

Evonik and Heraeus cooperate to expand the range of services for highly potent active pharmaceutical ingredients

12 July 2023

- Evonik specializes in mid- to large-scale, later clinical phase HPAPIs
- Heraeus Precious Metals focuses on small to mid-scale and taking pre-clinical projects to registration and market
- Customers benefit from a streamlined approach, joint understanding of capabilities and easy transfer

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Essen and Hanau, Germany. Evonik and Heraeus Precious Metals are collaborating to expand both companies' range of services for highly potent active pharmaceutical ingredients (HPAPIs). The cooperative effort leverages the specific HPAPI competencies of both companies and provides customers with a fully integrated offering from the pre-clinical stage to commercial manufacturing. Customers will benefit from a streamlined transfer between small and large-scale production between the two companies which is based on an understanding of each other's capabilities and assets, as well as the proximity of the Hanau manufacturing sites.

"As one of the earliest adopters of large-scale HPAPI production, our offering is perfectly complemented by that of Heraeus. This alliance benefits clients needing to develop and launch HPAPIs safely and quickly," said Stefan Randl, head of Evonik's Drug Substance product line.

Evonik's Health Care business is one of the world's leading CDMOs (Contract Development and Manufacturing Organizations) for active pharmaceutical ingredients (APIs) and intermediates, representing a key growth business for Evonik. It is part of the company's life sciences division Nutrition & Care. The partnership with Heraeus Precious Metals builds on the company's track record of delivering complex APIs to meet the clinical and commercial supply needs of biotech and large pharma customers around the world.

The Pharmaceutical Ingredients business at Heraeus Precious Metals offers customized solutions for both earlier and later

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clinical phases and smaller to mid-volume HPAPI commercial products in the marketplace.

“The supplementary approach with Evonik is thus a natural fit for Heraeus Precious Metals as it allows a smooth upscaling of small- and medium-scale projects that require larger scale commercial production at a later stage,” emphasized Dr. Marcus Hannakam, executive vice president business line Pharmaceutical Ingredients.

Extensive expertise as established service provider and world’s leading supplier of platinum-based HPAPIs

Heraeus Precious Metals’ Pharmaceutical Ingredients CDMO covers a full range of development and manufacturing services for cancer therapy, focusing on producing highly potent small molecules (HPAPIs), such as payloads including linkers and toxins for Antibody-Drug Conjugates (ADCs). The company is the leading supplier of platinum HPAPIs worldwide.

The range of services includes development and manufacturing under GMP for clinical trials, photochemistry in batch and continuous flow mode, high-containment systems for OELs (Occupational Exposure Limits) < 10 ng/m³, state-of-the-art equipment, CMC documentation for global approval and regulatory support. The Pharmaceutical Ingredients’ project teams can thus offer maximum flexibility, short lead times to execution and a customized approach for each customer.

With over 35 years of experience delivering active ingredients for oncology to its customers and operating exclusively out of Hanau, Germany, Heraeus Precious Metals’ Pharmaceutical Ingredients Business Line is a reliable and sought-after CDMO. With a proven track record in taking pre-clinical projects to registration, the company, additionally, has comprehensive know-how for process optimization.

Manufacturing large volumes of HPAPIs requires years of experience

Highly potent active pharmaceutical ingredients (HPAPI) represent an increasingly significant share of the pharmaceutical drug pipeline including anti-cancer treatments. Manufacturing highly potent APIs in large volumes requires extensive project experience with HPAPIs and a strong track record for audits, safety knowledge, systems and supply security.

Evonik has been one of the world's largest process developers and manufacturers of HPAPIs for more than 20 years. The company has set industry standards through its broad technology portfolio, excellence in process engineering and unrivalled safety standards. The Evonik Laboratories at Tippecanoe, Indiana in the U.S. can manufacture six different HPAPIs in parallel and has a total capacity of 170 m³. Evonik's facility in Hanau has process and analytical laboratories to develop and optimize HPAPIs requiring containment down to an OEL of 5 ng/m³.

To address the specific needs of large or complex projects, Evonik has established a broad portfolio of differentiating technologies which can be combined to support multi-step API and HPAPI synthesis. In addition to superior technological expertise and an integrated portfolio of services, customers are also attracted by Evonik's reliability and commitment to sustainability.

Further Information

<https://healthcare.evonik.com/en/drugsubstance/highly-potent-api>

https://www.heraeus.com/en/hpm/hmp_products_solutions/pharmaceutical_ingredients/overview.html

Company information

Evonik is one of the world leaders in specialty chemicals. The company is active in more than 100 countries around the world and generated sales of €18.5 billion and an operating profit (adjusted EBITDA) of €2.49 billion in 2022. Evonik goes far beyond chemistry to create innovative, profitable, and sustainable solutions for customers. About 34,000 employees work together for a common purpose: We want to improve life today and tomorrow.

About Nutrition & Care

The focus of the business of the Nutrition & Care division is on health and quality of life. It develops differentiated solutions for active pharmaceutical ingredients,

medical devices, nutrition for humans and animals, personal care, cosmetics, and household cleaning. In these resilient end markets, the division generated sales of €4.24 billion in 2022 with about 5,700 employees.

About Heraeus

The Heraeus Group is a broadly diversified and globally leading family-owned technology company, headquartered in Hanau, Germany. The company's roots go back to a family pharmacy started in 1660. Today, Heraeus bundles diverse activities in the Business Platforms Metals and Recycling, Health, Semiconductor and Electronics as well as Industrials. Customers benefit from innovative technologies and solutions based on broad materials expertise and technological leadership.

In the 2022 financial year, the FORTUNE Global 500 listed group generated revenues of €29.1 billion (US\$30.6 billion*) with approximately 17,200 employees in 40 countries. Heraeus is one of the top 10 family-owned companies in Germany and holds a leading position in its global markets.

About Heraeus Precious Metals

Heraeus Precious Metals is globally leading in the precious metals industry. The company is part of the Heraeus Group and covers the value chain from trading to precious metals products to recycling. It has extensive expertise in all platinum group metals as well as gold and silver.

With about 3,000 employees at 15 sites worldwide, Heraeus Precious Metals offers a broad portfolio of products that are essential for many industries such as the automotive, chemicals, semiconductor, pharmaceutical, hydrogen and jewelry industry. By 2025 Heraeus Precious Metals will be the first company in the industry that operates carbon neutral.

The Business line Pharmaceutical Ingredients has over 35 years of experience delivering highly active pharmaceutical ingredients for oncology to its customers and operating exclusively out of Hanau, Germany.

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