Vidac Pharma Submits Clinical Study Application to EMA for Advanced Actinic Keratosis Lesions

Comprehensive dossier underscores rigorous scientific, clinical, and CMC preparation, with key support from CRO partners

LONDON, UNITED KINGDOM, September 15, 2025 / EINPresswire.com/ -- Vidac Pharma Holdings Plc. a clinical-stage oncology biopharmaceutical company pioneering a novel class of cancer treatments, today announced the submission of a Clinical Trial Application (CTA) to the European Medicines Agency (EMA) for a new interventional study targeting advanced actinic keratosis (AK) lesions. The submission reflects a thorough cross-functional effort by Vidac Pharma's R&D, clinical operations, regulatory, and quality teams, working closely with Forschungsdock CRO GmbH to deliver a complete and scientifically robust dossier.

> Our Phase 2 research trial is designed to refine the endpoints we aim to carry into a pivotal Phase 3 program"
>
> *Dr. Max Herzberg*

The CTA package includes the full study protocol, Investigator's Brochure, patient-safety monitoring plan, statistical analysis plan, and comprehensive Chemistry, Manufacturing and Controls (CMC) documentation for the investigational product. The filing also encompasses nonclinical and prior clinical data, data-integrity and GCP frameworks, and GDPR-compliant processes to protect participant privacy. The study will take place at Centroderm in Wuppertal, Germany, a leading dermatology clinical site, under the direction of Prof. Thomas Dirschka.

Dr. Max Herzberg, Chief Executive Officer of Vidac Pharma, commented:
"This submission represents months of meticulous cross-functional work, with outstanding support from our CRO partners, to ensure EMA reviewers receive clear and comprehensive evidence supporting the scientific rationale, study design, and patient protections. Our Phase 2

research trial is designed to refine the endpoints we aim to carry into a pivotal Phase 3 program. We are proud of the collaborative effort behind this application, which reflects our commitment to advancing a well-controlled study addressing the unmet needs of patients with advanced AK lesions, while upholding the highest standards of quality and ethics."

About the Study Design
The planned Phase 2 study will evaluate the safety, tolerability, and efficacy signals of Vidac Pharma's investigational therapy in participants with advanced AK lesions. The protocol features well-defined inclusion criteria, clinically meaningful endpoints, centralized and site-level quality controls, blinded assessments where applicable, and predefined interim analyses to ensure robust, decision-enabling data.

Vidac Pharma will provide updates following EMA's validation phase and subsequent regulatory interactions in line with standard procedures.

Max Herzberg
Vidac pharma Holding Plc
72544257381
email us here
Visit us on social media:
LinkedIn