

INNATE PHARMA TO PRESENT NEW EFFICACY DATA FOR MONALIZUMAB IN COMBINATION WITH CETUXIMAB IN HEAD AND NECK CANCER AT THE ASCO20 VIRTUAL SCIENTIFIC PROGRAM

Phase II expansion cohort of "IO-pretreated patients" demonstrates 20% overall response rate

Data confirm previous preliminary efficacy data seen in this subpopulation

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Innate Pharma SA (Euronext Paris: IPH – ISIN: FR0010331421; Nasdaq: IPHA) ("**Innate**" or the "**Company**") today announced that it will present new data on its lead partnered asset, monalizumab, at the ASCO20 Virtual Scientific Program being held May 29-31, 2020. The presentation will highlight a Phase II expansion cohort investigating the combination of monalizumab and cetuximab in patients with recurrent or metastatic head and neck squamous cell cancer (R/M SCCHN) who have been previously treated with platinum-based chemotherapy and PD-(L)1 inhibitors ("IO-pretreated"). Monalizumab is a potentially first-in-class immune checkpoint inhibitor targeting NKG2A receptors expressed on tumor infiltrating cytotoxic CD8⁺ T cells and NK cells.

"We are pleased to present additional data on the combination of monalizumab and cetuximab in head and neck cancer at this year's ASCO Virtual Scientific Program. These data further strengthen the encouraging response rates previously reported in our head and neck clinical trial program," **commented Pierre Dodion, Chief Medical Officer of Innate Pharma.** "While the study was not randomized, numerically, these data compare favorably with historical data reported for cetuximab alone or for immuno-oncology (IO) single agent in recurrent or metastatic head and neck cancer after one line of previous systemic therapy."

The poster discussion presentation (#177, abstract #6516), entitled "Combination of Monalizumab and Cetuximab in Patients with Recurrent or Metastatic Head and Neck Squamous Cell Cancer Previously Treated with Platinum-based Chemotherapy and PD-(L)1 Inhibitors," will be available on demand beginning at 8 a.m. ET on Friday, May 29 under the Head and Neck Cancer track.

Key Highlights from Phase II Expansion Study Cohort 2 ("IO-pretreated")

As of March 2020, 40 platinum and IO-pretreated patients achieved an overall response rate (ORR) of 20%, which confirms the activity previously reported in the post-hoc analysis in the IO-pretreated subgroup in cohort 1 (ORR = 17%, n=18). Responses were observed in platinum-sensitive (3/21) and platinum-resistant patients (5/19), as well as in IO-sensitive (3/17) and IO-resistant patients (5/23), in patients exposed to IO as last previous therapy (5/34) and IO as earlier treatment (3/6).

The combination of monalizumab and cetuximab demonstrated a manageable safety profile, supporting continued investigation. No adverse events led to treatment discontinuation. Seventeen patients (42%) experienced grade 3-4 adverse events. Only one patient (2%) experienced a grade 3-4 adverse event considered related to monalizumab: peripheral sensory neuropathy and asthenia. No treatment-related deaths were reported.



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"The additional findings from this Phase II study are encouraging and validate the overall response rates previously observed with the combination of monalizumab and cetuximab for the treatment of recurrent or metastatic head and neck cancer, a malignancy with poor prognosis where novel, effective and tolerable therapies continue to be needed for this patient population," said Dr. Roger B. Cohen, Professor of Medicine at the Hospital of the University of Pennsylvania. "The dual-targeting action exhibited by the combination of this NKG2A monoclonal antibody, monalizumab, when paired with cetuximab has the potential to provide greater antitumor activity than cetuximab alone, the current standard of care. We look forward to further studies evaluating this novel combination."

As previously disclosed, the start of the Phase III trial of monalizumab in combination with cetuximab in IO-pretreated patients suffering from R/M SCCHN, which will be conducted by AstraZeneca (LSE/STO/NYSE: AZN), is expected in 2020.

About the Monalizumab Phase II Trial

This trial is an open-label, Phase Ib/II study testing monalizumab in combination with cetuximab in patients with R/M SCCHN. The Phase II portion of the trial is comprised of three expansion cohorts:

- Expansion Cohort 1, which enrolled 40 patients, evaluated the combination of monalizumab and cetuximab in patients with R/M SCCHN who had been previously treated with chemotherapy alone or chemotherapy followed by checkpoint inhibitors.
- Expansion Cohort 2, which enrolled 40 patients and is evaluating the combination of monalizumab and cetuximab in patients with R/M SCCHN who have received a maximum of two prior systemic regimens in the R/M setting and with prior exposure to a platinum and a PD-(L)1 inhibitor (who we refer to as IO-pretreated patients).
- Expansion Cohort 3, which is expected to enroll up to 40 patients, began recruiting in April 2019 and is evaluating the combination of monalizumab, cetuximab and durvalumab in IO-naïve patients with R/M SCCHN.

The primary endpoint for the Phase II portion of the trial is objective response rate. Secondary endpoints for the Phase II portion of the trial include duration of response, progression-free survival and overall survival.

In expansion cohort 1, the combination of monalizumab and cetuximab demonstrated a manageable safety profile and a response rate of 27.5% (36% and 17% in IO-naïve and IO-pretreated patients, respectively). Data were presented at the ESMO 2019 Congress. Expansion cohorts 2 and 3 are currently ongoing.

About Monalizumab:

Monalizumab is a potentially first-in-class immune checkpoint inhibitor targeting NKG2A receptors expressed on tumor infiltrating cytotoxic CD8⁺ T cells and NK cells.

NKG2A is an inhibitory checkpoint receptor for HLA-E. By expressing HLA-E, cancer cells can protect themselves from killing by NKG2A+ immune cells. HLA-E is frequently overexpressed in the cancer cells of many solid tumors and hematological malignancies. Monalizumab may reestablish a broad anti-tumor response mediated by NK and T cells, and may enhance the cytotoxic potential of other therapeutic antibodies.

AstraZeneca obtained full oncology rights to monalizumab in October 2018 through a codevelopment and commercialization agreement initiated in 2015. The ongoing Phase II



development for monalizumab is focused on investigating monalizumab in various combination strategies in different malignancies.

About Cetuximab:

Cetuximab is an anti-EGFR monoclonal antibody. NK cells mediate cetuximab-induced antibody dependent cellular cytotoxicity (ADCC) against SCCHN. Genetic and preclinical experiments suggest that ADCC can be enhanced by NK-stimulators.

The activity of cetuximab as a single agent in recurrent and/or metastatic SCCHN is limited, with a 12.6% overall response rate, a median time to progression of 2.3 months and a median overall survival of 5.8 months (Vermorken et al, JCO 2007).

About Innate Pharma:

Innate Pharma S.A. is a commercial stage oncology-focused biotech company dedicated to improving treatment and clinical outcomes for patients through therapeutic antibodies that harness the immune system to fight cancer.

Innate Pharma's commercial-stage product, Lumoxiti, in-licensed from AstraZeneca in the US, EU and Switzerland, was approved by the FDA in September 2018. Lumoxiti is a first-in class specialty oncology product for hairy cell leukemia. Innate Pharma's broad pipeline of antibodies includes several potentially first-in-class clinical and preclinical candidates in cancers with high unmet medical need.

Innate has been a pioneer in the understanding of natural killer cell biology and has expanded its expertise in the tumor microenvironment and tumor-antigens, as well as antibody engineering. This innovative approach has resulted in a diversified proprietary portfolio and major alliances with leaders in the biopharmaceutical industry including Bristol-Myers Squibb, Novo Nordisk A/S, Sanofi, and a multi-products collaboration with AstraZeneca.

Based in Marseille, France, Innate Pharma is listed on Euronext Paris and Nasdaq in the US.

Learn more about Innate Pharma at <u>www.innate-pharma.com</u>

Information about Innate Pharma shares:

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This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in Innate Pharma in any country.

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