
SEDANA MEDICAL RECEIVES APPROVAL IN FRANCE



Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the company has received market approval for inhaled sedation in France.

The approval applies to the drug Sedaconda (isoflurane)* for administration via the medical device AnaConDa (undergoing name change to Sedaconda ACD) for inhaled sedation in intensive care in France. The application has been approved by the French Medicines Agency, L'Agence nationale de sécurité du médicament et des produits de santé (ANSM) and is based on the DCP approval Sedana Medical received in July.

"The approval has gone faster than we expected. This is very gratifying as France is one of our most important markets and awareness of the treatment is already relatively high. Now, there will be a price and reimbursement process that is estimated to take four to six months before Sedaconda (isoflurane) can be used in intensive care clinics in France", said Jens Lindberg, Acting CEO of Sedana Medical.

The approval is based on the results of the Sedaconda study (SED001), Sedana Medical's pivotal phase III study. The study reached its primary endpoint; that Sedaconda administered via AnaConDa is an effective sedation method for ventilator-intensive care patients, comparable to propofol.

Secondary endpoints of the study show that Sedaconda administered via AnaConDa, had beneficial features compared with propofol; Sedaconda enables a faster and more predictable awakening, reduced opioid needs and facilitation of spontaneous breathing, improving the conditions for maintained lung function during and after ventilator treatment. Sedaconda was well tolerated, with a safety profile consistent with previously known findings for isoflurane.

"Effective sedation with rapid and predictable awakening after sedation is of great clinical importance for both the patient and healthcare. It enables comfort, safety and a faster recovery and facilitates important aftercare after ventilator treatment", said Peter Sackey, Chief Medical Officer of Sedana Medical.

*In France, the treatment will be marketed under the brand name Cedaconda.

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