



ESTEVE and KOWA Pharmaceuticals America enter into an Exclusive License and Commercialization Agreement for rights to E-58425 for the potential management of acute pain¹⁻⁹ in the United States^{8,9}

E-58425 is an investigational novel co-crystal form of celecoxib and tramadol¹⁻⁹ currently under FDA review^{8,9}

Barcelona, 3 May 2021.- Esteve Pharmaceuticals (ESTEVE), an international specialty pharmaceutical company devoted to the development and commercialization of innovative products, today announced an agreement with Kowa Pharmaceuticals America, Inc. (KPA) under which ESTEVE has granted KPA exclusive rights to commercialize E-58425 in the United States. E-58425 is an investigational medicinal product under development for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate¹⁻⁹.

E-58425 is a proprietary product that has been developed by ESTEVE's in-house R&D team. It is a new product comprised of a co-crystal form of celecoxib (an anti-inflammatory) and tramadol (an analgesic) for the management of acute pain in adults¹⁻⁷ currently under review by the U.S. Food and Drug Administration (FDA)^{8,9}. A decision on its approval is expected this year.

ESTEVE will be the supplier of the product and will retain worldwide rights to this product, except in the United States and Canada. If approved by the FDA, E-58425 will be ESTEVE's first proprietary research product to enter the US market.

Staffan Schüberg, CEO of ESTEVE, said: "The agreement with KPA marks a new milestone in the company's history with a product that has the potential to meet an unmet medical need in the United States and around the world. If approved by FDA, patients and healthcare providers will have access to a new treatment option for acute pain management in adults."

Ben Stakely, CEO of KPA, said: "We are delighted to be working with an innovative company like ESTEVE to introduce E-58425 to the United States market. We look forward to a productive long-term relationship."

About E-58425

E-58425 is an investigational new co-crystal entity of celecoxib and tramadol⁷ designed for acute pain management with complementary analgesic and anti-inflammatory properties^{3,5} in a multimodal treatment approach^{5,6}. Targeting four



complementary pain relief mechanisms⁶, E-58425 offers a potential new treatment option for acute pain management aligned with the multimodal analgesia now considered standard care¹⁰. This novel co-crystal structure produces a unique pharmacokinetic profile of its active pharmaceutical ingredients compared to their individual or combined administration^{1,2,4,7}.

E-58425 is also currently under review in several European regulatory agencies.

References

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About ESTEVE

For more information about ESTEVE visit www.esteve.com

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