Paxman Announces FDA Regulatory Progress for Limb Cryocompression System

Paxman today announces a significant regulatory milestone in the development of its Limb Cryocompression System for the reduction of chemotherapy-induced peripheral neuropathy (CIPN), with the U.S. Food and Drug Administration (FDA) identifying the De Novo process as an appropriate pathway for review of this novel indication.

While this development extends our timeline, the FDA's feedback provides a clear framework for advancing Paxman's CIPN programme towards potential U.S. market authorisation and reflects the innovative nature of the technology, which addresses a significant unmet need for cancer patients undergoing chemotherapy.

Paxman intends to progress the CIPN indication through the De Novo pathway. If successful, the resulting authorisation would establish a new FDA device classification and could position Paxman as the first company to obtain U.S. clearance specifically for the reduction or prevention of chemotherapy-induced peripheral neuropathy using cryocompression technology.

Confidence in this pathway is supported by the growing body of clinical evidence generated to date, ongoing studies including ICE COMPRESS, and the fact that Paxman's Limb Cryocompression System has already obtained regulatory approvals in the UK and Europe for the reduction of chemotherapy-induced peripheral neuropathy. These approvals were granted following review of clinical evidence supporting the safety and performance of the technology, providing a strong foundation as Paxman advances towards potential U.S. market authorisation.

Richard Paxman, Chief Executive Officer, commented:
"We are delighted that the FDA has identified a pathway forward for our CIPN programme. This represents another important step in the development of what we believe could become a transformative technology for patients affected by chemotherapy-induced peripheral neuropathy. Importantly, our Limb Cryocompression System has already secured regulatory approvals in the UK and Europe for the reduction of CIPN, supported by clinical evidence demonstrating the safety and performance of the technology. As we now focus on European commercialisation in Q4, we remain equally confident in the advancement of the programme in the United States. Chemotherapy-induced peripheral neuropathy remains one of the most common and challenging side effects of cancer treatment, affecting millions of patients worldwide. We believe our technology has the potential to make a meaningful difference to patient outcomes and quality of life, and we are excited about the opportunities ahead."

Paxman continues to advance its European commercialisation strategy, with pilot programmes expected to commence in the coming months. The Company will also continue its ongoing clinical activities, including the ICE COMPRESS study, as it progresses towards future regulatory submissions and broader market access opportunities.

Regulatory Disclosure

As part of its review, the FDA concluded that the proposed CIPN indication represents a new intended use and therefore is not eligible for review through the traditional 510(k) substantial equivalence process. The Agency indicated that the De Novo process is the appropriate regulatory pathway for consideration of the indication.

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About Us

The Paxman Scalp Cooling System has been developed by the Paxman family to reduce hair loss in breast cancer patients undergoing chemotherapy. The concept behind the system came when the mother of four, Sue Paxman, experienced first-hand the trauma of chemotherapy-induced hair loss. In 2025, PAXMAN AB acquired Dignitana, merging to form a stronger united company.
Today, PAXMAN's portfolio includes both the Paxman and DigniCap systems with several thousand installations in hospitals, clinics and treatment centres worldwide, reaffirming PAXMAN as the leading global supplier of Scalp Cooling technology.
PAXMAN AB (publ) has its headquarters in Karlshamn (Sweden). Subsidiaries of the PAXMAN Group are Paxman Coolers Limited (Huddersfield UK), Paxman Inc. (Houston, Texas US), Paxman Canada (Toronto, Ontario CA), Dignitana AB (Lund, Sweden), Dignitana Inc. (Dallas, TX US), and Dignitana S.r.l. (Milan, IT).

The PAXMAN share is listed on Nasdaq First North Growth Market.
FNCA Sweden AB is the company's Certified Adviser.

Attachments

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