



## European approval for Breakyl

Meda announced today that Breakyl (*fentanyl*) has received approval in Europe via the Decentralized Procedure with Germany acting as Reference Member State. Breakyl (also known as Onsolis or BEMA Fentanyl) is indicated for the management of breakthrough pain in opioid tolerant adult patients with cancer. National registration processes will now follow in each of the individual countries. Throughout next year, it is expected that major countries in Europe will issue marketing authorizations for Breakyl. Thereafter, price and reimbursement will be negotiated on a national level.

*"We are pleased with this achievement and we look forward making Breakyl available to patients across Europe who are afflicted with this indication. There is a growing medical need and Breakyl offers a unique and patented delivery technique compared with current treatment alternatives",* said Anders Lönner, CEO of Meda.

### About Breakyl

Breakyl uses a unique patented delivery system designed to ensure rapid and reliable delivery of fentanyl. The product consists of a small dissolvable film which is applied to the buccal (inner lining of cheek) membranes. Breakyl has recently also been approved in Canada and the US under the trademark Onsolis.

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#### For questions, please contact:

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