

HP API PIPELINE

POLPHARMA'S STRATEGIC INVESTMENT IN HPAPI FACILITY, THE FIRST OF THIS KIND IN POLAND

With the strategic investment in a HPAPI facility, Polpharma, and Poland are becoming a strong pillar of the European pharmaceutical industry in the coming decades.

We are investing € 35 million into a specialized facility for the R&D and Production of highly active substances with an OEL value down to 10 ng/m³ (OEB 6).

Construction of the new manufacturing building includes a separate **process development laboratory (PDL)**, **analytical development laboratory (ADL)** with **QC analysis capabilities** and a **GMP kilo-lab scale** production line of max batch size up to 1.5 kg, with further expansion potential to double its capacity. HPAPI kilo-lab will have three reactors ranging from 5L to 35 L. The plant's design assumes best-in-class isolator technology to be used for personnel and product safety.

The unit will become operative in Q3 2024. We are proudly joining the forefront of global API manufacturers with the ability to **deliver highly potent substances** which are critical for saving lives and treating patients around the world.

UNDER DEVELOPMENT

Product	Samples Availability
▲ Baricitinib*	available
▲ Enzalutamide	available
▲ Palbociclib*	available
▲ Carfilzomib	Q4 2023
▲ Trametinib	Q4 2023

INITIAL STAGE

Product	
▲ Azacitidine	▲ Ibrutinib*
▲ Cabozantinib	▲ Ozanimod
▲ Fulvestrant	▲ Vismodegib

* Products developed under strategic cooperation Polpharma & Egis

- ▲ OVER 70 YEARS OF EXPERIENCE IN DEVELOPMENT, SCALE-UP AND MANUFACTURING
- ▲ FDA-APPROVED PLANT LOCATED IN CENTRAL EUROPE
- ▲ R&D EXPERIENCED IN DEVELOPMENT OF CHEMICAL PROCESSES AND COMPLEX PROJECTS
- ▲ WORLD-CLASS REGULATORY SUPPORT

Products protected by patents (SPC) in Poland are developed solely for the purpose of Regulatory Submissions or R&D purposes intended to support Regulatory Submissions. These products are not offered for sale or made available in countries where such products are subject to patent (SPC) protection and where the offer for sale or any related activity constitutes patent infringement. It is within the buyer's responsibility and liability to check the patent situation of the product in the import market(s).





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