

Minakem opens new high containment facility for production of the highest class of HPAPI

Best-in-class facility enhances capacity to scale production of highly potent ingredients for customers demanding small to full GMP batches

Louvain-la-Neuve, Belgium, June 19, 2018 - [Minakem](#), the CDMO division of Minafin, specialized in custom development and manufacturing of building blocks, GMP intermediates and Active Pharmaceutical Ingredients (APIs and HPAPI), today announces it is in the final qualification run to open a new closed-controlled environment high containment production facility in August. This high-class production facility is among only a dozen of its kind in the world; roughly half are located in Europe.

The new facility, based at the Louvain-la-Neuve plant in Belgium, extends Minakem's capacity to develop and manufacture HPAPI compounds, such as Antibody Drug Conjugates (ADC) toxins, from small-scale development to full GMP batch releases. Unlike others in this category, Minakem's facility will be equipped with a preparative chromatography system that allows the isolation and purification of target molecules at varying scales, from milligrams to hundreds of grams, geared to addressing a range of client needs from routine activity to analytics.

Equally importantly, Minakem's HPAPI production will be carried out with an Occupational Exposure Limit (OEL) below 0,1µg/m³/8h. This emphasis on Environment, Health and Safety (EHS) reflects Minakem's more than 20 years' experience in continuously monitoring and controlling hazardous working environments, marking its leadership in this area.

"This new facility is a significant asset, strengthening Minakem's position as a leader in developing and producing substantial quantities of highly potent compounds more robustly, safely and economically," said Amadeo Ferreira, R&D manager at Minakem. "The Louvain-la-Neuve site has handled highly potent molecules for decades. Specialized training, adequacy of housekeeping measures and engineering controls are the pillars in the effectiveness of containment. This new investment allows an increased capacity to integrate new projects as well as handle the most highly potent molecules on the market. These measures are requested by our customers for use in Antibody Drug Conjugates at 10 ng/m³ levels. The entire team is proud to be part of the future generation of drugs aimed at treating cancers."

The new facility has state-of-the-art equipment. It consists of nine fume hoods and a double-barrier of protection in the form of new generation glove boxes in room - dedicated to dry powder handling and weighing, air locks, HEPA air filters and cascading flow.

According to [industry reports](#), the global HPAPIs market is expected to reach \$26.84 billion (€22.8bn) by 2023 from \$17.72 billion (€15bn) in 2018, at a CAGR 8.7%. Growth is driven in part by increased demand in oncology drugs, growing demand for antibody-drug conjugates and a growing focus on precision medicine. As a supplier to the HPAPI market, Minakem is anticipating the need for further expansion of its capacity in the next five years.

Minakem based the design of the laboratory on its own expertise and input from customers and equipment suppliers. It used a risk analysis approach to define a suitable

way to work with these compounds while maintaining great flexibility. The company anticipates that the high-performance equipment, including preparative chromatography, will increase its customers' market competitiveness. It will start operations in the new high containment facility in September.

About Minakem

Minakem, a leading supplier of pharmaceutical fine chemicals, specializes in developing and manufacturing pharmaceutical active ingredients. Minakem is a technology-driven company with expertise in complex multi-step synthesis, pressure chemistry, chiral synthesis, halogenation chemistry, steroid chemistry and 'prazole' chemistry. Total capacity represents 290m³. All manufacturing activities are supported by a highly skilled R&D technical center as well as solid form and process safety laboratories. As of 2017, Minakem has more than 450 highly skilled employees based in three facilities located in Dunkirk (FR), Beuvry-la-Forêt (FR) and Louvain-la-Neuve (BE). Minakem is an affiliate of the Minafin Group.

www.minakem.com/

Media and analyst contacts

Andrew Lloyd & Associates

Carol Leslie – Juliette dos Santos

carol@ala.com - juliette@ala.com

Tel: +44 1273 675 100

US: + 1 617 202 4491

[@ALA_Group](#)
