Incyte Announces Encouraging Results From Phase 2 Trial of Retifanlimab (INCMGA0012) in Patients With Previously Treated, Advanced Squamous Cell Carcinoma of the Anal Canal

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- *Independent central review confirmed responses include 1 complete response, 12 partial responses and 33 stable disease for an objective response rate of 14% and disease control rate of 49%*
- *Responses were observed regardless of PD-L1 status, presence of liver metastases or HIV+ status*
- *Presentation is available on-demand as part of the ESMO Virtual Congress 2020*
- *POD1UM-303/InterAACT 2, a Phase 3 trial evaluating retifanlimab plus chemotherapy in patients with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal is now open and recruiting patients.*

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced results from its Phase 2 POD1UM-202 trial evaluating retifanlimab, a PD-1 inhibitor, in previously treated patients with advanced squamous cell carcinoma of the anal canal (SCAC) who have progressed following standard platinum-based chemotherapy. The trial enrolled 94 patients, including those with well-controlled human immunodeficiency virus (HIV) infection (10%).

Retifanlimab monotherapy resulted in a confirmed objective response rate (ORR) of 14% as determined by independent central review (ICR) using RECIST v1.1. Responses were observed regardless of PD-L1 status, presence of liver metastases, age or HIV+ status. Retifanlimab was generally well-tolerated with a safety profile as expected of a PD-1 inhibitor and no loss of HIV infection control.

Key findings from POD1UM-202:

	N=94
ORR* (95% CI)	13.8% (7.6-22.5)
Best OR*, n	1 CR 12 PR 33 SD
DCR	48.9%
DOR, median (95% CI), months	9.5 (5.6-NE)
PFS, median (95% CI), months	2.3 (1.9-3.6)
OS, median (95% CI), months	10.1 (7.9-NE)

*Confirmed responses as determined by independent central review (ICR) using RECIST v1.1.
ORR: objective response rate; CI: confidence interval; OR: objective response; CR: complete response; PR: partial response; SD: stable disease; DCR: disease control rate; DOR: duration of response; PFS: progression-free survival; OS: overall survival; NE: not estimable.

“The results from the POD1UM-202 trial highlight the potential of retifanlimab to provide a meaningful treatment for patients with SCAC who have progressed following standard platinum-based chemotherapy and therefore have a very poor prognosis,” said Lance Leopold, M.D., Group Vice President, Immuno-Oncology Clinical Development, Incyte. “These data are especially important because this trial enrolled HIV+ patients who are at the greatest risk of developing SCAC and are typically systematically excluded from oncology clinical trials.”

These results are available on-demand as part of the European Society for Medical Oncology (ESMO) 2020 Virtual Congress mini-oral sessions beginning at 9:00 am CEST on September 18th, 2020; Presentation #LBA42.

“SCAC is a rare cancer with increasing incidence, including in patients who are HIV+, and represents a strong unmet medical need,” said Sheela Rao, M.D., Consultant Medical Oncologist, The Royal Marsden NHS Foundation Trust. “Data from the POD1UM-202 trial are encouraging and support further investigation of the potential of retifanlimab to become a much needed treatment option for patients with SCAC.”

SCAC is associated with human papillomavirus (HPV) and HIV infections and accounts for almost 3% of digestive system cancers.[1] Patients with metastatic SCAC have a poor 5-year survival and there are no standard treatments for patients who have progressed after first-line chemotherapy treatment.[2]

POD1UM-303/InterAACT 2 (NCT04472429), a Phase 3 trial of retifanlimab in combination with carboplatin and paclitaxel in patients with inoperable locally recurrent or metastatic SCAC is now open and recruiting patients.

About POD1UM

The POD1UM (PD1 Clinical Program in Multiple Malignancies) clinical trial program for retifanlimab includes POD1UM-202, POD1UM-303 and several other Phase 1, 2 and 3 studies for patients with solid tumors including squamous cell carcinoma of the anal canal (SCAC), microsatellite instability-high endometrial cancer, Merkel cell carcinoma and non-small cell lung cancer, among others.

About POD1UM-202

POD1UM-202 (NCT03597295) is an open-label, single-arm, multicenter, Phase 2 study evaluating retifanlimab in patients with squamous cell carcinoma of the anal canal (SCAC) who have progressed following platinum-based chemotherapy. Retifanlimab 500 mg is administered

intravenously every 4 weeks.

The primary endpoint is objective response rate (ORR) as determined by independent central review using RECIST v1.1. Secondary endpoints include additional measures of clinical benefit – duration of response (DOR), disease control rate (DCR), progression-free survival (PFS) and overall survival (OS); safety and pharmacokinetics.

For more information about the study, please visit https://clinicaltrials.gov/ct2/show/NCT03597295.

About POD1UM-303/InterAACT 2

POD1UM-303/InterAACT 2 (NCT004472429) is a Phase 3, randomized, multicenter, double-blind study evaluating retifanlimab or placebo plus carboplatin and paclitaxel in patients with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC).

Adult patients, including those with well-controlled HIV infection, who have not been previously treated with systemic chemotherapy will be randomized to receive retifanlimab or placebo with standard therapy of carboplatin and paclitaxel.

The primary endpoint is progression-free survival (PFS) as determined by blinded independent central review using RECIST v1.1. Key secondary endpoint is overall survival (OS). Other secondary endpoints include: objective response rate (ORR), duration of response (DOR), disease control rate (DCR), safety and pharmacokinetics.

For more information about the study, please visit https://clinicaltrials.gov/ct2/show/NCT04472429.

About Retifanlimab

Retifanlimab (formerly INCMGA0012), an investigational anti-PD1 antibody, is currently under evaluation in registration-directed trials as a monotherapy for patients with microsatellite instability-high endometrial cancer, Merkel cell carcinoma and squamous cell carcinoma of the anal canal (SCAC); and in combination with platinum-based chemotherapy for patients with non-small cell lung cancer and SCAC.

Retifanlimab has been granted Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of anal cancer.

In 2017, Incyte entered into an exclusive collaboration and license agreement with MacroGenics, Inc. for global rights to retifanlimab. In 2019, Incyte and Zai Lab announced a collaboration and license agreement for the development and commercialization of retifanlimab in Greater China.

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements about the potential of retifanlimab to provide a meaningful treatment for patients with SCAC, the retifanlimab development program, and the safety and efficacy of retifanlimab in patients with squamous cell carcinoma of the anal canal, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA; the Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses; expenses relating to litigation or strategic activities; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended June 30, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

References

1. Ghosn M, et.al. Anal cancer treatment: current status and future perspectives. *World J Gastroenterol* 2015;21:2294-2302.
2. Eng C, et al. The role of systemic chemotherapy and multidisciplinary management in improving the overall survival of patients with metastatic squamous cell carcinoma of the anal canal. *Oncotarget* 2014;5:11133-11142.

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