# ESTEVE announces FDA approval of a novel co-crystal form of celecoxib and tramadol for the management of acute pain

## This marks the first proprietary research product from ESTEVE to be approved in the United States

**Barcelona, Spain, October 18, 2021.-** The U.S. Food and Drug Administration (FDA) approved Seglentis® (celecoxib and tramadol hydrochloride), a proprietary product developed by Esteve Pharmaceuticals' (ESTEVE) R&D team. It is an innovative first-in-class product comprised of a co-crystal form of celecoxib (an anti-inflammatory) and tramadol (an analgesic) for the treatment of acute pain in adults.[1-9] This is ESTEVE's first proprietary research product to enter the United States market.

In words of Dr. Carlos Plata-Salamán, Chief Scientific Officer and Chief Medical Officer of ESTEVE **"**This innovation is the result of applying a crystallization technology to improve the physicochemical properties and pharmacokinetic characteristics of its active pharmaceutical ingredients.[1,2,4,7,9] The FDA approval means that clinicians and adult patients in the U.S. now have a new treatment option for acute pain management."

Seglentis® is the trade name for tablets that contain a co-crystal[7] composed of celecoxib and tramadol hydrochloride. It is a new analgesic designed for acute pain management in a multimodal treatment approach[3,5,6] targeting four complementary pain relief mechanisms.[5,6] It offers a new treatment option for acute pain management aligned with the multimodal analgesia now considered standard of care.[8]

The novel co-crystal structure produces a unique pharmacokinetic profile of its active pharmaceutical ingredients compared to their individual or combined administration.[1,2,4,9] The New Drug Application (NDA) was approved by the U.S. FDA on October 15, 2021.

Staffan Schüberg, Chief Executive Officer of ESTEVE, said: "We are proud of this milestone as we understand it as a recognition of our daily efforts to meet patient's needs and to address the challenges the pain community is facing nowadays".

Seglentis® will be commercialized in the United States by KOWA Pharmaceuticals America, Inc.

### About ESTEVE

ESTEVE is a global specialty pharmaceutical company with headquarters in Barcelona (Spain). The company's mission is to advance in innovation to improve people's lives, and ever since its foundation in 1929, it has focused on providing solutions for unmet medical needs. ESTEVE has an important presence in Europe thanks to its affiliates and its own production sites dedicated to the development and manufacture of active pharmaceutical ingredients in Spain, Germany, Mexico, and China. For more information about ESTEVE visit https://www.esteve.com/

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