



VERAXA Biotech Provides Overview on Implementation of FDA-Aligned Human-Relevant Models into R&D Strategy

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Consistent Use of New Approach Methodologies (NAMs) to Potentially Accelerate BiTAC® Oncology Pipeline and Significantly Reduce Animal Testing Needs

ZURICH, SWITZERLAND, Oct. 07, 2026 (GLOBE NEWSWIRE) -- VERAXA Biotech AG (NASDAQ: VRXA; "VERAXA" or the "Company"), a leading developer of next-generation antibody-based cancer therapies, today provided an update on its strategy and progress to implement a suite of U.S. Food and Drug Administration (FDA) aligned New Approach Methodologies (NAMs) across its preclinical research and development programs, potentially enabling faster clinical advancement while significantly reducing animal testing. This strategic implementation positions VERAXA ahead of the FDA's [2025 roadmap](#), which encourages the phased reduction and ultimate replacement of animal testing in favor of human-relevant, non-animal and non-clinical test methods for developing safe and effective therapies.

NAMs encompass a range of technologies, including cell-based assays, organ-on-chip systems, computational modeling and *ex vivo* tissue models, designed to more accurately predict human biological responses while reducing dependence on animal models. Beyond this regulatory alignment, the shift toward more sustainable and ethical research practices is also expected to reduce development costs and timelines, for example, by bypassing certain non-human primate (NHP) toxicology studies traditionally required ahead of clinical development.

"We see NAMs as not just a regulatory obligation, but also as a scientific opportunity," said Christoph Erkel, Ph.D., Chief Scientific Officer of VERAXA. "We've been investing in translational, human-relevant model systems well ahead of the FDA's 2025 roadmap, and we see this shift as beneficial and a win-win situation for both science and sustainability. Reducing our reliance on animal studies, particularly NHP toxicology testing, allows us to generate more clinically predictive data, move faster, and do so more efficiently and sustainably."

VERAXA has been building a multi-layered panel of NAMs to characterize and de-risk its pipeline of BiTAC (bi-targeted tumor-associated cytotoxicity) based T cell engagers (BiTAC-TCEs), BiTAC-based antibody drug conjugates (BiTAC-ADCs) and bispecific antibody-drug conjugates (bsADCs) technologies. At the AACR Annual Meeting 2026, the Company presented initial data on its most advanced BiTAC-TCE program. In those studies, the candidate performed as intended *in vitro* and *in vivo*, attacking cancer cells that displayed both target molecules while sparing cells expressing only one of the two, with a safety profile that was superior, and efficacy that matched, a more traditional TCE, pointing to the possibility of a meaningfully improved therapeutic index. The *in vitro* results came from three-dimensional, cell line-derived spheroid models, which recapitulate solid tumor architecture more closely than two-dimensional culture. VERAXA has since generated new spheroid data demonstrating consistent predictivity of T cell engagement specificity across diverse cancer cell lines and validating the model for IND-enabling studies, further reinforcing this model's translational value ahead of clinical development.

VERAXA further evaluated its lead BiTAC-TCE and bsADC candidates in an *ex vivo* panel of ten low-passage patient-derived xenograft models of non-small cell lung cancer, models that closely preserve the molecular characteristics, heterogeneity, and therapeutic response of the original tumors. Because these assays draw on tumor material from a small number of donor mice and can be split into many parallel patient samples, the panel required only about ten mice in total, versus an estimated 200 or more for comparable *in vivo* efficacy studies.

Across the panel, the combined BiTAC consistently induced potent T cell-mediated killing, while relevant controls, including commercial T cell engagers against non-expressed targets, showed only minimal activity, providing strong evidence that VERAXA's dual-targeting approach extends beyond cell line models into clinically meaningful anti-tumor activity, validating the need for simultaneous dual-target engagement and reinforcing BiTAC as a next-generation approach to T cell redirection. This *ex vivo* platform demonstrates how VERAXA's NAM strategy reduces both animal use and preclinical cycle time without compromising clinical relevance.

About VERAXA Biotech AG (NASDAQ: VRXA)

VERAXA is building a premier engine for the discovery and development of next-generation antibody-based cancer therapeutics, powered by a suite of transformative technologies and guided by rigorous quality-by-design principles. The company is rapidly advancing its pipeline of conditionally active T cell engagers (BiTAC-TCEs), bispecific antibody-drug conjugates (bsADCs), and proprietary BiTAC formats into clinical development. Uniquely, VERAXA has implemented FDA-aligned New Approach Methodologies across all preclinical programs, enabling faster clinical advancement while reducing reliance on animal testing. Founded on scientific breakthroughs from the European Molecular Biology Laboratory (EMBL), a world-renowned institution for pioneering life science research, VERAXA combines innovation with responsible research practices.

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In addition, any information contained in this press release was current as of the date presented and should not be relied upon as representing our estimates as of any subsequent date. While we may elect to update forward-looking statements at some point in the future, we specifically disclaim any obligation to do so, even if our estimates change, whether as a result of new information, future events or otherwise. Consequently, the company will not update the information contained in this press release and investors should not rely upon the information as current or accurate after the presentation date.

Attachment

- [20261007 VRXA NAM Strategy FINAL](#)

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