfying the requirements of the pharmaceuticals business.
- Striving for maximum product quality.
- Strengthening our presence in highly regulated markets (the United States, Europe and Japan).
- Safety of production processes.
- Protection of the environment.
- Health and safety in the workplace.

# GEOGRAPHICAL COMPOSITION OF PHARMACEUTICAL CHEMICALS SALES IN 2023









# 06. PRODUCTION SITES

OUR PRODUCTION SITES ARE EQUIPPED WITH STATE-OF-THE-ART INSTALLATIONS AND OUR RESEARCH LABORATORIES ARE FITTED WITH THE LATEST EQUIPMENT.

All plants operate in full compliance with environmental protection regulations and in compliance with the cGMP (current Good Manufacturing Practices).

# PHARMACEUTICAL MANUFACTURING PLANTS

PACKAGING AND DISTRIBUTION CENTRE dedicated to products for Rare Diseases

# **2** PHARMAC



# PHARMACEUTICAL CHEMICAL PLANTS



# PHARMACEUTICAL MANUFACTURING PLANTS

# ITALY

The Milan site occupies a surface area of around 5,000 sq.m., built vertically over a number of floors for a total of 21,000 sq.m. and produces around 67 million units per year. It is specialized in the manufacture and packaging of solid oral forms, liquids, and semi-solids for topical use. Recordati has undertaken a restructuring project in certain production areas, including the installation of a new blister packaging line, which has been added to the 5 already in place. The new line has been operational since the beginning of 2023 increasing significantly the production capacity.

# FRANCE

The plant at Saint Victor covers a surface of 6,750 sq.m. and produces 30 million units per year. It is specialized in the production and packaging of liquid, solid oral and spray formulations.

# SPAIN

The Spanish plant is situated near Zaragoza, covering a surface area of 7,100 sq.m. and producing around 24 million units a year. It is specialised in the production and packaging of solid and liquid oral and topical formulations. In particular, the plant manufactures a line of





gastroenterological products; furthermore a packaging-line was installed and approved few years ago for the packaging of tablets in bottles. In relation to our environmental commitment, the project to install a photovoltaic solar panel system with the capacity to generate up to 185 kWh of electricity for self-consumption has been successfully completed; in 2023, a new project for increasing the capacity up to 470 kWh within the next two years has been started.

# TÜRKIYE

The Turkish site is in Çerkezköy, Türkiye, built on 45,000 sq.m. of land, and covering approximately 11,300 sq.m.. It currently produces around 70 million units per year of solid oral and liquid formulations and products for topical use, of which 25% are for other pharmaceutical companies. The project for the installation of a new liquid line started in 2023 and will significantly increase the production capacity from 2025.

The Çerkezköy plant, in addition to the Turkish market, is authorized to produce medicines for the European Union, Azerbaijan, Libya, Kenya, the Russian Federation, Kyrgyzstan and Kazakhstan. In relation to our environmental commitment, the project to install a photovoltaic solar panel system with

the capacity to generate up to 476 kWh of electricity for self-consumption has already started in 2023 and will be completed in 2024.

# TUNISIA

The site is situated in Ariana, near Tunis. It covers an area of around 9,100 sq.m. and produces around 18 million units a year of liquid, semi-solid and oral solid forms for the local market and for some of the countries in the Arabian Peninsula. Certified GMP compliant, the manufacturing site was approved by the Gulf Health Council and the Saudi Food and Drug Authority.

During 2023 a project to expand the existing warehouse began. In relation to our environmental commitment, the project to install a photovoltaic solar panel system with the capacity to generate up to 1200 kWh of electricity for self-consumption has already started in 2023 and will be completed in 2025.

# SWITZERLAND

The facility, acquired in 2022 through agreements with Novartis for the acquisition of the rights to Signifor®, are located in the north-western part of Switzerland, Basel (within the Novartis Campus). The plant covers an area of approx. 1,500 sq.m. Since the successful qualification in 2012 and GMP



certification by Swissmedic, it is used for commercial production of Signifor® LAR Bulk – a specialised drug product used for the treatment of Acromegaly and Cushing's Disease.

# CZECH REPUBLIC

The plant, situated in Pardubice, produces creams, gels and ointments for a total of two million units per year.

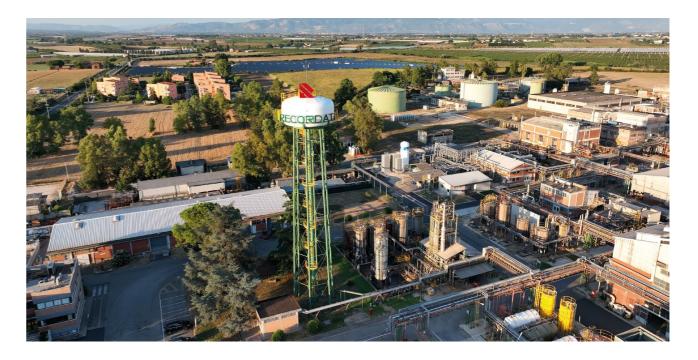


# PACKAGING AND DISTRIBUTION CENTER DEDICATED TO PRODUCTS FOR RARE DISEASES

A packaging and distribution site in Nanterre, near Paris, exclusively for products for the treatment of rare diseases is in operation. It occupies a surface area of 1,600 sq.m. and is entirely dedicated to the secondary packaging, storage and shipping of Rare Diseases products.

The site delivers, upon short notice, more than 27,000 orders annually to more than 60 countries worldwide thanks to its highly qualified staff and a modern GDP (Good Distribution Practices) certified logistics platform.

# PHARMACEUTICAL CHEMICAL PLANTS



# CAMPOVERDE DI APRILIA (ITALY)

- This plant is one of the most important producers in the world of verapamil HCl, phenytoin, papaverine HCl, dimenhydrinate, tribenoside and manidipine.
- In addition to supplying the active ingredients for our proprietary specialties, it is also an established independent producer of active ingredients and intermediates for the pharmaceutical industry internationally.
- The United States has become and continues to be the primary outlet market for its production.
- The site extends over approximately 375,000 sq.m., with an operational area of 35,000 sq.m., and produces approximately 600 MT/year of finished goods with approximately 4,000 MT/year of semifinished goods handled internally.
- A vast range of competencies in the field of organic synthesis allow us to quickly and effectively study new processes from research right through to final industrialisation.

- The Research & Development laboratories are fitted with the latest equipment such as a high containment HP-API pharmaceutical isolator (glove box) and a micro reactor for the development of new continuous production processes. An extremely versatile pilot plant equipped for the small-scale production of active ingredients, in accordance with cGMP (current Good Manufacturing Practices).
- Investments have been made to enhance the technological and production capacity of the plant, which – over the last 10 years – has resulted in the installation of 25 new reactors, a latest generation three stage distillation unit for high-temperature unstable liquids, two thin film evaporators, four filters for the isolation of solid products, three centrifuges and an anti-acid dryer.
- At the Campoverde di Aprilia site, in order to promote an approach aimed at the circular economy that reduces waste and the use of natural resources, various initiatives to recover and re-use chemical raw materials used in production processes

were analysed. Specifically, with the new contribution of the recovery of palladium from the flavoxate process, since 2022, the Group has been able to recover at least 55% of the palladium used in all processes. At the Campoverde plant, Recordati has also started a three-year project aimed to the installation of a 10 MW photovoltaic power generation facility and to the downsizing of the methane-based cogeneration unit currently operated. These measures will provide a significant reduction of the Recordati Group carbon footprint.

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 We operate in compliance with current Good Manufacturing Practice (cGMP) and is regularly inspected by national and international authorities such as AIFA (Agenzia Italiana del Farmaco), the FDA (Food and Drug Administration), ANVISA (the Brazilian agency), PMDA (the Japanese Ministry of Health), and the KFDA (Korean Food and Drug Administration). The plant's environmental management system has been certified according to the UNI EN ISO 14001:2015 standards by Det Norske Veritas Italia (DNV), an internationally accredited body, and is inspected on an annual basis.

# CORK (IRELAND)

- A dedicated plant built in Cork in Ireland guarantees adequate and continuous supplies of the active ingredient lercanidipine, an important original Recordati drug.
- Automated process control systems ensure constant high-quality and production.
- The site operates in accordance with GMP (Good Manufacturing Practices) and covers a surface area of around 43,000 sq.m., with an installed area of 8,300 sq.m.
- It received the 2012 National Energy Efficiency Award promoted by the sustainable Energy Authority of Ireland (SEAI) and in 2013 received the European Energy Efficiency Award promoted by the Chemical European Federation Industry Council (CEFIC).
- In 2016 the site was extended, the two buildings housing administration and the quality control laboratories were expanded. Photovoltaic panels for the generation of electricity were installed in 2022 for a total area of 1,100 sq.m. providing 10% of the site electricity demand.



# COMMITMENT, RIGOUR, CAPABILITY

# 07. RESEARCH & DEVELOPMENT AT RECORDATI

WE CONTINUOUSLY DEVELOP NEW SPECIALTIES ORIGINATING EITHER INTERNALLY OR ACQUIRED THROUGH DEVELOPMENT AGREEMENTS WITH OTHER PHARMACEUTICAL COMPANIES AND RESEARCH INSTITUTES.

Commitment, scientific rigour, capability and highly-specialized personnel allow us to develop new treatments and build an innovative product pipeline.



(includes depreciation relating to the purchase of new products)

+**16.2%** 

in Research & Development compared to 2022



# **PRODUCT DEVELOPMENT PIPELINE DEVELOPMENT STATUS** Phase II enrolment completed. Topline results expected in mid 2024 Filing in EU in 2023 Approved in the US, Europe, Switzerland, Australia, Israel and Japan. Filed in other countries. Work on-going to support potential label extension to Cushing's Syndrome in US Phase II enrolment initiated in 2024 Approved in the US and Europe. Development of new formulations in the US and EU Approved in China na Approved in the EU, UK, Australia, Brazil, China Hong Kong, Israel, Russia and Taiwan. The Group is working on addressing the FDA's comments from the Type C meeting in November 2023 and is planning further interactions in H1 2024 with the FDA. The dossier is under review in Switzerland Approved in over 40 countries including EU, US and China. Potential indication expansion evaluation ongoing

NAME	INDICATION
REC 0559*	Neurotrophic keratitis
REC 0545	Acute decompensation episodes in Maple Syrup Urine Disease (MSUD or leucinosis
ISTURISA®	Endogenous Cushing's Syndrome/ Cushing's Disease
PASIREOTIDE	Post-Bariatric Hypoglycaemia
CYSTADROPS®	Corneal cystine crystal deposits in patients with Cystinosis
CARBAGLU®	Hyperammonemia due to NAGS deficiency and to the main organic acidemias
QARZIBA®	Treatment of high-risk neuroblastom patients who achieved at least a partial response at the chemotherapeutical induction, followed by myeloablative therapy and stem cell transplantation, and of patients with relapsed or refractory neuroblastoma
SYLVANT®	Treatment of idiopathic Multicentric Castleman Disease (iMCD)

\* In-licensed from Mimetech.

RESEARCH & DEVELOPMENT AT RECORDATI





# AN IDEAL PARTNER

# 08. PARTNERING WITH RECORDATI

THANKS TO OUR ABILITY TO DEVELOP SUCCESSFUL RELATIONSHIPS, WE HAVE IMPLEMENTED A STRATEGY OF PARTNERING WITH COMPANIES WITH HIGH STANDARDS IN THE PHARMACEUTICAL SEGMENT.

We are a partner of choice due to our unique structure, bringing treatment options across Specialty & Primary Care, Consumer Healthcare, and Rare Diseases.

We have fully-integrated operations across Research & Development, chemical and finished product manufacturing through to commercialisation and licensing.

# STRONG CAPABILITIES & GLOBAL REACH

- Fully-integrated company with successful track record in developing, registering, manufacturing and commercialising medicinal products.
- Global footprint with direct presence in more than 50 countries and partnerships in remaining markets.

We have a strong track record in generating value through partnerships with other pharmaceutical companies, whether they are local or global players.

We are committed to generating further growth through mutually-beneficial R&D collaborations, licence agreements and acquisitions.

# FOCUS

- A "local brilliance" commercial approach to each and every market, ensuring growth opportunities are maximised.
- Growth driven by focus on few strategic products that add value to patients, payers and physicians.
- We treat each partnered product as if it were our own.

# BUSINESS DEVELOPMENT TRACK RECORD

- Creative and flexible deal structures to share value with partners.
- Long-lasting strategic partnerships.
- More than 35 transactions completed in the last 15 years.

# OUR BUSINESS DEVELOPMENT STRATEGY

WE ARE LOOKING FOR IN-LICENSING AND ACQUISITION OPPORTUNITIES AND TECHNOLOGIES TO STRENGTHEN OUR PIPELINE AND PORTFOLIO AND FOSTER INNOVATION IN THE FOLLOWING AREAS:

# 

# **RARE DISEASES**

Innovative products from Clinical Proof of Concept programmes to marketed products, in all therapeutic areas and with a particular focus on:

- Rare endocrinology.
- Rare metabolism.
- Rare oncology.

# SPECIALTY & PRIMARY CARE

Innovative products from Phase 2b clinical stage to marketed products in:

- Cardio-metabolism.
- Urology/ uro-oncology.
- Gastrointestinal.

Established and marketed products across any therapeutic area.

# CONSUMER HEALTHCARE

Well established and marketed CHC products mainly in categories such as:

- Digestive health.
- Women's health & intimate care.
- Respiratory health.



LICENSOR	TRADEMARK
✿tolmar	Eligard®
APEIRON BIOLOGICS	Qarziba®
AVEO ONCOLOGY an LG Chem company	Fotivda®
Simple Pharma	Vitaros®/Virirec®
🚯 Gedeon Richter	Reagila®
HELSINN Building quality canter care together	Ledaga®
KISSEI	Urorec®/Silodyx™/Silosin®
Kowa	Livazo®/Alipza®
plethora SOLUTIONS	Fortacin™
Widas <sup>®</sup> Pharma Trust. Expertise. Added Value.	Reselip®
Takeda	Peptazol®
AMRYT	Juxtapid®
SHIONOGI	Rizmoic®
GSK *	Avodart <sup>®</sup> and Combodart <sup>®</sup> Duodart <sup>®</sup>

\* Trademarks are owned by or licensed to the GSK group of companies

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# SELECTED PARTNERSHIPS

THERAPEUTIC AREA
Uro-oncology
Rare oncology
Rare oncology
Urology
CNS
Onco-dermatology
Urology
Cardiometabolism
Urology
Cardiometabolism
Gastrointestinal
Rare metabolism
Gastrointestinal
Urology

PARTNERING WITH RECORDATI

# 100%

of electricity purchased for our plants and annexed offices comes from renewable sources, in countries where this is possible<sup>1</sup>

# **1ST SUSTAINABILITY-LINKED** LOAN SIGNED

the credit facility is linked to two ESG KPIs: environmental protection (renewable energy installed power capacity) and responsible sourcing (ESG audits of suppliers)

# **MORE THAN 14,000 TREES PLANTED**

in the three years from 2021-2023, with a commitment to reach 24,000 by 2024, corresponding to approximately five trees per employee

# **APPROXIMATELY 1.100**

patients affected by rare diseases supported through the Patient Assistance Program, the Co-Pay Assistance Program and similar programmes



# **#THISCUSHING AWARENESS CAMPAIGN WINS AWARD**

Recordati Rare Diseases received the 2023 PMEA Patient-Centricity Award

# 11TH ARRIGO Prize Recordati RECORDATI PRIZE

international award promoting scientific research into rare diseases

1. This figure excludes Tunisia, where renewable energy is not available. For more information, please refer to the 2023 Consolidated Non-Financial Statemen 2. Including monetary and product donations measured at market value

# SUSTAINABLE AND RESPONSIBLE GROWTH



in donations to the community



# FIRST PEOPLE ENGAGEMENT SURVEY COMPLETED

with an excellent 80% participation rate



# SECOND D&I SURVEY COMPLETED

involving approximately 300 senior managers



# 56%

of women hired in 2023 out of total new hires, with the commitment to increase the percentage of women in Top and Senior management positions



# 94%

of employees hired on permanent contracts



# 115

suppliers audited in the two years 2022-2023 on ESG topics via de audits conducted by an independent third party



# **OVER 190**

supplier audits conducted by the pharmaceutical and chemical-pharmaceutical division, mainly on product quality and safety

# **OUR SUSTAINABILITY PLAN**



# 09. **SUSTAINABILITY**

# THE VALUES THAT HAVE ALWAYS **INSPIRED AND GUIDED US.**

We have a long history of entrepreneurial passion, a strong reputation and a desire to continue growing and creating value in an ethical, enduring, and sustainable way, all while respecting the laws and regulations that apply in the countries in which we operate, protecting people and the environment, and supplying safe, high-quality products.

# MAIN ESG INDICES AND RATINGS





\* The use by the Recordati group of any MSCI ESG Research LLC or its affiliates ("MSCI") data, and the use of MSCI logos, trademarks, service marks or index names herein, do not constitute a sponsorship, endorsement, recommendation, or promotion of Recordati Group by MSCI, MSCI services and data are the property of MSCI or its information providers, and are provided 'as-is' and without warranty. MSCI names and logos are trademarks or service marks of MSCI.

Our Sustainability Plan is the tool used to share our future trajectory with our stakeholders: it represents an expression of the ambitions of our group and the commitments we wish to prioritise in order to promote sustainable and responsible growth.

# ٥ľ٥ RESPONSIBLE ETHICS SOURCING AND INTEGRITY Integrity is our founding value Our ambition founding value and we lead We want to build by example. The principles of honesty and transparency towards our Shareholders and Stakeholders guide our daily actions relationships based on transparency and trust, sharing our values with suppliers and strategic partners We are committed to constantly promoting respect for ethical, environmental and social aspects along the entire value chain. 7 OLEAN ENERGY 8 BECENT WORK AND ECONOMIC ERROYTH 9 HOUSTRY, INNOVATION AND STRATEGY 12 RESPONSELE CONSUMPTION AND PRODUCTION 13 ACTION Image: Construction of the control of













# **SUPPORT FOR LOCAL COMMUNITIES**

We believe that contributing to the well-being of the community and dedicating part of our resources to acts of solidarity are not merely the fulfilment of company obligations or professional duty, but rather a moral imperative.

# WULTIPLE COMPANY VOLUNTEERING PROJECTS

involving our people were promoted

# € **4.8** million

in donations to the community (including monetary and product donations measured at market value)

# approximately 14,000 planted trees

in the years 2021-2023 (more than 11,000 in Italy and 3,000 in Tunisia) and planting of a further 10,000 is planned in Türkiye by 2024. In total, in the years 2021-2024, approximately 24,000 trees will have been planted, corresponding to five trees per employee





# THE **INTERNATIONAL PRIZE** FOR SCIENTIFIC RESEARCH **ARRIGO RECORDATI**



Established in 2000 in memory of Arrigo Recordati, the Prize is an international award which aims to promote scientific research:

- An award of € 100,000 is granted to a scientist in recognition for outstanding work in an innovative research project.
- The winner is chosen by a Jury composed of experts with high international standing.

The 2024 edition was dedicated to the promotion and recognition of excellence in research on paediatric oncology, specifically neuroblastoma.

At the 5th Annual Meeting of the European Society for Paediatric Oncology (SIOP) held in Milan, the 11th edition of the International Prize for Scientific Research Arrigo Recordati was awarded to Dr. Adam Durbin, M.D., PhD., Assistant Member at the Department of Oncology at St. Jude Children's Research Hospital in Memphis, Tennessee, USA, for providing new potential therapeutic strategies for children with neuroblastoma.



# Adam D. Durbin, MD, PhD

Assistant Member, Division of Molecular Oncology Department of Oncology St. Jude Children's Research Hospital, Memphis, Tennessee, USA.

SUSTAINABILITY



# **LEGAL ENTITIES AND OFFICES**



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RECORDATI S.P.A. INNOVA PHARMA S.P.A. ITALCHIMICI S.P.A. NATURAL POINT S.R.L. RECORDATI RARE DISEASES ITALY S.R.L. Headquarter and Registered Office: Via M. Civitali, 1 20148 Milan (Italy) Ph. +39 02 48787.1

**Operational Office:** Via Roncaglia, 12 20146 Milan (Italy)

www.recordati.com

Specialty & Primary Care: Ph. +39 02 48787.1

Rare Diseases: Ph. +39 02 48787.173

Pharmaceutical Manufacturing Plant: Via M. Civitali, 1 20148 Milan (Italy) Ph. +39 02 48787.1

Pharmaceutical Chemical Plant: Via Mediana Cisterna, 4 04011 Campoverde di Aprilia, LT (Italy) Ph. +39 06 92900010

#### ARGENTINA

RECORDATI ARGENTINA S.R.L.

Registered Office: Suipacha 1111 - 11º piso (C1008AAW) Buenos Aires (Argentina)

#### AUSTRALIA

RECORDATI RARE DISEASES AUSTRALIA PTY LTD. Registered Office: Suite 1802, Level 18, 233 Castlereagh Street NSW 2000 Sydney (Australia) Ph. +61 (0) 408 061403 Email: RRDAustraliainfo@recordati.com

# AUSTRIA

#### RECORDATI AUSTRIA GMBH Registered Office: c/o Next Pharma Logistiscs Julius Raab-Straße 26, A-2203 Großebersdorf (Austria) Ph: +43 2279 51018-0

# BENELUX

RECORDATI BV / S.R.L Registered Office: Avenue du Bourgmestre Demunter, 5, Boite 4 1090 Jette (Belgium) Ph: +32 2 461.01.36 Email: infobenelux@recordati.com

RECORDATI NETHERLANDS B.V.

Registered Office: Beechavenue, 54 1119PW Schiphol-Rijk (The Netherlands)

#### BRAZIL

#### RECORDATI RARE DISEASES COMÉRCIO DE MEDICAMENTOS LTDA Registered Office: Barueri, Estado de São Paulo, na Avenida Piraíba, 355, 2º andar, sala 06, Centro Comercial Jubran, CEP 06460-121 (Brazil)

Branch Registered Office: Cidade de São Paulo, estado de São Paulo na Rua Surubim, nº 504, conjunto 31 Edifício Berrini Park, Cidade Monções, CEP 04571-050 (Brazil)

#### BULGARIA

# **RECORDATI BULGARIA LTD.** Registered Office:

84 "Al. Stamboliiski" Blvd. Floor 8, Office No. 44 1303 Sofia (Bulgaria) Ph. +359 2 829 39 37 Email: Penkova.d@recordati.com

**Trade Representation Office:** 84, "Al. Stamboliyski" Blvd. Floor 8, Office No. 44 1303 Sofia (Bulgaria)

#### CANADA

#### RECORDATI RARE DISEASES CANADA INC. Registered Office: 333 Bay Street, Suite 2400

M5H 2T6 Toronto, ON (Canada) Email: infocanada@recordati.com

Operational Office: 3080 Yonge Street, Suite 6060 M4N 3N1 Toronto, ON (Canada)

#### **CHINA**

#### RECORDATI (BEIJING) PHARMACEUTICAL CO., LTD.

Registered Office: Unit 03, 05, 1T01, Office 26, 26th Floor, No. 81, Jianguo Road Chaoyang District, Beijing (China)

# COLOMBIA

#### RECORDATI RARE DISEASES COLOMBIA S.A.S Registered Office: Carrera 7 N° 127, 48 Oficina 1202, Edificio 128, Centro Empresarial Bogotá D.C. (Colombia) Ph. +57 1 6472780

Email: RRDColombiainfo@recordati.com

# CZECH REPUBLIC AND SLOVAKIA

HERBACOS RECORDATI S.R.O. Registered Office: Štrossova 239, 530 03 Pardubice (Czech Republic) Ph. +420 227 200 722 Email: recordati@recordati.cz

#### RECORDATI SK S.R.O Registered Office: Vavrinecká 5 831 52 Bratislava (Slovakia)

Pharmaceutical Manufacturing Plant: Štrossova 239 530 03 Pardubice (Czech Republic) Ph. +420 466 614 055 Email: recordati@recordati.cz

DENMARK

# EUSA PHARMA (DENMARK) APS

Registered Office: c/o Crowe Horwath Rygårds Allé 104 2900 Hellerup (Denmark) Ph. +44 (0) 3305001210

# FRANCE

**BOUCHARA-RECORDATI S.A.S** FIC MÉDICAL SARL (with representative offices in several C.I.S. countries) LABORATOIRES BOUCHARA **RECORDATI S.A.S RECORDATI RARE DISEASES** S.A.R.L TONIPHARM S A S Registered Office: Immeuble "Le Wilson 70, avenue du Général De Gaulle 92800 Puteaux (France) Ph. +33 1 45191000 Fmail<sup>.</sup> RRDFranceinfo@recordati.com

Pharmaceutical Manufacturing Plant: Parc Mécatronic 03410 Saint Victor (France) Ph. +33 4 70037900

Packaging and Distribution Center (dedicated to products for Rare Diseases): Eco River Parc, 30 Rue des Peupliers 92752 Nanterre (France) Ph. +33 1 70 82 44 31

# GERMANY

Registered Office: Eberhard-Finckh-Str. 55 89075 Ulm (Germany) Ph. +49 731 7047.0

#### RECORDATI RARE DISEASES GERMANY GMBH

Registered Office: Eberhard-Finckh-Str. 55 89075 Ulm (Germany) Ph. +49 731 140 554 0 Email:

RRDGermanyinfo@recordati.com

# GREECE

RECORDATI HELLAS PHARMACEUTICALS S.A.

Registered Office: 7, Zoodochou Pigis Str. 15231 K. Chalandri Atene (Greece) Ph. +30 210 6773822

#### IRELAND

RECORDATI IRELAND LTD. Registered Office: Raheens East

Ringaskiddy, Co. Cork P43 KD30 (Ireland) Ph. +353 21 437 94 00

JAPAN RECORDATI RARE DISEASES JAPAN K.K. Registered Office: 4-8-18, Akasaka Minato-ku, Tokyo (Japan) Ph. +81 3 4510 2910 Email: RRDJapaninfo@recordati.com

KOREA

# RECORDATI KOREA, CO., LTD.

Registered Office: DongHee Building, 4th Fl. 302 Gangnamdae-ro, Gangnam-gu 06236 Seoul (Korea)

#### MIDDLE EAST

RECORDATI RARE DISEASES MIDDLE EAST FZ-LLC Registered Office: Dubai Healthcare City

Building 25, Unit 205-206, P.O. Box 505075 Dubai (UAE) Ph. +971 4 363 5454 Email: RRDMiddleeastinfo@recordati.com

# RECORDATI RARE DISEASES

Registered Office: Building 8E, Office 402, DAFZA, P.O. Box: 505075 Dubai (UAE)

### RECORDATI RARE DISEASES MENA RHQ

Registered Office: Riyadh (Saudi Arabia)

# MEXICO

RECORDATI RARE DISEASES S.A. DE C.V. Registered Office:

Avenida Ejercito Nacional 418-307 Col. Polanco V Sección 11560 Miguel Hidalgo, Ciudad de México (Mexico) Email: RRDMexicoinfo@recordati.com

# Operational Office:

IZA Torre Prisma Av. Insurgentes Sur 1647 Floor 4 Office 421 Col. San José Insurgentes 03900 Delegación Benito Juárez, Ciudad de México (Mexico) Ph. +525526140975

#### POLAND

RECORDATI POLSKA SP. Z O.O. Registered Office: al. Armii Ludowej 26 00-609 Warsaw (Poland) Ph. +48 22 206 84 50

# PORTUGAL

JABA RECORDATI S.A. CASEN RECORDATI PORTUGAL UNIPESSOAL L.D.A. BONAFARMA - PRODUTOS FARMACÊUTICOS S.A. JABAFARMA - PRODUTOS FARMACÊUTICOS S.A. Registered Office: Av. Jacques Delors

Ed. Inovação 1.2, Piso 0 Taguspark 2740 122 Porto Salvo (Portugal) Ph. +351 21 4329.500

#### EUSA PHARMA (UK) LTD. -SUCURSAL EM PORTUGAL

Registered Office: Rua Braamcamp, n. 6 – 1° Esq. Lisboa (Portugal) Ph.+351 (0) 308801554

## ROMANIA

**RECORDATI ROMANIA S.R.L.** Registered Office:

92-96 Izvor street, Office B, 4th floor, Rooms 2-8, 5th District Bucarest (Romania) Ph. +40 21 667 17 41 - 2 **RUSSIA AND C.I.S.** 

# RUSFIC LLC 000 ACCENT LTD.

Registered Office: Krasnopresnenskaya Naberezhnaya 12 Entrance 7, floor 6, premises 2 123610, Moscow (Russian Federation) Email: info@rusfic.com Email: RRDRussiainfo@recordati.com

#### SPAIN

CASEN RECORDATI S.L. RECORDATI RARE DISEASES SPAIN S.L. EUSA PHARMA IBERIA S.L.

Registered Office: Autovia de Logroño, km. 13,300 50180 Utebo, Zaragoza (Spain) Ph. + 34 97 646 26 26

#### Operational Office: Vía de las Dos Castillas, 33 3° planta Ática, Edificio 7 28224 Pozuelo de Alarcòn, Madrid (Spain) Ph. +34 91 351 88 00 Ph. +34 91 659 15 50

Pharmaceutical Manufacturing Plant: Autovia de Logroño, km. 13,300 50180 Utebo, Zaragoza (Spain) Ph. + 34 97 646 26 26

### SWEDEN

RECORDATI AB. Registered Office:

Jan Stenbecks Torg 17, 2 tr 16440 Kista (Sweden) Ph. +46 8 545 80 230 Email: InfoNordic@recordati.com

#### **SWITZERLAND**

# **RECORDATI AG**

Pharmaceutical

Lindenstrasse, 8

Manufacturing Plant

6340 Baar (Switzerland)

Ph. +41 41 769.1000

Registered Office: Lindenstrasse, 8 6340 Baar (Switzerland) Ph. +41 41 769.1000 Email: info@recordati.ch

#### RECORDATI AG, RARE DISEASES BRANCH

Registered Office: Uferstrasse, 90 4057 Basel (Switzerland) Ph. + 41 61 205 61 00 Email: info.rarediseases.ch@recordati.com

# EUSA PHARMA (CH) GMBH

Registered Office: C/O Curator & Horwath AG Zweigniederlassung Zug Industriestrasse 7 6300 Zug (Switzerland) Ph. +41 (0) 800001415

# TUNISIA

# OPALIA RECORDATI S.A.R.L.

Registered Office: 27 Avenue De La Livre Sterling Les Berges du Lac 2 1053 Tunis (Tunisia) Ph. +216 70 5559 070-064 Email: communication@opalia.com.tn

# OPALIA PHARMA S.A.

Registered Office and Pharmaceutical Manufacturing Plant: Zone Industrielle de Kalaat El Andalous, Lot 3 à 8 - 2022 Ariana (Tunisia)

# TÜRKIYE

### RECORDATI ÍLAÇ SANAYI VE TICARET A.S.

Registered Office and Manufacturing Plant: Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi Atatürk Caddesi No:36 Kapaklı 59510 Tekirdağ Istambul (Türkiye)

Administrative Office: Maslak Mah. Sümer Sok. No: 4 Maslak Office Building Istanbul (Türkiye) Ph. +90 212 401 91 00

# Pharmaceutical

Manufacturing Plant: Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi Atatürk Caddesi No:36 Kapaklı 59510 Tekirdağ Istambul (Türkiye) Ph. +90 282 999 16 00

#### RECOFARMA ILAÇ VE HAMMADDELERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Maslak Mahallesi Sümer Sk. Kar Plaza Apt. No: 4/21 Sarıyer/Istanbul (Türkiye)

# UKRAINE

# **RECORDATI UKRAINE LLC**

Registered Office: 40, Hlybochytska Str. 04050 Kyiv (Ukraine) Ph. +380 44 351 18 63

### **UNITED KINGDOM**

# RECORDATI PHARMACEUTICALS LTD.

Registered Office: Breakspear Park Hemel Hempstead HP2 4TZ (United Kingdom) Ph. +44 1 49 1576 336 Email: customerservice@recordati.com

### EUSA PHARMA (UK) LTD.

Registered Office: Breakspear Park Hemel Hempstead HP2 4TZ (United Kingdom) Ph.+44 (0) 330 500 1140

#### RECORDATI RARE DISEASES UK LTD.

Registered Office: Greengarth, Thicket Grove, Maidenhead Berkshire, SL6 4LW (United Kingdom) Email: infoRRDUK@recordati.com

# **Operational Office**

Breakspear Park Hemel Hempstead HP2 4TZ (United Kingdom) Ph. +44 1 49 1576 336 Email: customerservice@recordati.co.uk

# **UNITED STATES**

# RECORDATI RARE DISEASES INC.

Registered Office: c/o the Prentice – Hall Corporation System, Inc., 2711 Centerville Road, Suite 400, Wilmington, County of New Castle 19801 Delaware (USA) Email: info@recordatirarediseases.com

nfo@recordatirarediseases.co

# Operational Office:

440 Rte 22 E, Suite 205 Bridgewater 08807 New Jersey (USA)

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