PHP Biotech Reports Preclinical Efficacy and Safety Data for PHP53-nb, a First-in-Class Nanobody for Mutant-p53 Tumors

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Humanized camelid nanobody reduced cell viability across twelve p53-mutant cancer lines, showed a greater than 20-fold safety margin in zebrafish, and delivered 41% tumor growth inhibition in a rodent triple-negative breast cancer xenograft

PHP Biotech International Inc., a privately held biotechnology company developing humanized nanobody therapeutics for aggressive solid tumors, today reported preclinical efficacy, safety and biodistribution results for its lead candidate, PHP53-nb, and outlined the experimental program it expects to complete ahead of regulatory testing.

PHP53-nb is a first-in-class humanized camelid nanobody engineered to induce apoptosis in tumor cells carrying mutant p53 ? a mutation class that has resisted conventional drug development for decades. At roughly one-tenth the size of a conventional monoclonal antibody, the molecule potentially carries lower immunogenicity, greater stability and more efficient tissue and tumor penetration. It selectively targets a receptor expressed on tumor cells, uPAR, an for internalization, then acts inside the cell through proteasome

modulation, ER stress and unfolded protein response activation, mitochondrial permeabilization and caspase cascade activation.

Activity across multiple p53 mutations. In a twelve-line cell panel, PHP53-nb decreased cell viability in tumor lines carrying both DNA-binding-domain and structural TP53 mutations: triple-negative breast cancer (MDA-MB-231, R280K; HCC1395, R175H), pancreatic cancer (MiaPaCa-2, R248W; Su86.86, G245S; BxPC-3, Y220C), non-small cell and small cell lung cancer (NCI-H820, T284P; NCI-H1963, H214R), osteosarcoma (KHOS/NP, R156P) and neuroblastoma (SK-N-BE(2), C135F). All results were statistically different from the non-tumorigenic MCF10A control. A wide safety margin. In zebrafish, no lethality was observed up to 20 times the MDA-MB-231 in vitro IC50, and malformations appeared only at concentrations at or above that threshold (p<0.0001). Published work places doxorubicin?s LD50 at six times plasma concentration in the same model. At non-toxic doses, PHP53-nb produced tumor growth reduction comparable to doxorubicin in zebrafish TNBC xenografts, with activity observed against both primary tumor and metastatic burden.

In vivo results in mice. In a triple-negative breast cancer xenograft model, PHP53-nb dosed at 200 mg/kg achieved 41% tumor growth inhibition by day 29, compared with 59% for paclitaxel at 15 mg/kg (p<0.05, two-sided Welch?s t-test versus vehicle). Fluorescent biodistribution imaging at 20 mg/kg showed efficient systemic distribution, delivery to the target tissue, and persistent tumor localization at least 24 hours after administration ? addressing rapid clearance and low target retention, two limitations that have historically constrained nanobody development.

?Mutant p53 sits inside a large share of human cancers, and the field has spent decades trying to reach it,? said Robert Gahagen, Chief Executive Officer of PHP Biotech. ?What these data show is a molecule that gets inside the cell, works across several different mutations rather than one, and does it with a safety margin that leaves real room to dose. That combination is what makes this a program worth partnering on.?

PHP53-nb is built on GEN01-AD, PHP Biotech?s proprietary nanobody platform. The scaffold embeds a theragnostic sequence directly in the nanobody paratope, producing a single recombinant molecule with no linker or conjugation chemistry ? a design intended to lower manufacturing cost and improve commercial viability. GEN01-AD can carry other bioactive sequences as well, with potential applications in immunology, antimicrobial therapy, imaging and metabolic disease alongside oncology. Four patents covering the peptide, the scaffold, the production method and the lead molecule have been filed in the United States and under the Patent Cooperation Treaty.

?The scaffold is what makes the rest possible,? said Patrícia Bezerra, PhD, Research Leader at PHP Biotech. ?It gives bioactive sequences stability and a possible route into the cell, and it manufactures like a single protein rather than a conjugate. The same chassis can generate multispecifics, antibody-drug

conjugates and radioligands.?

. PHP Biotech?s analysis of GLOBOCAN 2022, IARC TP53 Database v20, COSMIC v98 and TCGA PanCancer Atlas data across eight tumor types puts five-year prevalence at approximately 9.61 million patients, of whom roughly 5.52 million carry a TP53 mutation and about 828,000 carry one of the three hotspot variants represented in the company?s responsive cell panel ? R175H, G245S and R280K.

Planned work through the first quarter includes mechanism-of-action validation, toxicity and efficacy studies in mice, ADME and blood-brain-barrier studies, an in vivo combination study with anti-PD-1 therapy, technology transfer to a contract development and manufacturing organization, and regulatory testing. The program is supported by research and manufacturing partners including ATUM, BioReperia, TD2 Precision Oncology, Pace Life Sciences, Thermo Fisher Scientific, PanomeBio and RayBiotech.

PHP Biotech is engaged in partnering discussions with pharmaceutical companies and investors evaluating PHP53-nb as both a standalone candidate and an add-on therapeutic in tumors carrying p53 mutations.

Disclaimer

PHP53-nb is an investigational biologic and has not been approved by the U.S. Food and Drug Administration or any other regulatory authority. It is not available as a treatment outside authorized research. Preclinical findings in cell, zebrafish and mouse models do not predict or guarantee clinical benefit in humans. Statements regarding planned experiments, technology transfer, regulatory testing and partnering activity are forward-looking and subject to scientific, regulatory and financing risks. This release is informational and is not medical advice.

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PHP Biotech

Our goal: better treatments for aggressive cancers. We developed PHP53-nb?pairing our 3-NAntC p53-reactivating peptide with the GEN01-AD nanobody platform to restore tumor-suppressing function. Promising results in TNBC and pancreatic cancer.

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