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## INNATE PHARMA PRESENTS EARLY CLINICAL DATA ON IPH5401 AND MONALIZUMAB AT THE ESMO 2019 CONGRESS

- **IPH5401 dose-escalation study in combination with durvalumab in advanced solid tumors, STELLAR-001, shows manageable safety profile**
  - Initiation of two expansion cohorts in non-small cell lung cancer (NSCLC) with secondary resistance to immuno-oncology (IO) treatment and IO-naïve hepatocellular carcinoma (HCC)
  - Based on early signals, the Company plans to add a third expansion cohort in IO-pretreated HCC
- **Survival data of monalizumab in combination with cetuximab in head and neck cancer supports current expansion cohort in IO-pretreated and IO-naïve patients**

Marseille, France, October 1, 2019, 07:00 AM CET

Innate Pharma SA (the "Company" - Euronext Paris: FR0010331421 – IPH) today announced that new data on IPH5401 and monalizumab were presented at the European Society for Medical Oncology (ESMO) 2019 Congress in Barcelona, Spain.

Poster presentations highlighted:

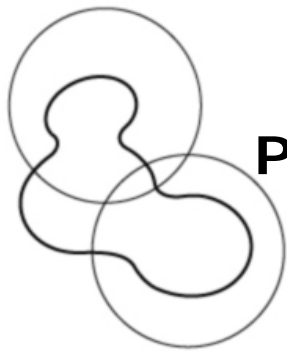
- Preliminary results of STELLAR-001, a Phase I dose-escalation study of IPH5401, an anti-C5aR antibody, in combination with durvalumab in advanced solid tumors;
- One-year survival data of the first expansion cohort of the Phase II trial evaluating monalizumab in combination with cetuximab in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN)

*"We are pleased with the continued progress of monalizumab and IPH5401. We believe that by targeting C5a receptors, IPH5401 is a potentially first-in-class therapeutic antibody for cancer treatment. The preliminary clinical data set from the STELLAR-001 dose-escalation trial prompted us to start and broaden the expansion cohorts in three different settings where anti-PD-(L)1 have shown no or limited activity," said Pierre Dodion, Chief Medical Officer of Innate Pharma. "In addition, the survival data set for the combination of monalizumab and cetuximab in head and neck cancer support further development in IO-pretreated and IO-naïve patients, populations with high unmet medical need."*

### Key Highlights from IPH5401's STELLAR-001 Study

In the STELLAR-001 dose-escalation study, 14 patients were included across four doses. Six patients had NSCLC, five had HCC, two had urothelial carcinoma (UCC), and one had renal cell carcinoma (RCC).

The combination of IPH5401 and durvalumab was reported to be well tolerated. No dose limiting toxicity was reported and no dose relationship was observed regarding safety. Pharmacodynamic analyses confirmed full receptor saturation at all dose levels and provided the basis for dose selection for the expansion cohorts.



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Twelve patients were evaluated for efficacy. Early activity signals were observed in HCC and NSCLC patients, which included:

- One confirmed partial response was reported in a HCC patient with prior progression after nivolumab
- One prolonged stable disease (40 weeks) was reported in a NSCLC patient with prior progression after nivolumab

The Company will initiate the planned expansion cohorts in NSCLC patients with secondary resistance to prior IO treatment and in IO-naïve HCC patients to generate additional safety and efficacy data as well as additional translational analyses on tumor biopsies. In addition, based on the data generated in the dose escalation, the Company plans to add an additional cohort testing IPH5401 in combination with durvalumab in IO-pretreated HCC patients, subject to regulatory approval.

### **Key highlights from the Phase II study of monalizumab in combination with cetuximab in patients with R/M SCCHN, one-year survival data**

In a cohort of 40 SCCHN patients previously treated with chemotherapy alone or chemotherapy followed by PD-1/L1 checkpoint inhibitors, 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). Responses were observed in platinum-resistant patients and human papillomavirus (HPV) positive and negative patients.

Additional efficacy highlights included:

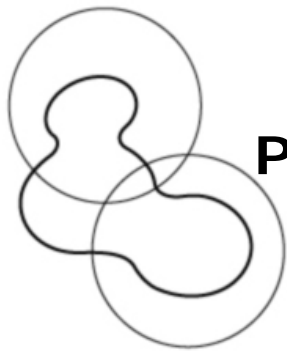
- Median overall survival of 8.5 months with median follow-up time of 17 months;
- Trend for improved survival in IO-pretreated patients (14.1 months in IO-pretreated patients and 7.8 months in IO naïve patients); and
- 12-month overall survival rate of 44% (60% in IO-pretreated and 32% in IO naïve patients)

These data suggest that the combination of monalizumab and cetuximab may provide promising response rates and favorable trends in overall survival. The Company is moving forward with the planned expansion cohorts in IO-pretreated and IO-naïve R/M SCCHN patients.

### **About IPH5401:**

IPH5401 is a potentially first-in-class therapeutic antibody that specifically binds and blocks C5a receptors (C5aR) expressed on subsets of myeloid-derived suppressor cells (MDSC) and neutrophils. Part of the innate immune system, these types of cells promote tumor growth by secreting inflammatory and angiogenic factors, potentially suppress anti-tumor T and NK cells and hamper the activities of PD-1 checkpoint inhibitors.

C5a, a factor in the complement cascade, is often overexpressed in tumors, where it attracts and activates MDSCs and neutrophils in the tumor microenvironment. Preliminary evidence suggests high expression of the C5a receptor in both NSCLC and HCC.



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### **About Monalizumab:**

Monalizumab is a potentially first-in-class dual 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. Hence, monalizumab may re-establish a broad anti-tumor response mediated by NK and T cells. Monalizumab may also enhance the cytotoxic potential of other therapeutic antibodies.

AstraZeneca (LSE/STO/NYSE: AZN) obtained full oncology rights to monalizumab in October 2018 through a co-development and commercialization agreement initiated in 2015. The ongoing clinical development for monalizumab is focused on investigating monalizumab in combination strategies.

### **About Durvalumab:**

Durvalumab, a human monoclonal antibody directed against PD-L1, blocks PD-L1 interaction with PD-1 and CD80 on T cells, countering the tumor's immune-evading tactics and inducing an immune response.

As part of a broad development program, durvalumab is being investigated as monotherapy and in combination with IO, small molecules, and chemotherapies across a range of tumors and stages of disease.

### **About Cetuximab:**

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

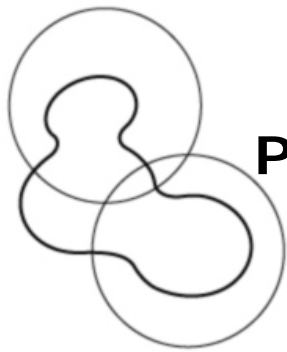
The activity of cetuximab single agent in R/M SCCHN is limited with a 12.6% ORR, a median PFS of 2.3 months and a median OS of 5.8 months (Vermorken et al, JCO 2007).

### **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, was approved by the FDA in September 2018. Lumoxiti is a first-in class specialty oncology product for hairy cell leukemia (HCL). 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 NK cell biology and has expanded its expertise in the tumor microenvironment and tumor-antigens, as well as antibody engineering. This



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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.

Learn more about Innate Pharma at [www.innate-pharma.com](http://www.innate-pharma.com)

### Information about Innate Pharma shares:

<b>ISIN code</b>	FR0010331421
<b>Ticker code</b>	IPH
<b>LEI</b>	9695002Y8420ZB8HJE29

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