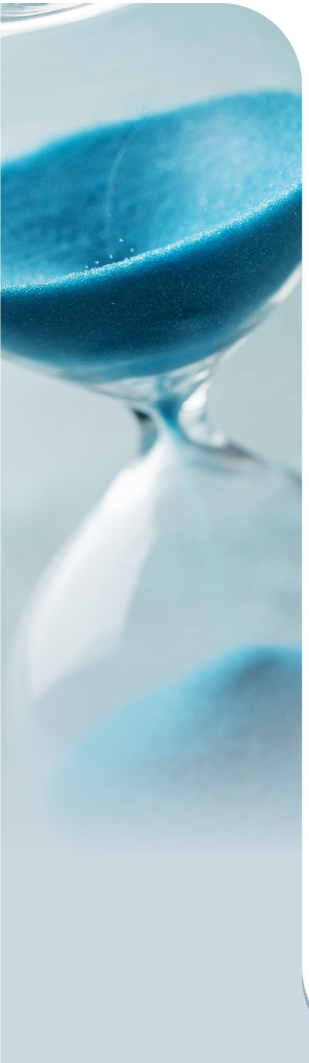

MENARINI
MENARINI
group
COMPANY PROFILE
6th March 2024
CORPORATE PRESENTATION - NOT FOR PROMOTION

Menarini was
founded in 1886.

In 1915 its
headquarters were
established
in **Florence.**



Milestones

Since 1992, the Menarini Group has reinvested all profits in its growth

1886

MENARINI FOUNDATION

1964

INTERNATIONAL PRESENCE

The internationalization of Menarini begins with the opening of **Laboratorios Menarini in Spain**, followed on by **Greece, Portugal, Central America** and **France.**

1978

RESEARCH & DEVELOPMENT

Menarini's Research & Development department opened and patents on pharmaceuticals were introduced.

1992

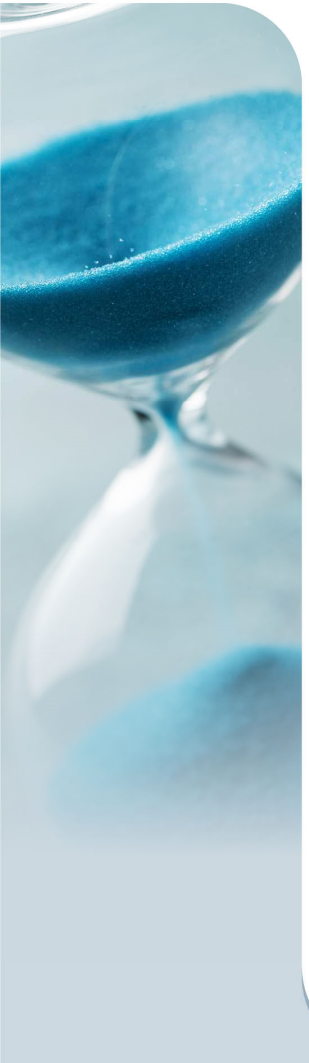
CENTRAL AND EASTERN EUROPE

Menarini acquires ex-GDR company **Berlin-Chemie** thanks to which it makes its entry into **Germany** and Central and Eastern Europe.

2003

MENARINI BIOTECH

Opening of Menarini Biotech, specialised in the research, development and manufacturing of **biotech pharmaceuticals**, from the lab to the patient.



Milestones

2011

ASIA PACIFIC

Menarini makes its entry into Asia Pacific thanks to the acquisition of a company based in **Singapore** and present in **13 countries** throughout the region, from China to Australia.

2013 2016

SILICON BIOSYSTEMS

Acquisition of Silicon Biosystems, a start-up of innovative technologies for liquid biopsies.

CELLSEARCH

Acquisition of Cell Search, an FDA approved technology in the field of **circulating tumor cells.**

2020

U.S.A.

Menarini makes its entrance into the USA through to the acquisition of **Stemline Therapeutics**, biopharmaceutical company publicly listed on NASDAQ, and their product **Tagraxofusp**, the only FDA approved therapy available for BPDCN, thus strengthening Menarini's presence in oncology.

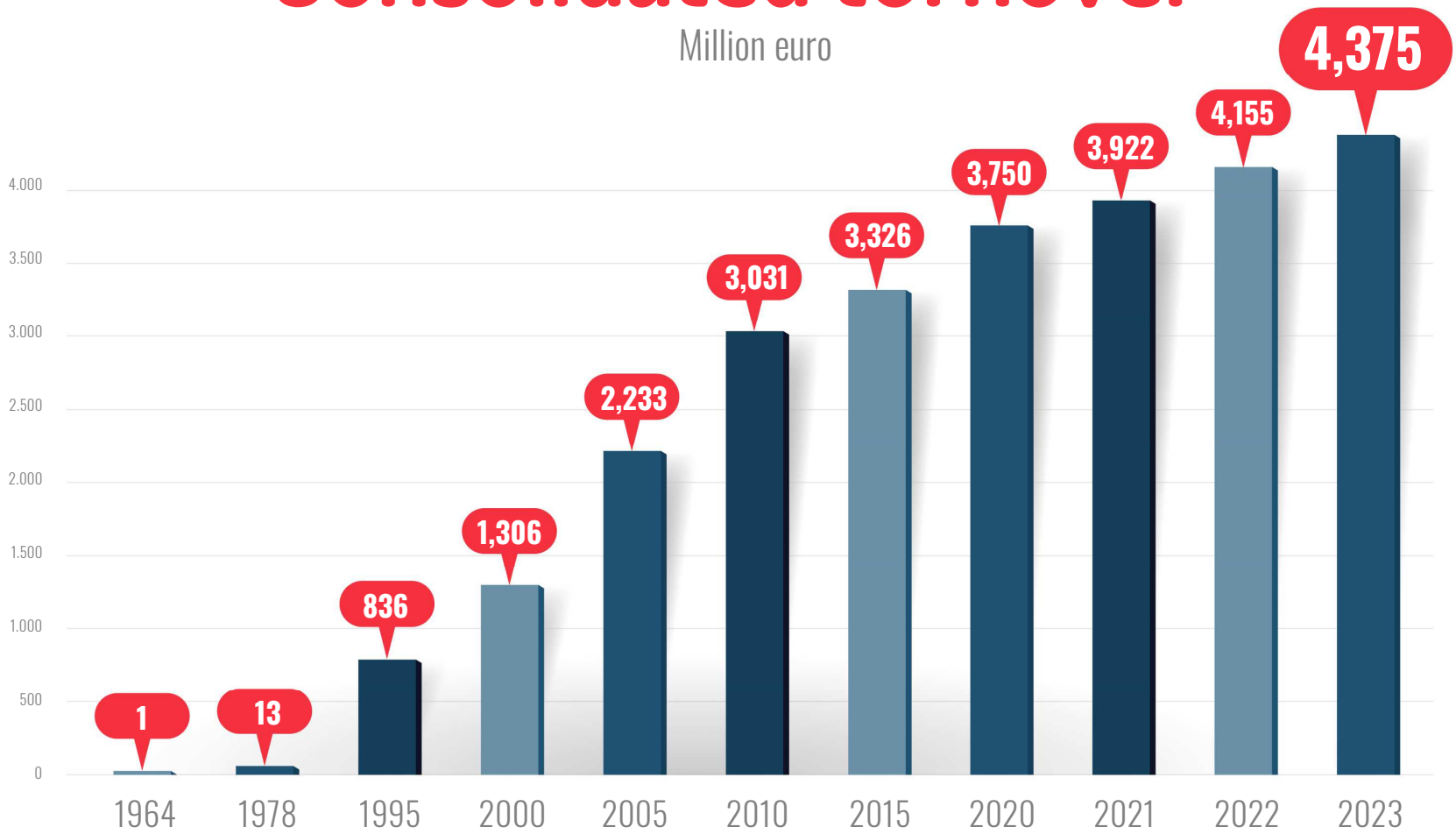
2023

FDA&EMA

U.S. FDA and EU (EMA) approve **Elacestrant** as the first oral treatment for patients with ER+/HER2-, ESR1-mutated advanced or metastatic breast cancer.

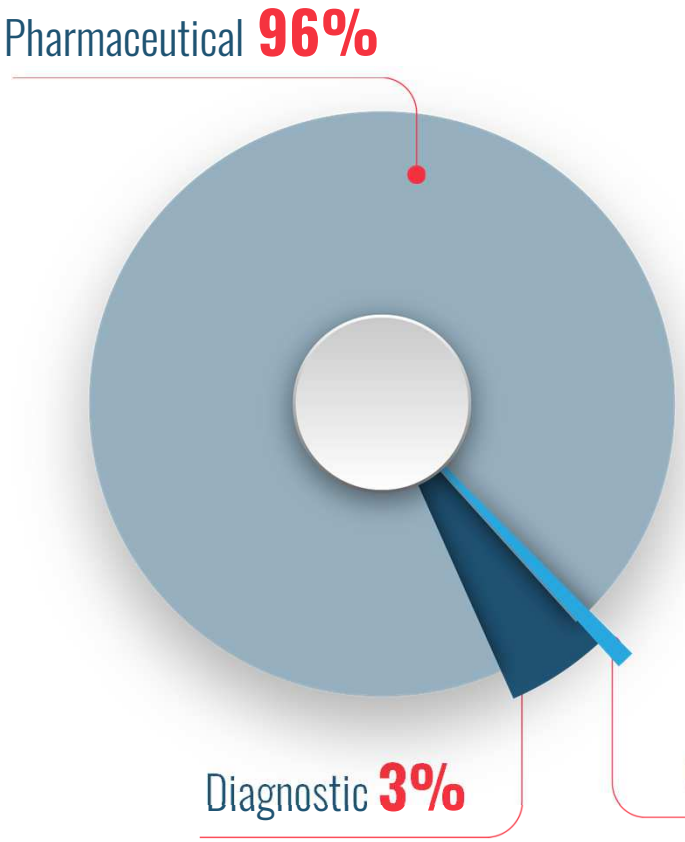
Consolidated turnover

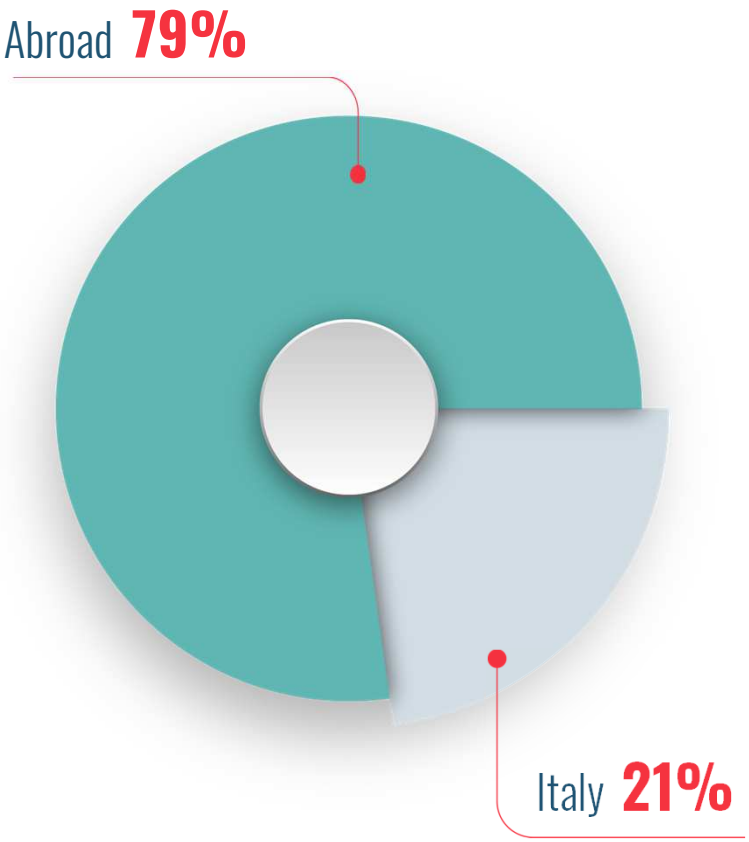
Million euro



Source: internal data.

Consolidated turnover



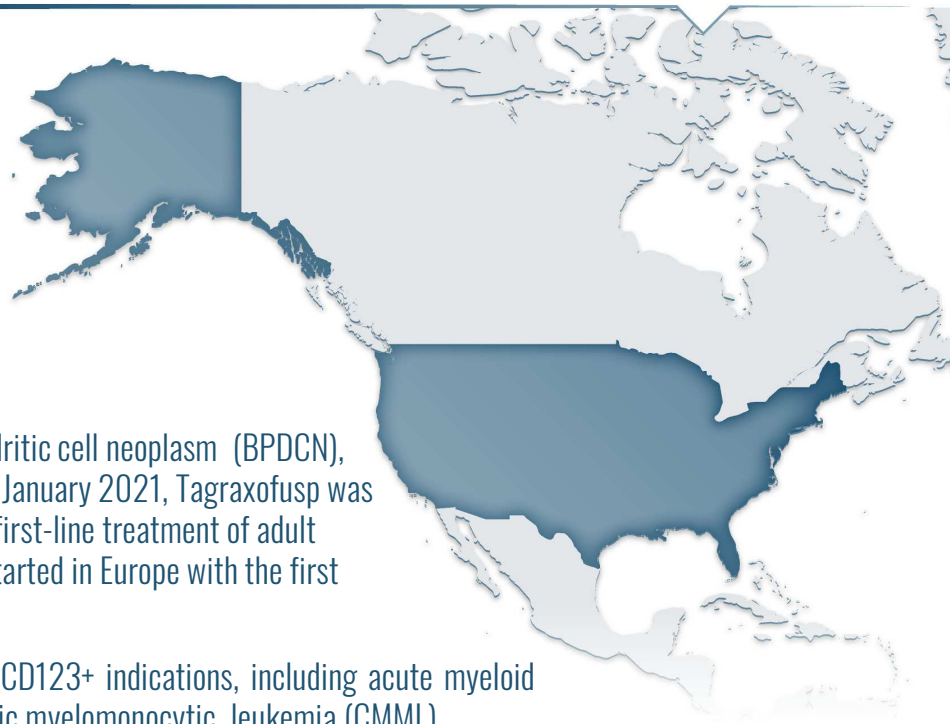


Source: internal data.

Menarini in the WORLD

Present in **140 countries** worldwide (with its affiliates, distributors and franchises).

U.S.A.



Stemline

acquisition June 2020

Tagraxofusp

- For the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), commercially available in the US. In Europe, in January 2021, Tagraxofusp was approved by the EMA, as monotherapy for the first-line treatment of adult patients with BPDCN and commercialization started in Europe with the first launch in Germany in July 2021.
- Tagraxofusp is also in clinical trials in other CD123+ indications, including acute myeloid leukemia (AML), myelofibrosis (MF) and chronic myelomonocytic leukemia (CMML).

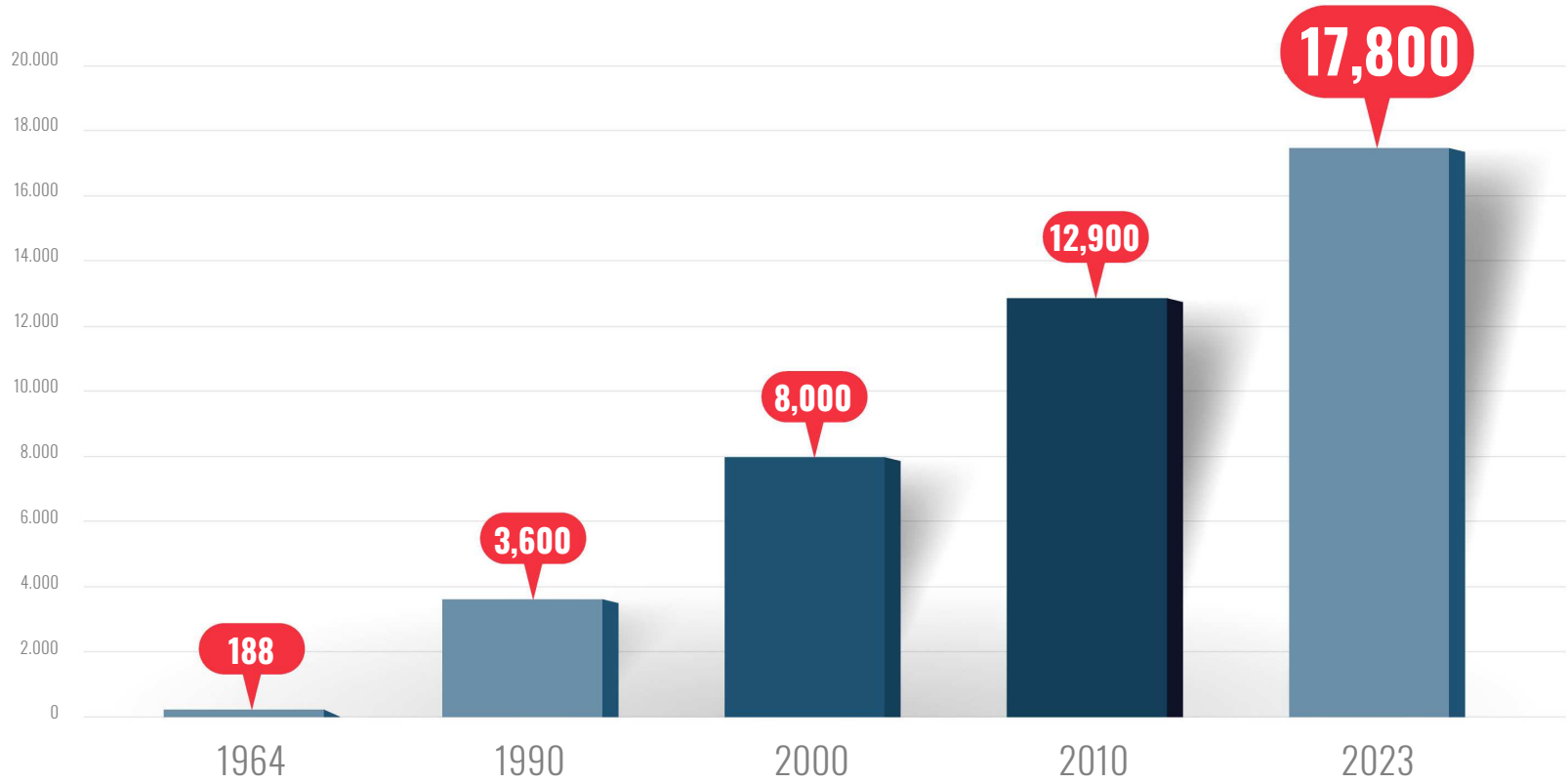
Elacestrant

For the treatment of postmenopausal women or adult men with ER+/ HER2-, ESR1-mutated advanced or metastatic breast cancer. Elacestrant, in 2023, was approved: by the US FDA in January 2023; by the EMA (Europe) in September, followed by the Norwegian Medicine Agency in Norway and the Icelandic Medicines Agency (IMA) in Iceland; by the Ministry of Health (MOH) in the United Arab Emirates (UAE) and by SFDA (Saudi Food & Drug Authority) in Kuwait; by the MHRA in the United Kingdom in December.

Additional studies of elacestrant in combination with other drugs and monotherapy have been initiated to provide further treatment options to patients with breast cancer.

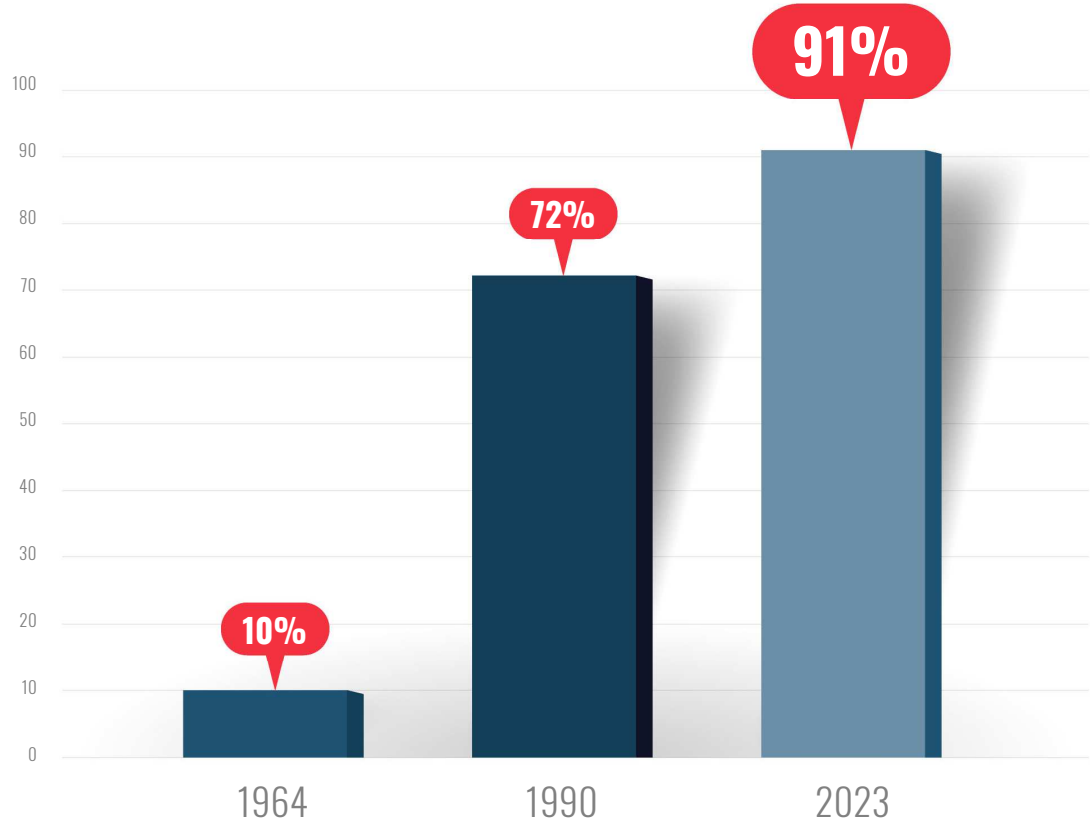
Location: New York, U.S.A.

Number of employees



Source: internal data.

Employees % of graduates and technicians



18 manufacturing plants

EUROPE is the Group's heart of production

In 2023 **609 million packs** were produced at these sites

Italy	Pisa (2 plants), Florence (2 plants) Pomezia*, L'Aquila, Lomagna (Lecco), Casaletto Lodigiano (Lodi)
Spain	Barcelona
Germany	Berlin (2 plants), Dresden

Plants dedicated to the **production for local markets** are located in Central America (Guatemala City), Ireland (Shannon), Turkey (Istanbul), Russia (Kaluga) and Indonesia (Jakarta).

U.S.A. (Philadelphia - Huntingdon Valley): **diagnostic production**

*Biotech manufacturing with development and production processes also for third parties.

9 Research & Development centers

*Pomezia.

Research & Development Projects ONCOLOGY

COMPOUND	DRUG CLASS (TARGET)	INDICATION	DEVELOPMENT STAGE
Elacestrant°	SERD (ER)	Monotherapy: ER+/HER2- Metastatic Breast Cancer	**EMA and FDA: approved**
Elacestrant	SERD (ER)	Monotherapy: CDK4/6 Inhibitor-naïve ER+/HER2- Metastatic Breast Cancer (ELCIN trial)	**Phase II**
Elacestrant	SERD (ER)	Combination therapy: ER+/HER2- Metastatic Breast Cancer (ELEVATE trial)	**Phase II**
Elacestrant	SERD (ER)	Combination therapy: ER+/HER2- Breast Cancer with brain metastasis (ELECTRA trial)	**Phase II**
Tagraxofusp	TB (CD123)	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)	**EMA and FDA: approved**
Tagraxofusp	TB (CD123)	Chronic myelomonocytic leukemia (CMML)	**Phase II**
Tagraxofusp	TB (CD123)	Myelofibrosis (MF)	**Phase II**
Tagraxofusp	TB (CD123)	Acute Myeloid Leukemia (AML)	**Phase II**
SL-701	IT (IL-13Rα2, EphA2, Survivin)	Recurrent Glioblastoma	**Phase II**
MEN1703	SME (PIM/FLT3i)	Relapsed/refractory Diffuse Large B-cell Lymphoma (DLBCL)	**Phase II**
MEN1611	SME (PI3Ki)	Colorectal cancer	**Phase II**
MEN1611	SME (PI3Ki)	Breast cancer	**Phase II**
MEN1309	ADC (Anti-CD205)	Solid tumors	**Phase Ib**
MEN2312	KAT6i	Breast Cancer/Solid and Heme Tumors	**Phase I**
Selinexor°°	SME (XPO1i)	Multiple Myeloma	**EMA and FDA: approved**

°https://www.menarini.com/en-us/news/news-detail/european-commission-approves-menarini-groups-orserdu174-elacestrant-for-the-treatment-of-patients-with-er-her2-locally-advanced-or-metastatic-breast-cancer-with-an-activating-esr1-mutation
°°https://www.menarini.com/it-it/news/dettaglio-news/karyopharm-and-menarini-group-receive-full-marketing-authorisation-from-the-european-commission-for-nexpovio174-selinexor-for-the-treatment-of-patients-with-multiple-myeloma-after-at-least-one-prior-t

TB, Targeted Biologic: ; SERD, Selective Estrogen Receptor Degrader: IT, Immunotherapy: SME, Small Molecule Entity: ADC, Antibody Drug Conjugate.

Research & Development Projects CARDIO-METABOLIC

COMPOUND	DRUG CLASS	INDICATION	DEVELOPMENT STAGE
Obicetrapib	Cholesteryl ester transfer protein (CETP) inhibitor	Lipid Lowering agent administered to patients previously treated with statins Prevention of Major Adverse CardioVascular events	**Phase III**
Obicetrapib+Ezetimibe	Cholesteryl ester transfer protein (CETP) inhibitor + Niemann-Pick C1-like 1 (NPC1L1) protein inhibitor	Lipid Lowering agent administered to patients previously treated with statins	**Phase III**

https://www.menarini.com/en-us/news/news-detail/newamsterdam-pharma-and-the-menarini-group-sign-licensing-deal-to-commercialize-obicetrapib-in-europe

Research & Development Projects ANTI-INFECTIVES

COMPOUND	DRUG CLASS	INDICATION	DEVELOPMENT STAGE
Meropenem + Vaborbactam	Carbapenem + β-lactamase inhibitor	Complicated urinary tract infections, Complicated Intra abdominal infections, Hospital acquired pneumonia, Ventilator associated pneumonia and Bacteremia	**EMA, FDA and Thailand: approved**
Delafloxacin	Anionic fluoroquinolone	Acute Bacterial Skin and Skin Structure – ABSSSI Community Acquired Bacterial Pneumonia - CABP	**EMA and FDA: approved**
Oritavancin	Semisynthetic glycopeptide	Acute Bacterial Skin and Skin Structure - ABSSSI	**EMA and FDA: approved**
Oritavancin (new formulation)	Semisynthetic glycopeptide	Acute Bacterial Skin and Skin Structure - ABSSSI	**EMA and FDA: approved**
Cefepime + Taniborbactam	beta-lactam + β-lactamase inhibitor	Complicated urinary tract and intra abdominal infections, Hospital-acquired bacterial pneumonia and Ventilator-associated bacterial pneumonia	**Phase III**

Menarini For People: our social responsibility projects

Wheelchair basketball

Volpi Rosse Menarini and Menarini Joventut

When sport can help break down barriers and foster inclusion and independence

A pediatricians' network

Help up 15.000 "sentinel doctors" recognise child abuse

Together with Red Cross

Contributions to support populations in emergency

Menarini Forest

15.000 trees planted in several countries all over the world

Standing by children in difficulty

Healthcare, nutrition and education for children from economically disadvantaged families

Donations of medicines

To support those in need and promote better health for all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