

RESEARCH & DEVELOPMENT

We are convinced that our future will be innovation-based. Research, which is the major driver of innovation, must be efficient and should receive constant support.

In its latest research, sigma-tau focused on a number of key areas. One area concerns studies with carnitine – a natural substance which is particularly suitable for correcting the biochemical and metabolic defects that cause various conditions. A second headline of research relates to the company's involvement in therapeutic areas where it has specific knowledge, such as cardiovascular, metabolic and central nervous system disorders.

In addition, Sigma-Tau, in cooperation with the non-profit Medicines for Malaria Venture (MMV), has embarked on a project aimed at obtaining international marketing authorization for the treatment of malaria. Here we have been applying our own knowledge of the industry in an effort to make this drug available in countries where millions are still falling victim to this disease.

Pharmaceutical product development is divided into two consecutive stages:

- Preclinical development of a drug consists of experiments that are performed before it is tested in humans.
- Clinical development is aimed at establishing the product's efficacy and tolerability in healthy volunteers (Phase I) and then in patients (Phases II and III).

This means that the trials not only produce experimental data but also provide patients with additional treatment options.

The following table provides an overview of the key clinical trials.

Products in development

Therapeutic area	Drug	Indication	Phase
Cardiovascular	Thymosin β 4 ¹	Myocardial infarction	Preclinical
	Thymosin β 4 ¹	Wound healing & venous leg ulcers	Phase II
	Istaroxime ²	Heart failure (HF)	Phase II
	Rostafuroxin	Hypertension	Phase II
	Statins/Omega-3 PUFA	Cardiovascular prevention	Phase III
	Propionyl-L-carnitine	Intermittent claudication	NDA submitted
Metabolism	L-Carnitine ³	Peritoneal dialysis	Phase II
	Teglicar	Type II diabetes	Phase II
Oncology	SST0001 ⁴	Multiple myeloma & advanced metastatic cancers	Preclinical
	Namitecan	Various tumours	Phase I
	Adarotene	Various tumours	Phase I
	Acetyl-L-carnitine	Cancer-induced fatigue	Phase II
	Gimatecan	Various tumours (solid)	Phase II
	Acetyl-L-carnitine	Chemotherapy-induced peripheral neuropathy	Phase III
	Leuprolide	Prostate cancer	Phase III
Immunology & inflammation	Defibrotide ⁵	Venous occlusive disease (VOD)	Phase III (USA)
	DN30 ⁶	Various tumours	Preclinical
	PTX3	Immunotherapy	Preclinical
	Pretargeted antibody-guided radioimmunotherapy (PAGRIT [®])	Glioma & non-Hodgkin's lymphoma (NHL)	Phase I
	Propionyl-L-carnitine	Inflammatory bowel disease	Phase II (Planned)
	Intraoperative Avidination for Radionuclide Treatment (IART [®])	Breast cancer	Phase II
	Thymosin α 1 ⁷	Melanoma, hepatocellular carcinoma	Phase II/III
Central & peripheral nervous system	Thymosin α 1 ⁷	Hepatitis C	Phase III
	ST1936	Unipolar disorders	Preclinical
	ST1535	Parkinson's disease	Phase I
Infectious diseases	Acetyl-L-carnitine	Diabetic peripheral neuropathy	Phase III
	EurartesimTM ⁸ (dihydroartemisinin / piperazine)	Malaria	Phase III
	Artesunate i.v. ⁹	Severe malaria	Phase III (USA)

1. Developed in collaboration with RegenerX Biopharmaceutical Inc. (USA)

2. Licence granted to Debiopharm S.A. (Switzerland)

3. Developed by Iperboreal Pharma S.r.l. (Italy)

4. Property of Sigma-Tau Research Switzerland S.A. (Switzerland)

5. Under licence from Gentium S.p.A. (Italy) for the American market

6. Managed by Sigma-Tau Research Switzerland S.A. (Switzerland)

7. Developed in collaboration with SciClone Pharmaceuticals International Ltd. (USA)

8. Developed in collaboration with the Medicines for Malaria Venture (Switzerland)

9. In collaboration with Walter Reed Army Institute of Research (USA)

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