



**MENARINI**  
*group*



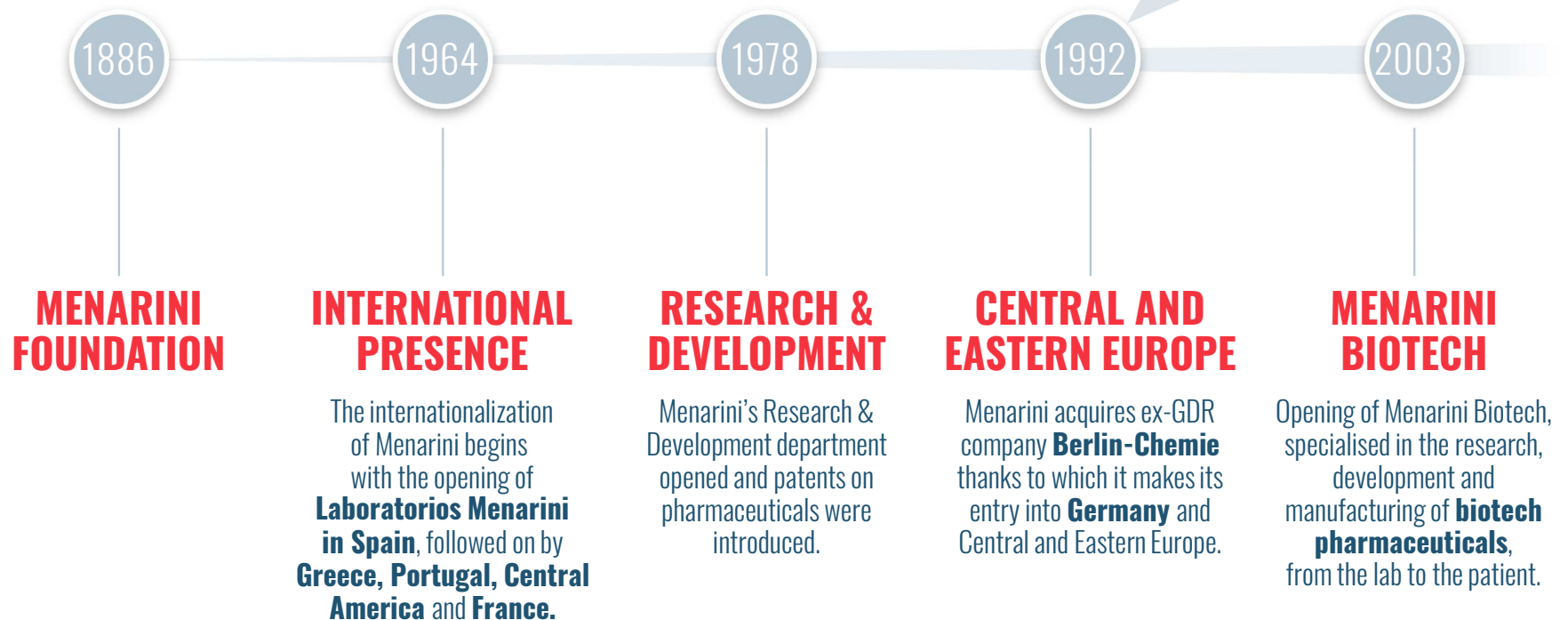
## COMPANY PROFILE



Menarini was  
**founded in 1886.**

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

# Milestones



# 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 thanks to the acquisition of **Stemline**, 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

U.S. FDA approves **Elacestrant** as the first oral treatment for patients with ER+/HER2-, ESR1-mutated advanced or metastatic breast cancer.

# Consolidated turnover

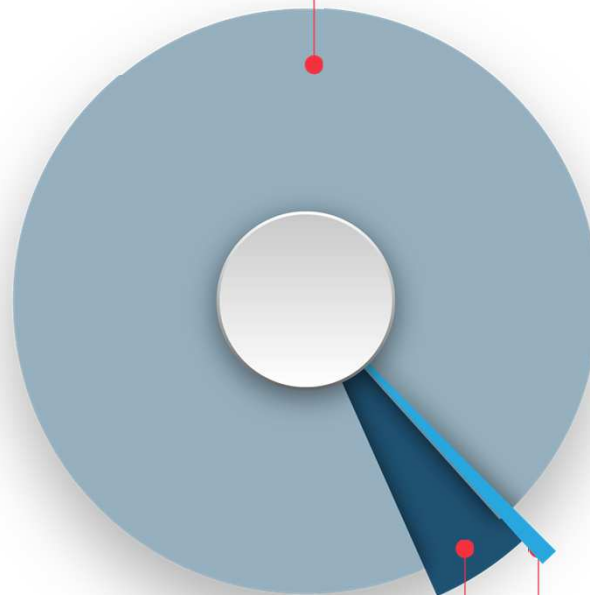
Million euro



Source: internal data. \*Source: Iqvia WRMP 12/2021 - Retail Market.

# Consolidated turnover

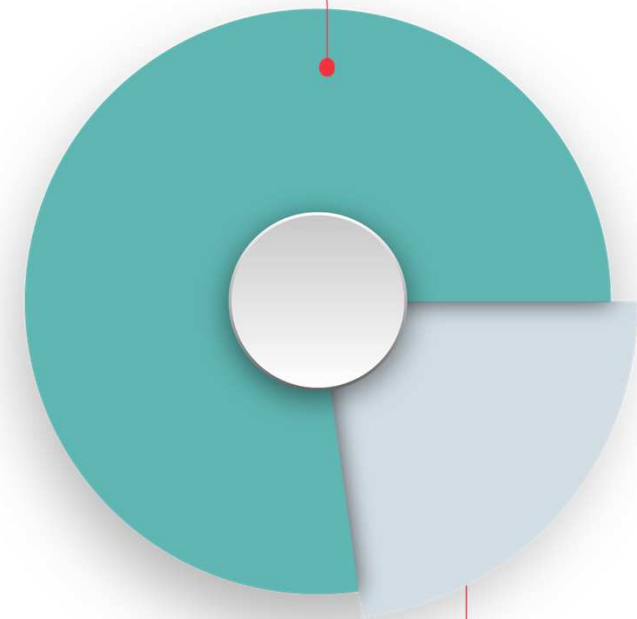
Pharmaceutical **94%**



Diagnostic **5%**

Other **1%**

Abroad **78%**



Italy **22%**

Source: internal data.

# Menarini in the **WORLD**

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



# Western Europe



**8,400 employees**



## Presence

**Florence - Italy (headquarters)**, Austria, Belgium, Cyprus, France, Germany, Greece, Ireland, Luxembourg, Portugal, Spain, Sweden\*\*, Switzerland, Netherlands\*\*, United Kingdom.



Source: internal data. \*\*Menarini Diagnostics presence.



# Central & Eastern Europe



**3,300 employees**



## Presence

**Berlin (headquarters)**, Albania, Armenia, Azerbaijan, Belarus, Bosnia&Herzegovina, Bulgaria, Czech Republic, Croatia, Estonia, Finland, Georgia, Hungary, Kazakhstan, Kyrgystan, Kosovo, Latvia, Lithuania, Moldova, Mongolia, Montenegro, North Macedonia, Poland, Romania, Russia, Serbia, Slovak Republic, Slovenia, Turkmenistan, Ukraine, Uzbekistan.



Source: internal data.

# Asia Pacific



**3,600 employees**



## Presence

**Singapore (headquarters)**, China, India, Australia, South Korea, Taiwan, Thailand, The Philippines, Indonesia, Vietnam, New Zealand, Hong Kong and Malaysia.

Source: internal data.

 Distributors – Japan: Menarini Silicon Biosystems presence.

# Turkey, Africa & Middle East



**1,000 employees**



**Presence\***

Turkey, United Arab Emirates, Saudi Arabia, Egypt,  
Tunisia.



Source: internal data.

\*In other countries we are present through distributors

# LATAM & Central America



**1,100 employees**



**Presence\***

Colombia, Costa Rica, Dominican Republic, El Salvador,  
Guatemala, Honduras, Mexico, Nicaragua, Panama, Peru.

Source: internal data.

\*In other countries we are present through distributors

# 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 indications, including chronic myelomonocytic leukemia (CMML), acute myeloid leukemia (AML) and myelofibrosis (MF).

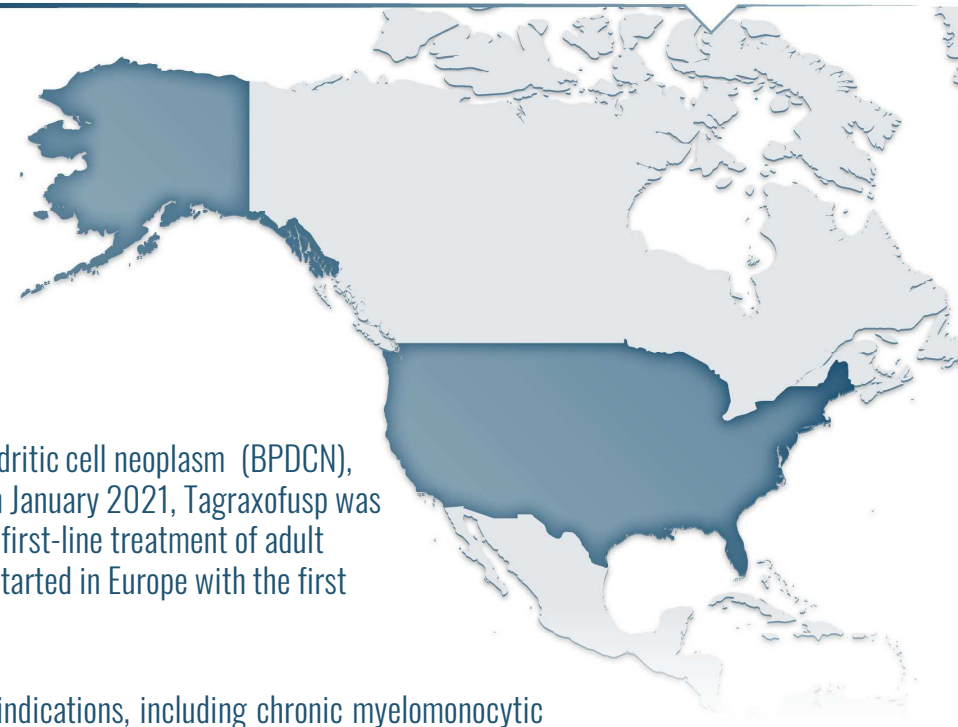
### Elacestrant

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, by the EMA (Europe), Ministry of Health (MOH) in the United Arab Emirates (UAE) and by SFDA (Saudi Food & Drug Authority) in Kuwait.

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.



# U.S.A and Canada



Menarini Group's lead company in the high-tech diagnostics area.

The main instruments, **DEPArray™ PLUS**, **Ampli1™** and **CELLSEARCH®** are used in personalized oncology to identify possible tumor mutations, and to determine the best therapeutic approach for the patient.

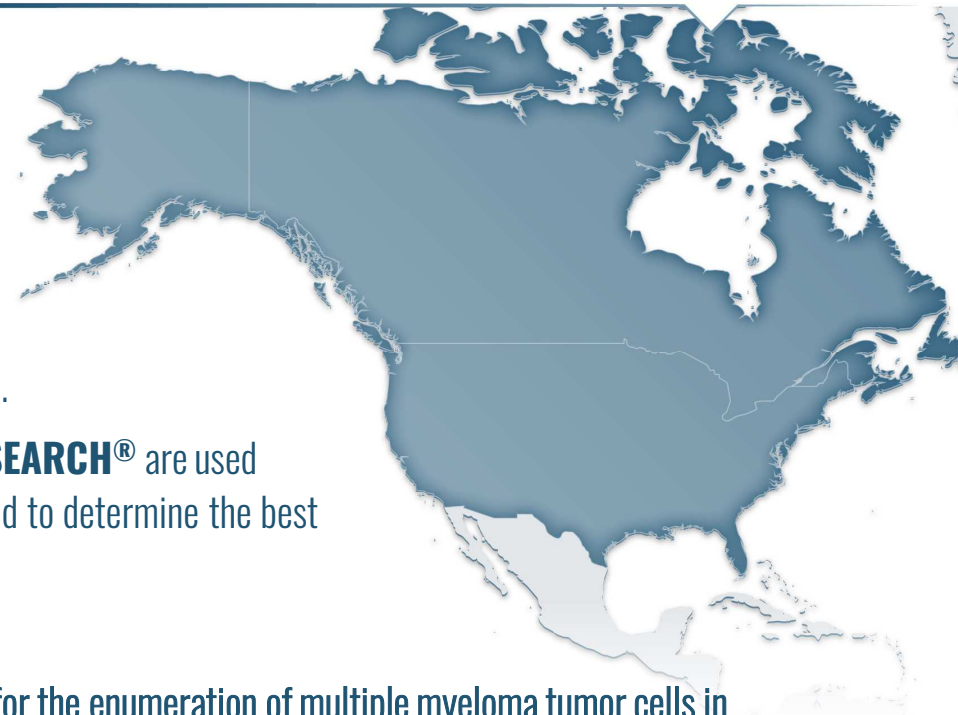
All this from a simple blood sample.

Menarini Silicon Biosystems' latest development is the **new test for the enumeration of multiple myeloma tumor cells in the blood (CMMC)**. A recent study, conducted in collaboration with Dana-Farber Cancer Institute, confirmed that enumeration of these cells represents an important biomarker of disease aggressiveness. Thanks to the CELLSEARCH technology, minimal residual disease (MRD) could be measured in the future in a minimally invasive way, reducing the need for bone marrow biopsy.

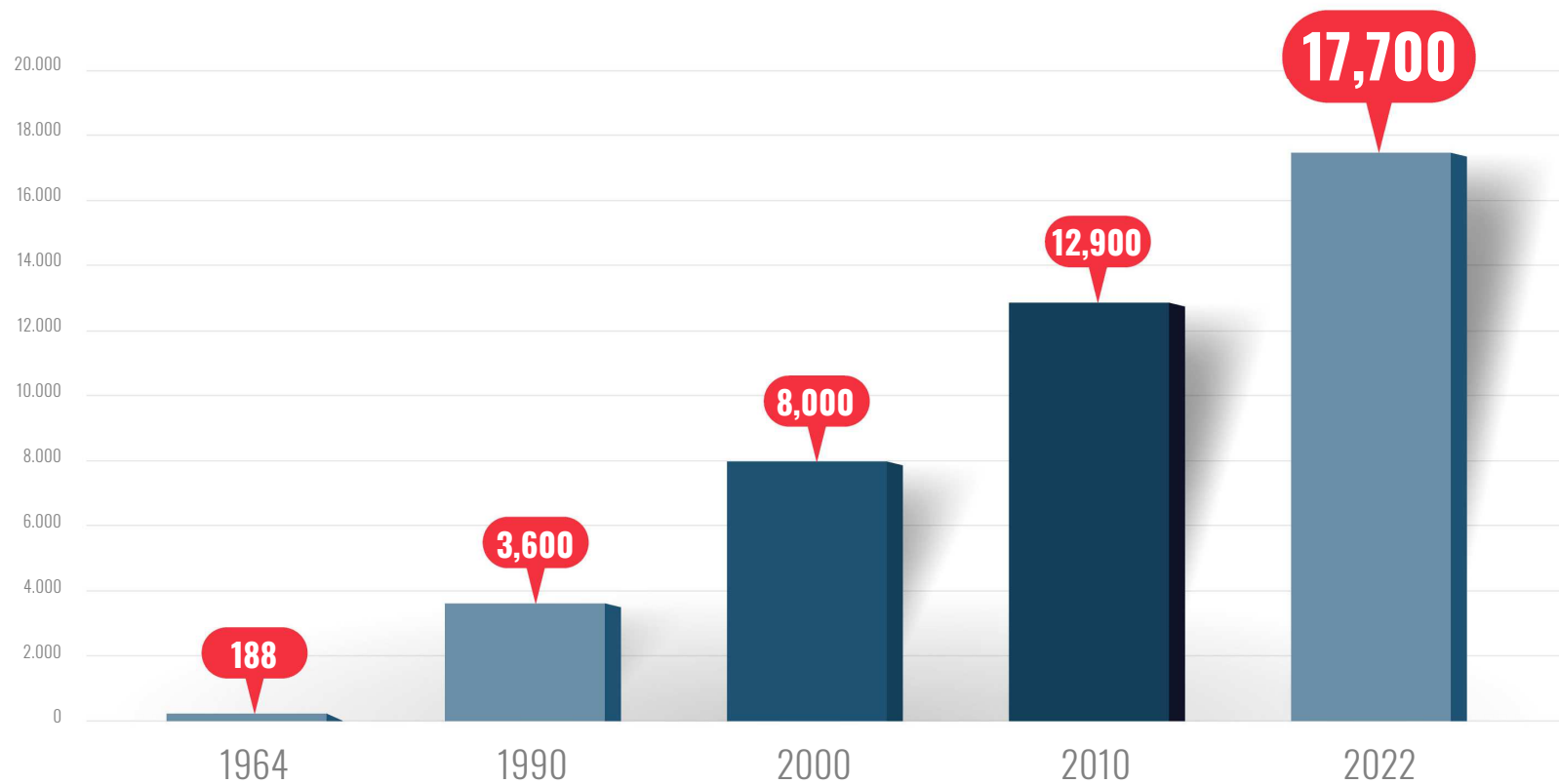
The new test is already available to American oncologists through the company's CLIA-certified Clinical Laboratory located in Pennsylvania.



Locations: Philadelphia, U.S.A.  
Bologna, ITALY

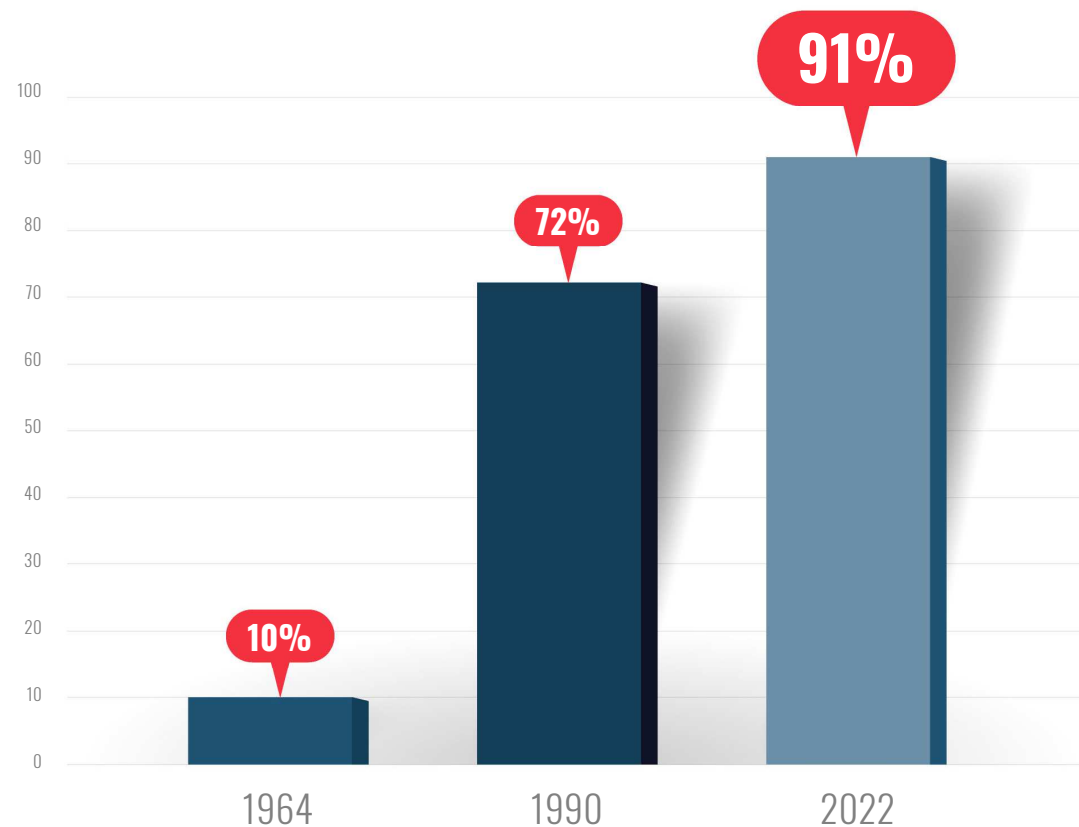


# Number of employees



Source: internal data.

# Employees % of graduates and technicians





# 18 manufacturing plants

## EUROPE is the Group's heart of production

In 2022 **578 million packs** were produced at these sites

### Italy

Pisa (2 plants), Florence (2 plants and 1 plant under construction<sup>°</sup>), Pomezia\*, L'Aquila, Lomagna (Lecco), Casaleto Lodigiano (Lodi), Rapolano (Siena) plant nearing completion<sup>°</sup>

### 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.

<sup>°</sup> Not included in the total number of active plants.

# 9 Research & Development centers

933 employees



\*Pomezia.

# Research & Development Projects **ONCOLOGY**

COMPOUND	DRUG CLASS (TARGET)	INDICATION	DEVELOPMENT STAGE
<b>Elacestrant<sup>o</sup></b>	SERD (ER)	Monotherapy: ER+/HER2- Metastatic Breast Cancer	<b>EMA and FDA: approved</b>
<b>Elacestrant</b>	SERD (ER)	Monotherapy: CDK4/6 Inhibitor-naïve ER+/HER2- Metastatic Breast Cancer (ELCIN trial)	<b>Phase II</b>
<b>Elacestrant</b>	SERD (ER)	Combination therapy: ER+/HER2- Metastatic Breast Cancer (ELEVATE trial)	<b>Phase II</b>
<b>Elacestrant</b>	SERD (ER)	Combination therapy: ER+/HER2- Breast Cancer with brain metastasis (ELECTRA trial)	<b>Phase II</b>
<b>Tagraxofusp</b>	TB (CD123)	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)	<b>EMA and FDA: approved</b>
<b>Tagraxofusp</b>	TB (CD123)	Chronic myelomonocytic leukemia (CMML)	<b>Phase II</b>
<b>Tagraxofusp</b>	TB (CD123)	Myelofibrosis (MF)	<b>Phase II</b>
<b>Tagraxofusp</b>	TB (CD123)	Acute Myeloid Leukemia (AML)	<b>Phase II</b>
<b>SL-701</b>	IT (IL-13R $\alpha$ 2, EphA2, Survivin)	Recurrent Glioblastoma	<b>Phase II</b>
<b>MEN1703</b>	SME (PIM/FLT3i)	Relapsed/refractory Diffuse Large B-cell Lymphoma (DLBCL)	<b>Phase II</b>
<b>MEN1611</b>	SME (PI3Ki)	Colorectal cancer	<b>Phase II</b>
<b>MEN1611</b>	SME (PI3Ki)	Breast cancer	<b>Phase II</b>
<b>MEN1309</b>	ADC (Anti-CD205)	Solid tumors	<b>Phase Ib</b>
<b>Felezonexor</b>	SME (XPO1i)	Solid tumors	<b>Phase Ib</b>
<b>SL-901</b>	SME (PI3Ki)	Solid tumors	<b>Phase Ia</b>
<b>Selinexor<sup>oo</sup></b>	SME (XPO1i)	Mieloma Multiplo	<b>EMA and FDA: approved</b>

<sup>o</sup><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>

<sup>oo</sup><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 Degradator; IT, Immunotherapy; SME, Small Molecule Entity; ADC, Antibody Drug Conjugate.

# Research & Development Projects **CARDIO-METABOLIC**

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

<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
<b>Meropenem + Vaborbactam</b>	Carbapenem + $\beta$ -lactamase inhibitor	Complicated urinary tract infections, Complicated Intra abdominal infections, Hospital acquired pneumonia, Ventilator associated pneumonia and Bacteremia	<b>EMA and FDA: approved</b>
<b>Delafloxacin</b>	Anionic fluoroquinolone	Acute Bacterial Skin and Skin Structure - ABSSSI	<b>EMA and FDA: approved</b>
<b>Delafloxacin</b>	Anionic fluoroquinolone	Community Acquired Bacterial Pneumonia - CABP	<b>EMA* and FDA: approved</b>
<b>Oritavancin</b>	Semisynthetic glycopeptide	Acute Bacterial Skin and Skin Structure - ABSSSI	<b>EMA and FDA: approved</b>
<b>Oritavancin</b>	Semisynthetic glycopeptide	Acute Bacterial Skin and Skin Structure - ABSSSI	(new formulation) <b>EMA: submitted</b> <b>FDA: approved</b>

\*On April 2021, Delafloxacin has been approved in EU for the for the treatment of CABP.



**MENARINI**  
*group*

