

Ona Therapeutics advances as a clinical-stage company and appoints Aleix Prat, MD, PhD, as Chief Medical Officer

- *More than half of the patients planned for the clinical study have already been enrolled, with the trial progressing rapidly through dose escalation*
- *Advancement of ONA-255 marks an important milestone following Ona's \$86.6 million Series B financing*
- *Internationally recognized oncologist and physician-scientist Aleix Prat, MD, PhD, appointed Chief Medical Officer, as Jutta Amersdorffer, MD, MBA, transitions to Chief Development Officer*

Barcelona, Spain, 24 September 2026: Ona Therapeutics (“Ona”), a clinical-stage biotech developing a novel, patient-derived, target-focused portfolio of next-generation ADCs to overcome growing treatment resistance across major cancer indications, today announced continued progress in the Phase 1a clinical development of its lead first-in-class antibody-drug conjugate (ADC), ONA-255, for the treatment of advanced cancers. More than half of the patients planned for the study have already been enrolled, with the trial continuing to progress through dose escalation.

The advancement of ONA-255 represents an important milestone for Ona following its \$86.6 million Series B financing earlier this year and forms part of the company’s broader strategy to build a differentiated pipeline of ADCs targeting treatment-resistant cancer biology. Alongside ONA-255, Ona is advancing ONA-389, a first-in-class ADC in development for colorectal cancer and hepatocellular carcinoma. ONA-389 is progressing through IND-enabling studies and is expected to enter the clinic in the second half of 2027. The company is also advancing ONA-418, the third program in its ADC portfolio, which incorporates dual-linker, dual-payload technology designed to further expand the potential of Ona’s ADC pipeline.

To support the advancement of its pipeline, Ona has appointed Aleix Prat, MD, PhD, as Chief Medical Officer. An internationally recognized medical oncologist, physician-scientist and biotech entrepreneur, Dr. Prat brings deep expertise in breast cancer, precision oncology, biomarker development and drug development. He is Director of the Clínic Barcelona Comprehensive Cancer Center, Professor of Medicine at the University of Barcelona, co-founder of Reveal Genomics and author of more than 350 peer-reviewed publications. Since becoming Chair of Ona’s Scientific Advisory Board in 2025, he has worked closely with the company and, together with Ona’s advisor Roger Gomis, PhD, contributed to the identification and functional validation of the target underlying ONA-255.

*“This has been a transformational year for Ona. Advancing ONA-255 into the clinic and achieving rapid enrollment in our Phase 1a study represent important milestones for the company,” said **Valerie Vanhooren, PhD, Co-Founder and Chief Executive Officer of Ona Therapeutics.** “Aleix brings exceptional clinical, translational and drug development expertise that will be instrumental as we advance ONA-255 and our broader ADC pipeline. These achievements reflect years of work building our discovery platform and establishing a differentiated pipeline of programs designed to address treatment-resistant cancer biology.”*

ONA-255 is a first-in-class ADC designed to target treatment-resistant tumor biology through a novel mechanism, with an initial focus on HR+/HER2-negative advanced breast cancer and

gastric cancer. The ongoing Phase 1a study is progressing through dose escalation, with Ona focused on study execution and the generation of clinical, pharmacologic and biomarker data to inform the program's next stage of development.

"I have worked closely with Ona for several years and am delighted to take on this role as ONA-255 advances in the clinic," commented Aleix Prat, MD, PhD, Chief Medical Officer of Ona Therapeutics. "The ongoing Phase 1a study represents an important opportunity to build our understanding of ONA-255's clinical profile and generate the evidence needed to guide its future development. By integrating clinical, pharmacologic and biomarker findings, we aim to establish a strong foundation for subsequent studies and fully explore the potential of this novel approach to addressing treatment resistance in cancer, ultimately helping us bring innovative new therapies to patients."

As Chief Development Officer, Jutta Amersdorffer, MD, MBA, will continue to lead development execution, working closely with Dr. Prat on clinical strategy and with the broader team as Ona advances ONA-255 and its pipeline through the next stages of development.

The ongoing Phase 1a trial is a multicenter, open-label study evaluating the safety, tolerability, preliminary efficacy, pharmacokinetics and pharmacodynamics of ONA-255 in patients with advanced cancer. The dose-escalation portion is evaluating ONA-255 as a monotherapy and will inform dose selection for subsequent stages of the study. These stages will further assess the safety and preliminary antitumor activity of ONA-255 in patients with HR+/HER2-negative advanced breast cancer and metastatic gastric cancer.

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About Ona Therapeutics

Ona Therapeutics is a clinical-stage biotechnology company developing a novel target-focused portfolio of next-generation antibody-drug conjugates (ADCs) to overcome growing treatment resistance across major cancer indications. The company's programs are built around a first-in-class, resistance-linked target, identified through translational and clinical research, and have initial applications across breast, gastric, colorectal and liver cancers.

Central to Ona's approach is a unique patient-led discovery engine. Through direct access to metastatic tumor biopsies and longitudinal patient samples, Ona studies how cancers evolve under therapeutic pressure, enabling the identification of clinically relevant resistance mechanisms and potentially accelerating the development of tailored therapies in very defined patients from the outset without the need for basket trials. The company's integrated team of clinical oncologists, translational scientists and drug developers combines frontline clinical expertise with advanced drug discovery capabilities to translate patient insights into novel therapeutic candidates.



Ona's lead first-in-class clinical program, ONA-255, is in advanced HR-positive/HER2-negative breast cancer and gastric cancer and is designed to address the growing unmet need among patients who have progressed on current-generation ADC therapies.

Ona's second program, ONA-389, is a first-in-class ADC for advanced colorectal and liver cancers and other prevalent solid tumors. The company is also advancing ONA-418, the third program in its ADC portfolio, designed to harness the full potential of its dual-linker, dual-payload technology and expand the reach of its next-generation ADC pipeline. Supported by a strong biomarker strategy and a growing portfolio of ADC candidates targeting different resistance pathways, Ona is advancing a differentiated pipeline aimed at delivering more durable treatment options for patients. For further information, please visit <https://ona-therapeutics.com/>