



MEDIA RELEASE

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Novugen Becomes Malaysia's First and Southeast Asia's Only with USFDA Approved Oncology Manufacturing Facility to Produce Drugs Locally for the U.S.

Bandar Enstek, Negeri Sembilan, 4 December 2023 – Novugen Oncology Sdn. Bhd. (Novugen) announced a ground-breaking milestone in Malaysia's pharmaceutical industry, as the company was granted approval by the U.S. Food and Drug Administration (USFDA) for its manufacturing facility specialising in high potent oncology drugs. This approval is part of Novugen's commitment to promote Malaysia as a manufacturing hub to produce technology-intensive pharmaceutical and oncology products locally.

The sought-after approval by the U.S. federal agency came just a year after the company's first USFDA approval for Novugen Pharma Sdn. Bhd., focusing on oral solid dosage forms for general medicines. With these approvals, Novugen becomes the first in the country and the only in the Southeast Asia region to be accredited by the USFDA for pharmaceutical and oncology manufacturing facilities to produce affordable and high-quality medicines for the U.S. market, from Malaysia.

Datuk Wira Arham Abdul Rahman, Chief Executive Officer (CEO) of the Malaysian Investment Development Authority (MIDA) said, "We congratulate Novugen for their achievement in securing USFDA approval for their high potent oncology drug manufacturing facility. This accomplishment is nothing short of phenomenal, as it significantly strengthens the Malaysian pharmaceutical industry by enhancing its capabilities and technological expertise to produce complex pharmaceutical products. It aligns perfectly with Mission 1 of the New Industrial Master Plan (NIMP) 2030 to establish advanced economic complexity in the high technology manufacturing of complex products and services. Beyond this, it not only strengthens Malaysia's position within the global value chain but also reaffirms our commitment to long-term resilience and sustainability."

Novugen has shown promising signs for their future as the company commercialised two products in the U.S. with Abbreviated New Drug Application (ANDA) approval from USFDA for Abiraterone 250mg and 500mg tablets and Midodrine 2.5mg, 5mg and 10mg. The successful launch of the two products in the U.S. marks the commencement of Novugen's journey towards unveiling future phases of a comprehensive range of life-changing medicines, designed to benefit millions of patients while meeting the stringent USFDA requirements.

Dr. Madan Mulukuri, Senior Vice President, Quality Operations of Novugen said “As Novugen enters the next phases of becoming a multi-product facility with growing complexity, we put significant focus on training our current employees in elaborate containment principles and technologies. We leverage our current collaborations with local universities offering programs for undergraduates to acquire world-class manufacturing expertise and competencies. Ultimately, our mission is to create access for the Malaysian workforce to get acquainted with intricate pharmaceutical operations and be exposed to stringent global regulations to create a sustainable ecosystem of highly skilled talents in the local pharmaceutical industry.”

Novugen’s USFDA approved manufacturing facilities play a major role in advancing the nation’s pharmaceutical industry and healthcare sector by reducing the dependency on imports and ensuring self-sufficiency in manufacturing and supplying high-quality products, especially those with elaborate formulations that lack robust generic alternatives. It also fortifies Malaysia’s capacity to export and enter the world's largest economy and market - the U.S. - for pharmaceutical and oncology product sectors.

The continued support from MIDA brought forth many successes for Novugen’s successful establishment in Malaysia and in developing a strong business foundation throughout the years. The company is committed to undertaking great efforts to guarantee the safety of public health by ensuring every product undergoes rigorous testing and meeting the necessary standards to strengthen local accessibility of medicines with identical efficacy to those exported to the U.S. Novugen is immensely proud to contribute great impact to Malaysia, a nation that values international trade and strategic investments to boost the economic growth.

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About MIDA

MIDA is the government's principal investment promotion and development agency under the Ministry of Investment, Trade and Industry (MITI) to oversee and drive investments into the manufacturing and services sectors in Malaysia. Headquartered in Kuala Lumpur Sentral, MIDA has 12 regional and 21 overseas offices. MIDA continues to be the strategic partner to businesses in seizing the opportunities arising from the technology revolution of this era. For more information, please visit www.mida.gov.my and follow us on X, Instagram, Facebook, LinkedIn, TikTok and YouTube.

About Novugen

Novugen is a wholly owned subsidiary company of a UAE based group, SciTech International. With over 30 years of experience in the healthcare industry, the company is equipped with vast and successful experience of venturing into strategic healthcare businesses and development of world

class healthcare facilities around the globe. Novugen’s passion for science, bold global strategy and wealth of international experience prepared us to respond to challenges of bringing hard-to-source and technology-intensive pharmaceutical products to the market.

Novugen specializes in niche and difficult to formulate generics for all therapeutic areas of pharmaceutical and oncology medicines while meeting stringent global quality standards. With vertical integration from Active Pharmaceutical Ingredients (API) to Finished Products R&D and manufacturing based in Malaysia, it gives us greater control over the supply chain.

We are committed to ensuring early access to high-quality products that lack robust generic alternatives due to their complexity. We strive to strengthen the accessibility of affordable and global quality standard products in Malaysia with same efficacy to medicines exported to the U.S. For more information about Novugen, please visit www.novugen.com and follow us on LinkedIn, Facebook, and X (Twitter).

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