Tallac Presents First Clinical Data for TAC-001 at SITC 2023

Marks the First Clinical Data for a Systemically Administered TLR9 Agonist Antibody Conjugate (TRAAC) Activating B Cells to Drive a Clinical Response in Solid Tumors

Preclinical Data From TAC-003, a Potentially Best-in-Class Nectin-4 TRAAC, Will Also be Featured

BURLINGAME, California, November 3, 2023 (BUSINESS WIRE) --Tallac Therapeutics, Inc., a privately held biopharmaceutical company harnessing the power of innate and adaptive immunity to fight cancer, today announced the first presentation of TAC-001 Phase 1 clinical safety and efficacy data in solid tumor patients. TAC-001 is an investigational, systemically delivered, TRAAC molecule comprised of a potent TLR9 Agonist conjugated to a CD22 antibody, designed to selectively activate B cells to drive an anti-tumor immune response.

The findings presented in the TAC-001 poster ***"INCLINE-101: Preliminary Safety, Tolerability, Pharmacokinetics (PK), and Pharmacodynamics (PD) of TAC-001 (TLR9 Agonist Conjugated to a CD22 mAb) in Patients With Advanced or Metastatic Solid Tumors"*** ***(Hyperlink to Tallac Website)*** demonstrate that single-agent TAC-001 (0.1 to 3 mg/kg) given systemically every 2 weeks is well tolerated, demonstrates pharmacodynamic activity consistent with its proposed MOA and resulted in preliminary clinical activity with patients achieving durable stable disease (≥6 months) and partial response per RECIST v1.1.

"These TAC-001 clinical data provide evidence that systemic administration of a TLR9 immune agonist targeting and activating B cells is generally well tolerated and induces immune activation consistent with preclinical studies. We also observed single-agent clinical benefit in late-stage metastatic cancer patients which supports the use of this novel agent for treating cancer," said Kevin N. Heller, M.D., Chief Medical Officer at Tallac Therapeutics. "The pharmacodynamic biomarker data collected from these patients is highly encouraging. We look forward to continuing TAC-001 monotherapy dose escalation and further evaluating activity in selected patient populations. We would like to thank the participants and their families for their participation in our study."

Additionally, the Company presented preclinical data in the poster titled ***"TAC-003, a TLR9 Agonist Antibody Conjugate for Targeted Immunotherapy of Nectin-4 Expressing Tumors"*** ***(Hyperlink to Tallac Website)*** that demonstrate TAC-003 induces robust immune cell activation, leading to innate and adaptive immunity against Nectin-4 positive cancers and potent single-agent anti-tumor activity. TAC-003 single agent treatment results in durable curative responses in models with a range of low to high Nectin-4 expression, including anti-PD-1 refractory tumors, with improved efficacy compared to enfortumab vedotin. TAC-003 has completed pre-clinical testing, including exploratory toxicological studies in cynomolgus monkeys, and has been selected as the Company's third clinical candidate.

"We are excited to see these initial clinical data with TAC-001, the first program from Tallac's TRAAC platform," said Dr. Hong I. Wan, president, CEO and co-founder of Tallac Therapeutics. "As we advance the TAC-001 program, we are also progressing our pipeline of immunotherapy candidates. TAC-003 represents a differentiated asset with potential to address unmet medical needs in multiple cancer types."

TLR9 agonists are a class of immunotherapy that generate both innate and adaptive immune response, which may produce more robust and durable anti-cancer immunity to help overcome resistance to standard-of-care oncology treatments. TLR9 agonists have demonstrated clinical activity in melanoma patients when administered intratumorally. Tallac Therapeutic's TRAAC platform is designed to deliver a potent and differentiated TLR9 agonist (T-CpG) for targeted immune activation via systemic administration.

About TAC-001 (CD22 TRAAC)

TAC-001 is a Toll-like Receptor Agonist Antibody Conjugate (TRAAC) comprised of a potent toll-like receptor 9 agonist (T-CpG) conjugated to an antibody against CD22, a receptor restricted to B cells, including tumor-infiltrating B cells. TAC-001 is designed to systemically deliver T-CpG to B cells by binding to CD22, leading to internalization of TAC-001, TLR9 signaling, B cell activation and a cascade of immune reactions. Preclinical studies demonstrate that the innate and adaptive immune responses triggered by TAC-001 lead to potent anti-tumor activity. TAC-001 is being developed for the treatment of solid tumors and is currently in a Phase 1/2 Study in cancer patients (NCT05399654)

About TAC-003 (Nectin-4 TRAAC)

TAC-003 is a Toll-like Receptor Agonist Antibody Conjugate (TRAAC) comprised of a T-CpG conjugated to a novel Nectin-4-targeting antibody for systemic administration and TME delivery of a potent TLR9 agonist. Nectin-4 is a cancer associated antigen over-expressed in many solid tumor types with limited expression in normal tissues. Additionally, Nectin-4 over-expression correlates with poor prognosis. Preclinical data demonstrate that TAC-003 triggers TLR9 signaling, induces myeloid and dendritic cell activation, phagocytosis, cytokine production and lymphocyte activation, resulting in potent single-agent anti-tumor efficacy.

About Tallac Therapeutics, Inc.

Tallac Therapeutics is a privately held biopharmaceutical company harnessing the power of innate and adaptive immunity to fight cancer. Tallac's pipeline of immunotherapy candidates is derived from the company's novel Toll-like Receptor Agonist Antibody Conjugate (TRAAC) platform to deliver a potent Toll-like receptor (TLR9) agonist (T-CpG) for targeted immune activation via systemic administration. Several TRAAC molecules are in various stages of discovery and development. TAC-001, the company's lead clinical candidate, is the first to enter the clinic and is currently in an ongoing Phase 1/2 clinical trial in patients with advanced or metastatic solid tumors. For more information, please visit www.tallactherapeutics.com.

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