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Valerio Therapeutics Provides Clinical Development Update on Its Phase 1/2 VIO-01 Clinical Trial

- **The first dose level, evaluating 3 patients of the VIO-01-101 trial has been cleared as per the recommendations of the Clinical Review Committee.**
- **No clinically significant adverse events or serious adverse events were reported and no MTD was declared.**
- **Three sites are activated which include, NEXT Oncology San Antonio, Florida Cancer Specialists, and University of Oklahoma.**

Paris (France), May 22, 2024 - 8:00 pm CET – Valerio Therapeutics S.A. (Euronext Growth Paris: **ALVIO**), a clinical-stage biotechnology company specializing in the development of innovative drugs targeting tumor DNA Damage Response (DDR) and driver oncogenes, today announced the completion of dosing for the first cohort of subjects in its Phase 1/2 trial of lead candidate, VIO-01, a pan-DDR decoy for the treatment of solid tumors.

VIO-01 is the next-generation DNA decoy generated from Valerio Therapeutics' proprietary PlatON platform. An optimized product with modifications for increased half-life, plasma stability and tumor targeting, VIO-01 is a potent pan-DDR trapper capable of abrogating multiple DNA damage pathways including homologous recombination and non-homologous end joining. The pan trapping nature of VIO-01 allows for treatment of a wide range of potential solid tumor indications rather than restrictions to BRCA1/2 mutations or HRD positivity as with other DNA damage inhibitors.

The Clinical Review Committee (CRC) is composed of Valerio Therapeutics Medical and Safety teams as well as Principal Investigators convened to review all available and relevant safety information from the first cohort of 3 patients. No clinically significant adverse events or serious adverse events were reported and no MTD was declared, allowing the Clinical Review Committee to unanimously agree to escalate to the second dose cohort.

The VIO-01-101 Phase 1b portion of the trial aims to determine to recommended phase 2 dose and/or pharmacologically active dose in patients with selected solid tumors including, HRD+ Ovarian cancer, BRCA1/2 mutant Breast Cancer, HRR mutated prostate cancer, and solid tumors with HRR mutations. The dose escalation to clinically relevant exposures and safety expansion is expected to continue through 2024.

Dr. Shefali Agarwal, Chairwoman of the Board of Directors and CEO, stated:

"*The result of this meeting represents one of the key milestones in the development of VIO-01 and the PlatON platform. This is an import step on our way to becoming a leader in the development of innovative drugs with unique mechanisms of action. We are pleased with the encouraging tolerability seen in this first cohort of patients and look forward to bringing this drug-candidate another step closer to patients. Most*

importantly, we'd like to thank our dedicated investigators and patients for their willingness to participate in this trial and are excited for our continued future work together."

About Valerio Therapeutics

ValerioTX (Euronext Growth Paris: ALVIO) is a clinical-stage biotechnology company developing innovative oncology drugs targeting tumor DNA-binding functions through unique mechanisms of action in the sought-after field of DNA Damage Response (DDR). The Company is focused on bringing early-stage first-in-class or disruptive compounds from translational research to clinical proof-of-concept, a value-creating inflection point appealing to potential partners.

PlatON is ValerioTX's proprietary chemistry platform of oligonucleotides acting as decoy agonists, which generates new innovative compounds and broaden the Company's product pipeline.

VIO-01 (formerly OX425), the second compound from platON™, is a novel pan-DDR Decoy with high antitumor activity. It also mediates multiple immunostimulatory effects by activating the STING pathway. In 2023, VIO-01 underwent IND-enabling preclinical development until IND submission and positive feedback from the FDA to initiate its clinical development.

DecoyTAC: the 3rd generation platON™ platform, leveraging the unique MOA of DNA decoy therapeutics coupled to targeted protein degradation (PROTAC). This evolution expands the activity of platON™ platform beyond DNA repair by targeting other proteins such as transcription and epigenetic factors, in oncology and outside oncology for other diseases like inflammatory and muscular diseases.

For further information, please visit www.valeriotx.com

Forward looking statements

This communication expressly or implicitly contains certain forward-looking statements concerning Valerio Therapeutics and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Valerio Therapeutics to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Valerio Therapeutics is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise. For a discussion of risks and uncertainties which could cause actual results, financial condition, performance or achievements of Valerio Therapeutics to differ from those contained in the forward-looking statements, please refer to the risk factors described in the most recent Company's registration document or in any other periodic financial report and in any other press release, which are available free of charge on the websites of the Company Group (https://valeriotx.com/) and/or the AMF (www.amf-france.org).

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