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Business news

PolyPeptide customer Cara Therapeutics with FDA approval for novel treatment of moderate-to-severe pruritus in hemodialysis patients

Long-term collaborative development process for peptide API successfully completed and continued with commercial supply agreement

Zug, 1 September 2021 – PolyPeptide is pleased to announce that its customer Cara Therapeutics (Nasdaq: CARA) recently received the approval by the U.S. Food and Drug Administration (FDA) for KORSUVA™ (difelikefalin) injection for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis. PolyPeptide partnered with Cara Therapeutics for over ten years to develop a peptide-based API as key component of KORSUVA™ and is proud to support Cara Therapeutics going forward with a supply agreement.

Sophie Marechal, PolyPeptide Head of Program Management: "The forthcoming market introduction of KORSUVA™ injection means a substantial improvement in symptoms and meaningful relief for people suffering from severe and debilitating itch. At PolyPeptide we are proud to be part of that process and that our close collaboration with Cara Therapeutics over so many years has now proven to be successful".

Steve O'Connor, Cara Therapeutics Executive Director, Chemistry Research and CMC: "The FDA approval of KORSUVA™ injection is a milestone for Cara Therapeutics and we are thankful to the team at PolyPeptide for the continued excellent partnership from early stages on. We're continuing to work together as we prepare the product launch and as we seek further drug approvals in other important markets."

As part of the supply agreement with Cara Therapeutics, PolyPeptide will manufacture the API in its site in Strasbourg, France, which is one of PolyPeptide's smaller GMP-certified facilities providing flexible support with a special focus on innovative projects.

About Cara Therapeutics
Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors, or KORs. Cara is developing a novel and proprietary class of product candidates, led by KORSUVA™ (CR845/difelikefalin), a first-in-class KOR agonist that targets the body's peripheral nervous system, as well as certain immune cells. In two Phase 3 trials, KORSUVA injection has

demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP). Oral KORSUVA has completed Phase 2 trials for the treatment of pruritus in patients with CKD and atopic dermatitis and is currently in Phase 2 trials in primary biliary cholangitis and notalgia paresthetica patients with moderate-to-severe pruritus.