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Precigen Provides Pipeline and Corporate Updates at the 41st Annual J.P. Morgan Healthcare Conference

Jan 11, 2023

– Company achieved significant progress for its clinical pipeline in 2022 –

– Precigen to host R&D Day virtual event on January 24, 2023, at 4:30 PM ET to share safety and efficacy data from the Phase 1 dose escalation and expansion cohorts of PRGN-2012 AdenoVerse™ immunotherapy in recurrent respiratory papillomatosis (RRP)–

GERMANTOWN, Md., Jan. 11, 2023 /PRNewswire/ -- [Precigen, Inc.](https://www.precigen.com) (Nasdaq: PGEN), a biopharmaceutical company specializing in the development of innovative gene and cell therapies to improve the lives of patients, today presented pipeline and corporate updates at the 41st Annual J.P. Morgan Healthcare Conference. Helen Sabzevari, PhD, President and CEO of Precigen, presented a summary of 2022 achievements and set forth Precigen's goals for 2023.



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ADVANCING MEDICINE WITH PRECISION

"Precigen continued to make significant clinical progress for our UltraCAR-T and AdenoVerse programs in 2022 and we were able to meet or exceed substantially all of the clinical goals we outlined at the J.P. Morgan Healthcare Conference last year. For example, the PRGN-2012 study in RRP continues to accelerate at a rapid pace and we look forward to hosting an R&D update call on January 24th to share safety and efficacy data from the Phase 1 dose escalation and expansion cohorts," said Helen Sabzevari, PhD, President and CEO of Precigen. "In 2023, we will continue to advance our clinical programs with a focus on a rapid path to licensure for programs addressing high unmet patient need."

PRGN-2012 AdenoVerse™ Immunotherapy in RRP

- **Overview:** PRGN-2012 is an investigational off-the-shelf (OTS) AdenoVerse immunotherapy designed to elicit immune responses directed against cells infected with HPV 6 or HPV 11 for treatment of RRP. PRGN-2012 is currently under evaluation in a Phase 2 clinical trial (clinical trial identifier: [NCT04724980](https://clinicaltrials.gov/ct2/show/study/NCT04724980)). The clinical trial evaluates PRGN-2012 as an adjuvant immunotherapy following standard-of-care surgical removal of visible papillomas in adult patients with RRP. PRGN-2012 has been granted [Orphan Drug Designation](#) in patients with RRP by the US Food and Drug Administration (FDA).
- **Program Status:** Enrollment (N=15) was completed in the Phase 1 study. Precigen initiated dosing in the Phase 2 trial and is rapidly enrolling patients, with 20 patients enrolled to date. The Company will host a [virtual R&D event on January 24, 2023](#) to showcase complete clinical trial data from the Phase 1 dose escalation and expansion cohorts of PRGN-2012 AdenoVerse Immunotherapy in RRP. The event will be led by Clint T. Allen, MD, Senior Investigator, Surgical Oncology Program, Center for Cancer Research, National Cancer Institute (NCI) and lead associate investigator for the PRGN-2012 clinical trial and Helen Sabzevari, PhD, President and CEO of Precigen. The Company plans to outline the regulatory strategy for PRGN-2012 in 2023 based on discussions with the FDA.

PRGN-2009 AdenoVerse™ Immunotherapy in HPV-associated Cancers

- **Overview:** PRGN-2009 is an OTS investigational immunotherapy utilizing the AdenoVerse platform designed to activate the immune system to recognize and target HPV-positive (HPV+) solid tumors. PRGN-2009 is currently under evaluation in a Phase 1/2 clinical trial (clinical trial identifier: [NCT04432597](https://clinicaltrials.gov/ct2/show/study/NCT04432597)). The Phase 1 trial is evaluating safety and response of

PRGN-2009 as a monotherapy (Arm A) and in combination with M7824 (Arm B) in previously treated patients with recurrent or metastatic HPV-associated cancers.

- **Program Status:** Enrollment was completed in the Phase 1 monotherapy (N=6) and combination therapy (N=11) arms in patients with recurrent or metastatic HPV-associated cancers and patient follow up is ongoing. The Company expects Phase 1 monotherapy and combination therapy safety and efficacy data to be presented in the first half of 2023. Enrollment is nearing completion in the Phase 2 monotherapy arm in newly diagnosed oropharyngeal squamous cell carcinoma (OPSCC) patients with 19 of 20 estimated patients enrolled as of the end of 2022. Interim clinical data presentation from the Phase 2 monotherapy arm is expected in the second half of 2023.

PRGN-3006 UltraCAR-T® in Acute Myeloid Leukemia (AML)

- **Overview:** PRGN-3006 is an investigational multigenic, autologous chimeric antigen receptor T cell (CAR-T) therapy engineered to simultaneously express a CAR specifically targeting CD33, membrane bound IL-15 (mbIL15), and a kill switch. PRGN-3006 UltraCAR-T is under evaluation in a Phase 1b clinical trial (clinical trial identifier: [NCT03927261](#)) for the treatment of patients with relapsed or refractory AML or higher-risk myelodysplastic syndromes (MDS). PRGN-3006 UltraCAR-T has been granted [Orphan Drug Designation](#) in patients with AML and [Fast Track Designation](#) in patients with relapsed/refractory AML by the FDA.
- **Program Status:** Enrollment was completed in the Phase 1 dose escalation cohorts of the study. Precigen presented [positive Phase 1 dose escalation data for autologous PRGN-3006 UltraCAR-T® manufactured overnight for next day infusion in relapsed or refractory AML patients](#) at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition. The Phase 1b dose expansion study of PRGN-3006 UltraCAR-T was expanded to Mayo Clinic in Rochester, Minnesota, enhancing the decentralized manufacturing model. The first patient was successfully dosed at the expansion site with PRGN-3006 UltraCAR-T. Site activation activities are in progress at several additional major cancer centers across the US as part of the multicenter expansion of the study. The Company received FDA clearance to incorporate repeat dosing in the Phase 1b expansion phase of the study, at the discretion of the treating physician. Phase 1b clinical trial data presentation is expected in 2024.

PRGN-3005 UltraCAR-T® in Ovarian Cancer

- **Overview:** PRGN-3005 UltraCAR-T is an investigational multigenic, autologous CAR-T cell therapy engineered to express a CAR specifically targeting the unshed portion of MUC16, which is highly expressed on ovarian tumors with limited normal tissue expression, mbIL15, and a kill switch. PRGN-3005 UltraCAR-T is under evaluation in a Phase 1b clinical trial (clinical trial identifier: [NCT03907527](#)) for the treatment of patients with advanced, recurrent platinum-resistant ovarian cancer.
- **Program Status:** Enrollment was completed in the Phase 1 dose escalation cohorts of the intraperitoneal (IP) and intravenous (IV) arms without lymphodepletion as well as in the lymphodepletion cohort in the IV arm. Patient follow up is ongoing and the Company expects Phase 1 data to be presented in the first half of 2023. The first patient received a repeat PRGN-3005 dose via IV infusion, following FDA clearance to incorporate repeat dosing in the study protocol. Enrollment is ongoing in the Phase 1b expansion study of PRGN-3005 UltraCAR-T at Dose Level 3 with lymphodepletion prior to IV infusion. Site activation activities are in progress at multiple major cancer centers in the US. Phase 1b clinical trial data presentation is expected in 2024.

PRGN-3007 Next Generation UltraCAR-T® with Intrinsic PD-1 Inhibition

- **Overview:** PRGN-3007, based on the next generation of the UltraCAR-T platform, is an investigational multigenic, autologous CAR-T cell therapy engineered to simultaneously express a CAR targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1), mbIL15, a kill switch, and a novel mechanism for the intrinsic blockade of PD-1 gene expression. ROR1 is aberrantly expressed in multiple hematological tumors, including chronic lymphocytic leukemia (CLL), mantle cell leukemia (MCL), acute lymphoblastic leukemia (ALL), and diffuse large B-cell lymphoma (DLBCL) and solid tumors, including breast adenocarcinomas such as triple negative breast cancer (TNBC), pancreatic cancer, ovarian cancer, and lung adenocarcinoma. ROR1 is minimally expressed in healthy adult tissues.
- **Program Status:** Precigen presented an abstract titled, "[A Phase1/1b Dose Escalation/Dose Expansion Study of PRGN-3007 UltraCAR-T Cells in Patients with Advanced Hematologic and Solid Tumor Malignancies](#)," at ASH. Tech transfer was completed for initiation of the Phase 1 umbrella trial in ROR1+ hematological (CLL, MCL, ALL, DLBCL) and solid tumors (TNBC). The trial is currently open for enrollment and the Company expects to dose the first patient in the first quarter of 2023.

Precigen's J.P. Morgan presentation is available on the Company website in the [Events & Presentations](#) section.

Precigen: Advancing Medicine with Precision™

Precigen (Nasdaq: PGEN) is a dedicated discovery and clinical stage biopharmaceutical company advancing the next generation of gene and cell therapies using precision technology to target the most urgent and intractable diseases in our core therapeutic areas of immuno-oncology,

